FEDERAL GRANT PROGRAMS

Announcing a New Weekly Feature

To assist readers wishing to keep abreast of federally funded grant programs, the FEDERAL REGISTER is adding a new listing to the weekly Reminders section published every Wednesday. Beginning with the issue of August 2, 1978, the Wednesday Reminders section will include a listing of grants related documents published in the FEDERAL REGISTER during the previous week.

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Questions and requests for specific information may be directed to the following numbers. General inquiries may be made by dialing 202-523-5240.

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#### Proposed Rules:
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**FEDERAL REGISTER**

**PROPOSED RULES:**

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**FEDERAL REGISTER, VOL. 43, NO. 146—FRIDAY, JULY 28, 1978**

xiii
PART 213—EXCEPTED SERVICE

Executive Office of the President

AGENCY: Civil Service Commission.

ACTION: Final rule.

SUMMARY: The Schedule A authority under 5 CFR 213.3121 for the National Security Council is transferred to 5 CFR 213.3103 to show that the National Security Council is part of the Executive Office of the President.


FOR FURTHER INFORMATION CONTACT:

Michael D. Sherwin, 202-632-4533.

Accordingly, 5 CFR 213.3103 is amended by adding paragraph (g) and 5 CFR 213.3121 is revoked, as follows:

§ 213.3103 Executive Office of the President:

• • • • • •

(g) National Security Council.

(1) All positions on the staff of the Council.

• • • • • •

§ 213.3121 [Revised]


UNITED STATES CIVIL SERVICE COMMISSION,

JAMES C. SPRY,

Executive Assistant to the Commissioners.

[FR Doc. 78-20957 Filed 7-27-78; 8:45 am]

PART 870—REGULAR LIFE INSURANCE

PART 871—OPTIONAL LIFE INSURANCE

Reduction in Rates for Regular and Optional Federal Employees’ Group Life Insurance

AGENCY: Civil Service Commission.

ACTION: Final rule.

SUMMARY: The Civil Service Commission is amending its Federal Employees’ Group Life Insurance (FEGLI) regulations to effect a reduction in both regular and optional insurance rates. This action is indicated by the latest actuarial valuation of program operations as of September 30, 1977. In view of the facts that the Commission is authorized by law to determine FEGLI rates and that the amendments will effect a liberalization in benefits, the Commission finds that it is unnecessary to delay the effective date to allow for notice of proposed rulemaking and public procedure thereon.

EFFECTIVE DATE: These amendments will be effective with the first pay period which begins on or after September 1, 1978.

FOR FURTHER INFORMATION CONTACT:


SUPPLEMENTARY INFORMATION:

FEGLI RATES

By law, the Civil Service Commission is directed to determine Government and employee contributions for regular FEGLI on the basis of the level cost of each $1,000 of insurance and to determine the cost of optional FEGLI to employees, and annuitants under age 65, on the basis of such age groups as it considers appropriate (5 U.S.C. 8707, 8708, 8714a(e)). Present contributions for regular FEGLI have been in effect since March 1975, and total 53.25 cents biweekly per $1,000 of insurance, i.e., 35.5 cents from insured employees and 17.75 cents from employing Government agencies. Employees, and annuitants under age 65, must pay the full cost when optional FEGLI is elected. The current biweekly rates for optional insurance have been in effect since July 1973, and are as follows:

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Biweekly Rate for $1,000</th>
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<tbody>
<tr>
<td>Under 35</td>
<td>$0.60</td>
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<tr>
<td>35 to 59</td>
<td>$0.80</td>
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</table>
### FEGLI Valuation

The latest actuarial valuation of the FEGLI program as of September 30, 1977, indicates that both the regular and optional FEGLI rates can be substantially reduced. This is possible for a number of reasons, among them, sharply reduced mortality rates, higher investment yields and with respect to optional FEGLI, a marked increase in employee participation since the last valuation. The method of computing the rates, which takes into account the current earnings of the fund, is explained in the Valuation section of this part. Inflation factor in the actuarial assumptions since the last valuation is effective through June 30, 1973. Also, the current valuation includes an inflation factor in the actuarial assumptions since the high rate of inflation in recent years has established it as an important component of salary increases and interest rates, both of which have a direct impact on program costs.

Accordingly, 5 C.F.R. § 870.401 (a) and (b) and § 871.401c are amended as set out below:

#### § 870.401 Withholdings and contributions.

(a) During any period in any part of which an insured employee is in a pay status there shall be withheld from the biweekly pay of such employee the sum of 25.5 cents for each $1,000 of regular insurance. The amount withheld from the pay of an employee who is paid on other than a biweekly basis is determined at a biweekly rate, adjusted to the nearest cent.

(b) The amount withheld from the pay of an insured employee whose annual pay is paid during a period shorter than 52 workweeks is the sum obtained by converting the biweekly rate of 25.5 cents for each $1,000 of regular insurance to an annual rate and prorating the annual rate over the number of instalments of pay regularly paid during the year.

(c) The biweekly full cost of the $10,000 of optional insurance (and, for a person in receipt of annuity or compensation for work injury, of optional life insurance), until determined by the Commission on the basis of experience to be otherwise, is:

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<tr>
<th>Age group:</th>
<th>Biweekly rate for $1,000</th>
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<td>50 to 54</td>
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<td>55 to 59</td>
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<tr>
<td>60 and over</td>
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<td>60 to 64</td>
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In accordance with the above, 7 CFR Part 6 is amended by inserting the following subparagraph after Subpart—Section 22 Import Quotas:

Subpart—Section 22 Import Quotas

EXEMPTION FROM FEES—SUGAR

Sec.
6.50 Definitions.
6.51 Issuance of an import license.
6.52 Transferability of an import license.
6.53 Entry of sugar.
6.54 Entry of sugar by an agent.
6.55 Application for an import license.
6.56 Bond requirements.
6.57 Default.
6.58 Certificate of use.
6.59 Revocation.


§ 6.50 Definitions.

As used in this subpart: (a) The term “person” means an individual, partnership, corporation, association, estate, trust, or other business enterprise or legal entity, and, wherever applicable, any unit, instrumentality, or agency of a government, domestic or foreign.

(b) The term “Department” means the U.S. Department of Agriculture.

(c) The term “Secretary” means the Secretary of Agriculture or any officer or employee of the Department to whom the Secretary has delegated the authority or to whom authority may hereafter be delegated to act in his place.

(d) The term “appropriate customs official” means the district or area Director of Customs, his designee, or any other customs officer of similar authority and responsibility, for the customs district in which the port of entry is located.

(e) The term “import license” means a license issued by the Secretary permitting the entry of sugar exempt from the fees provided for in items 956.05, 956.15, and 957.15 of the tariff schedules of the United States, on condition that such sugar will be used solely for the production (other than by distillation) of polyhydric alcohols, except polyhydric alcohols for use as a substitute for sugar in human food consumption.

(f) The term “manufacturer” means a person that is engaged in the production (other than by distillation) of polyhydric alcohols from sugar.

(g) The term “agent” means a licensed customs broker.

(h) The term “sugar” means sugars, sirups, and molasses as defined in items 956.05, 956.15, and 957.15 of the tariff schedules of the United States.

§ 6.51. Issuance of an import license.

(a) An import license may be issued to a manufacturer which complies with the provisions of this subpart.

The license shall state the time period during which the license shall be effective and the maximum amount of sugar which may be imported under the license. In no case shall the effective period of a license exceed 1 year, nor shall the maximum amount of sugar, which may be imported under the license exceed the anticipated requirements of the manufacturer for the 12-month period following the effective date of the license. The license may contain such other conditions as the Secretary, in his discretion, deems necessary.

(b) No more than one effectiv e license may be issued and outstanding at any one time to any one manufacturer. In order to insure a dependable and orderly supply of sugar to a manufacturer may apply for a license prior to the expiration of a previously issued license. The previously issued license shall be deemed to have expired on its stated expiration date, or on the effective date of the succeeding license, whichever is earlier. A succeeding license may be issued until the previously issued license has been returned to the Horticultural and Tropical Products Division, Foreign Agricultural Service, U.S. Department of Agriculture, Washington, D.C. 20250.

§ 6.52 Transferability of an import license.

An import license may not be transferred or assigned by the manufacturer to any other persons. Any attempt to transfer or assign an import license shall be null and void and shall constitute grounds for the revocation of the license by the Secretary.

§ 6.53 Entry of sugar.

(a) A manufacturer or its agent may enter sugar into the United States exempt from the fees contained in items 956.05, 956.15, and 957.15 of the tariff schedules of the United States under an import license issued pursuant to this subpart. The import license must be presented to the appropriate customs official at the time of entry. Entry of the sugar exempt from fees shall be allowed only in conformity with the conditions of the import license, if any.

(b) The appropriate Customs official shall enter on the license: (1) The amount of sugar entered; (2) the date of entry; and (3) the customs entry number.

(c) A copy of the license, as marked by the appropriate customs official, shall be transmitted to the Horticultural and Tropical Products Division, Foreign Agricultural Service, U.S. Department of Agriculture, Washington, D.C. 20250, by the person entering the sugar, within 10 business days after each entry of sugar.

§ 6.54 Entry of sugar by an agent.

(a) In those cases where sugar is to be entered by an agent of the manufacturer, the agent shall produce for inspection by the appropriate customs official a written authorization by the manufacturer designating such person to act as the agent of the manufacturer for the purpose of entering sugar.

(b) A copy of such authorization shall be attached to the relevant copy of the import license that is transmitted to the Horticultural and Tropical Products Division pursuant to § 6.53(c).

§ 6.55 Application for an import license.

(a) Only manufacturers are eligible to receive an import license.

(b) Each application for an import license shall contain the following information:

(1) Name and address of the manufacturer.

(2) A statement of the anticipated requirements of the manufacturer for sugar to be used in the production (other than by distillation) of polyhydric alcohols, except polyhydric alcohols for use as a substitute for sugar in human food consumption, during the effective period of the license.

(3) The anticipated amount of sugar to be imported during the specified effective period.

(4) The effective period of the import license (but not to exceed 1 year).

(c) Each application for an import license shall contain a certification that the manufacturer shall use the quantity of sugar entered under an import license solely for the production (other than by distillation) of polyhydric alcohols, except polyhydric alcohols for use as a substitute for sugar in human food consumption.

§ 6.56 Bond requirements.

(a) Sugar entered under an import license shall be subject to all customs bond requirements (see 19 CFR Parts 113, 141, 143, and 144). The appropriate customs official may assess liquidated damages under the customs entry bond for violation of any provision of the import license or this subpart.

(b) The appropriate customs official may release all or part of the amount of sugar entered under an import license if the Secretary determines that the destruction or other disposition of a quantity of sugar entered under an import license renders performance under the bond impossible or inequitable. In such case the Secretary shall notify the appropriate customs official of his determination. The determination shall be treated as a certificate of use which has been properly and timely filed.
§ 6.57 Default.

Upon a failure to comply with the provisions of this subpart or the import license, payment of the obligation under the bond shall be made to the appropriate customs official in accordance with the conditions of the bond.

§ 6.58 Certificate of use.

(a) The certificate of use shall be a certification by the manufacturer that a quantity of sugar entered under an import license has been used for the purpose stated in § 6.50(e). Certificates of use shall be transmitted to the appropriate customs official and the Horticultural and Tropical Products Division by the manufacturer on a monthly basis. In no case shall a certificate of use be accepted more than 180 days after the expiration of the import license under which the sugar was imported, unless the Secretary, in his discretion, extends the time period in which a certificate may be filed.

(b) The certificate of use shall be signed by the manufacturer and shall contain the following certification:

The undersigned hereby certifies that between ____ 19__, and ____ 19__—, the undersigned has used ___ pounds of sugar for the sole purpose of producing (other than by distillation) polyhydric alcohols except polyhydric alcohols for use as a substitute for sugar in human food consumption. The undersigned further certifies that the quantity of sugar shown on this certificate of use does not include any sugar previously covered by another certificate of use.

§ 6.59 Revocation.

(a) If, at any time, the Secretary determines that the manufacturer has failed to comply with the requirements of this subpart or the import license, the Secretary may, in his discretion, revoke the import license.

(b) Notice of the revocation shall be given to the manufacturer and the Customs Service.


THOMAS R. HUGHES, Administrator.

[FR Doc. 78-20927 Filed 7-27-78; 8:45 am]

RULES AND REGULATIONS

[3410-30]

CHAPTER II—FOOD AND NUTRITION SERVICE, DEPARTMENT OF AGRICULTURE

SUBCHAPTER A—CHILD NUTRITION PROGRAMS

[Amend. I]

PART 225—SUMMER FOOD SERVICE PROGRAM FOR CHILDREN

Implementation of Special Account System for Issuing Checks for Food Service Payments to Special Accounts on Temporary Basis

AGENCY: Food and Nutrition Service, USDA.

ACTION: Final rule.

SUMMARY: The Department is issuing an amendment to final regulations for the Summer Food Service Program for Children. This amendment provides for the implementation of a special account system for issuing checks for food service payments to special accounts on a temporary basis. This method will be required for nongovernmental sponsors in the State of New York and will be optional in all other States. It is intended that the special account system be implemented and evaluated to determine whether it continues to be necessary to ensure that food service management companies receive payments on a timely basis.


FOR FURTHER INFORMATION CONTACT:

Henry S. Rodriguez, Acting Director, Child Care and Summer Programs Division, 201 14th Street SW., Washington, D.C. 20250, 202-447-8211.

SUPPLEMENTAL INFORMATION: The Department believes that it is in the interest of the program to examine methods which would assist food service management companies in receiving proper payments from sponsors. The Department is, therefore, implementing a special account system on a temporary basis for nongovernmental sponsors in New York State for the 1978 summer program. In other States, the State agency may elect to implement a special account system for nongovernmental sponsors for whom program payment has been, or is expected to be, a particular problem. For other FNSRO-administered programs the special account may be established only at the request of the sponsor. Under this system, nongovernmental sponsors contracting with food service management companies must agree to establish special accounts with financial institutions for amounts intended for payments to food service management companies. The special account agreement must specify that any disbursement of monies from the account must be authorized by both the sponsor and the food service management company.

The Department is implementing the special account system on a temporary basis to assure that food service management companies will receive payment by alerting them to the time and amount of payments to the sponsors and granting them an opportunity to participate in the disbursement of monies.

Publication of proposed rules is impracticable and contrary to the public interest since the special account system is to be implemented this summer (1978).

Accordingly, 7 CFR part 225 is amended as set forth below:

(1) Subpart D of the table of contents is amended to read as follows:

Sec. 225.18a Special account payment provision.

(2) In § 225.2 a new paragraph (gg) is added to read as follows:

§ 225.2 Definitions.

(gg) "Special account" means an account with a sound and reputable recognized financial institution in which net program payments are deposited by FNS and released only in accordance with the terms of the special account agreement.

(3) A new § 225.18a is added and reads as follows:

§ 225.18a Special account payment provision.

(a) The Department shall, on a temporary basis in the State of New York for program operations undertaken in fiscal year 1978, require as a condition for participation that nongovernmental sponsors under contract with food service management companies establish special accounts for the deposit of checks for net program payments. A separate account shall be established for each food service management company under contract with the sponsor.

(b) Each sponsor shall, under its written agreement with the Department, agree to the issuance of checks payable to sponsor for net Program payments to a special account. The account agreement must specify that checks payable to the sponsor will be deposited in the special account by the financial institution and disburse-
ments from the account shall be made only with the written concurrence of both the sponsor and the food service management company. The special account agreement may contain such other terms as are agreed to by both sponsor and food service management company. Provided, however, that such terms are not inconsistent with the terms of the contract between the sponsor and the food service management company. A copy of the special account agreement shall be submitted to the Department and another copy maintained on file by the sponsor. Any charges by the financial institution for the accounts which are borne by the sponsor shall be considered an administrative cost.

(c) While these procedures are being used, any State agency may require the special account payment system for nongovernmental sponsors for whom proper payment has been, or is expected to be, a particular problem. Such State agency must include an appropriate provision in its written agreement with sponsors, and appropriately amend its program management and administration plan in accordance with §225.6(c). In States where FNSRO administers the program, special accounts may be established only at the request of the sponsor.

(d) In order to assess the effectiveness of the special account payment system, the Department shall, subsequent to completion of Program operations for this fiscal year, evaluate the results of these procedures as implemented in the State of New York and in other States which so utilize the system.

(Catalog of Federal Domestic Assistance Programs No. 10.599.)

Note.—The Food and Nutrition Service has determined that this document does not contain significant proposals requiring preparation of an economic impact statement under Executive Order 11231 and Office of Management and Budget Circular A-107.

Note.—The reporting and/or recordkeeping requirements contained herein have been approved by the Office of Management and Budget in accordance with the Federal Reports Act of 1942.


CAROL TUCKER FOREMAN, Assistant Secretary.

[3410-02]

CHAPTER IX—AGRICULTURAL MARKETING SERVICE (MARKETING AGREEMENTS AND ORDERS; FRUITS, VEGETABLES, NUTS), DEPARTMENT OF AGRICULTURE

PART 958—ONIONS GROWN IN CERTAIN DESIGNATED COUNTIES IN IDAHO AND MALHEUR COUNTY, OREG.

Handling Regulation

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This regulation requires fresh market shipments of onions grown in certain designated counties in Idaho and Malheur County, Oreg., to be inspected and meet minimum quality and size requirements. The regulation should promote orderly marketing of such onions and keep less desirable qualities and sizes from being shipped to consumers.

EFFECTIVE DATE: August 1, 1978.

FOR FURTHER INFORMATION CONTACT:


SUPPLEMENTARY INFORMATION:

Marketing agreement No. 130 and order No. 958, both as amended (7 FR Part 958), regulate the handling of onions grown in certain designated counties in Idaho and Malheur County, Oreg. It is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601-674). The Idaho-Eastern Oregon Onion Committee, established under the order, is responsible for its local administration.

Notice of rulemaking was published in the Federal Register in the July 3, 1978, Federal Register (43 FR 28816). The notice afforded interested persons through July 18, 1978, to file written data, views, or arguments pertaining to that proposal. None was filed.

This regulation is based upon recommendations made by the committee at its public meeting in Ontario, Oreg., on June 20, 1978. The recommendations of the committee reflect its appraisal of the composition of the 1978 crop of Idaho-Eastern Oregon onions and the marketing prospects for this season and are consistent with the marketing policy it adopted. Harvesting of onions is expected to begin about August 1.

The grade, size, pack, maturity, and inspection requirements specified herein are necessary to prevent onions of low quality or less desirable sizes from being distributed in fresh market channels. They will also provide consumers with good quality onions consistent with the overall marketing policy for the crop, and maximize returns to producers for the preferred quality and sizes.

Exception are provided to certain of these requirements to recognize special situations in which such requirements would be inappropriate or unreasonable. Shipments are allowed to certain special purpose outlets without regard to the grade, size, pack, maturity, and inspection requirements. Provided, That safeguards are met to prevent such onions from reaching unauthorized outlets.

Special purpose shipments are allowed for planting, livestock feed, charity, dehydration, extraction, and pickling since such shipments do not normally enter the commercial fresh market channels and no useful purpose would be served by regulating such shipments. Onions for canning and freezing are exempt under the legislation's authority for these purposes.

Findings. After consideration of all relevant matters, including the proposal set forth in the aforesaid notice which was recommended by the Idaho-Eastern Oregon Onion Committee, it is hereby found that the handling regulation, as herein set forth, will tend to effectuate the declared policy of the act.

It is hereby further found that good cause exists for not postponing the effective date of this regulation until 30 days after its publication in the Federal Register (5 U.S.C. 553) in that: (1) Shipments of onions grown in the production area will begin on or about the effective date specified herein, (2) to maximize benefits to producers, this regulation should apply to as many shipments as possible during the marketing season, (3) information regarding the provisions of this regulation, which are similar to those in effect during the previous season, has been made available to producers and handlers in the production area, (4) compliance with this regulation will not require any special preparation by handlers which cannot be completed by the effective date, and (5) notice of the proposed regulation was published in the Federal Register of July 3, 1978.

The regulation is as follows:

§958.323. Handling regulation.

During the period August 1, 1978, through April 30, 1979, no person may handle any lot of onions except braided red onions, unless such onions are at least "moderately cured," as defined in paragraph (f) of this section, and meet the requirements of paragraphs (a) and (b) of this section, or unless such onions are handled in accordance with paragraphs (c) and (d) or (e) of this section.

FEDERAL REGISTER, VOL. 43, NO. 145—FRIDAY, JULY 28, 1978
(a) Grade and size requirements.—

(1) White varieties. Shall be either: (i) U.S. No. 2, 1 inch minimum to 2 inches maximum diameter; or

(ii) U.S. No. 2, if not more than 30 percent of the lot is comprised of onions of U.S. No. 1 quality, and at least 1½ inches minimum diameter. However, none of these three categories of onions may be commingled in the same bag or other container.

(2) Red varieties. U.S. No. 2 or better grade, at least 1½ inches minimum diameter.

(3) All other varieties. Shall be either: (i) U.S. No. 2 grade, at least 3 inches minimum diameter, if not more than 30 percent of the lot is comprised of onions of U.S. No. 1 quality; or

(ii) U.S. No. 1, 1¼ inches minimum to 2½ inches maximum diameter; or

(iii) U.S. No. 1, at least 2¼ inches minimum diameter.

However, none of these three categories of onions may be commingled in the same bag or other container.

(b) Inspection. No handler may handle any onions regulated hereunder unless such onions are inspected by the Federal-State inspection service and are covered by a valid applicable inspection certificate, except when relieved of such requirement pursuant to paragraphs (c) or (e) of this section.

(c) Special purpose shipments. The minimum grade, size, quality, and inspection requirements of this section shall not be applicable to shipments of onions for any of the following purposes: (1) Planting, (2) livestock feed, (3) charity, (4) dehydration, (5) pickling, (6) freezing, (7) extraction, and (8) commingling.

(d) Safeguards. Each handler making shipments of onions for dehydration, canning, freezing, extraction, or pickling may not to paragraph (c) of this section shall:

(1) First apply to the committee for and obtain a certificate of privilege to make such shipments;

(2) Prepare, on forms furnished by the committee, a report in quadruplicate on each individual shipment to such outlets authorized in paragraph (e) of this section;

(3) Bill or consign each shipment directly to the applicable processor; and

(4) Forward one copy of such report to the committee office and two copies to the processor for signing and returning one copy to the committee office. Failure of the handler or processor to report such shipments by promptly signing and returning the applicable report to the committee office may be cause for cancellation of the handler’s certificate of privilege and/or the processor’s eligibility to receive further shipments pursuant to such certificate of privilege. Upon cancellation of any such certificate of privilege the handler may appeal to the administrator for reconsideration.

(e) Minimum quantity exemption. Each handler may ship up to, but not to exceed, 1 ton of onions each day without regard to the inspection and assessment requirements of this part, if such onions meet minimum grade, size, and maturity requirements of this section. This exemption shall not apply to any portion of a shipment that exceeds 1 ton of onions.

(f) Definitions. The terms “U.S. No. 1” and “U.S. No. 2” have the same meaning as defined in the U.S. Standards for Grades of Onions (Other Than Bermuda-Granex-Grano and Creole Types), as amended (7 CFR 2851.2830-2851.2854), or the U.S. Standards for Grades of Bermuda-Granex-Grano Type Onions (7 CFR 2851.3195-2851.3209), whichever is applicable to the particular variety, or variations thereof specified in this section. The term “braided red onions” means onions of red varieties with tops braided (interlaced). The term “moderately cured” means the onions are mature and are more nearly well cured than fairly well cured. Other terms used in this section have the same meaning as when used in marketing agreement No. 130 and this part.

(g) Applicability to imports. Pursuant to §8e of the act and §980.117 Import regulations; onions (43 FR 5499); onions imported during the effective period of this section shall meet the grade, size, quality, and maturity requirements specified in the introductory paragraph and paragraph (a) of this section.

(8) When used in market and processing purposes: (1) Planting, (2) livestock feed, (3) dehydration, (4) extraction, and (5) pickling.


FLOYD F. HEDLUND, Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[FR Doc. 78-20962 Filed 7-27-78; 6:45 am]

[3410-02]

[LeMon Reg. 156, LeMon Reg. 156, Amdt. 1]

PART 910—LEMONS GROWN IN CALIFORNIA AND ARIZONA

Limitation of Handling

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This action establishes the quantities of California-Arizona lemons that may be shipped to the fresh market during the period July 30-August 5, 1978, and increases the quantity of such lemons that may be shipped to the fresh market during the periods specified due to the marketing situation confronting the lemon industry.


FOR FURTHER INFORMATION CONTACT:


SUPPLEMENTARY INFORMATION: Findings. Pursuant to the marketing agreement, as amended, and order No. 910, as amended (7 CFR Part 910), regulating the handling of lemons grown in California and Arizona, effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601-674), and upon the basis of the recommendations and information submitted by the Lemon Administrative Committee, established under this marketing order, and upon other information, it is found that the limitation of handling of lemons, as hereafter provided, will tend to effectuate the declared policy of the act.

The committee met on July 25, 1978, to consider supply and market conditions and other factors affecting the need for regulation, and recommended quantities of lemons deemed advisable to be handled during the specified weeks. The committee reports the demand for lemons continues good.

It is further found that it is impractical and contrary to the public interest to give preliminary notice, engage in public rulemaking, and postpone the effective date until 30 days after publication in the Federal Register (5 U.S.C. 553), because of insufficient time between the date when information became available upon which this regulation and amendment are based and the effective date necessary to effectuate the declared policy of the act. Interested persons were given an opportunity to submit information and views on the regulation at an open meeting, and the amendment relieves restrictions on the handling of lemons. It is necessary to effectuate the declared purposes of the act to make these regulatory provisions effective as specified, and handlers have been apprised of such provisions and the effective time.

§910.456 Lemon regulation 156.

Order. (a) The quantity of lemons grown in California and Arizona which may be handled during the period July 30, 1978, through August 5, 1978, is established at 300,000 cartons.
(b) As used in this section, "handled" and "carton(s)" mean the same as defined in the marketing order.

§910.455 [Amended]

2. Paragraph (a) of §910.455—Lemon regulation 155 (43 FR 31313) is amended to read as follows: "The quantity of lemons grown in California and Arizona which may be handled during the period July 23, 1978, through July 29, 1978, is established at 325,000 cartons."

(43 FR 31313)


CHARLES R. BRADER,
Deputy Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[FR Doc. 78-21104 Filed 7-27-78; 8:45 am]

PART 231—ARRIVAL-DEPARTURE MANIFESTS AND LISTS; SUPPORTING DOCUMENTS

Submission of Aircraft/Vessel Reports (Forms 1–92) for Direct Flights Between the United States and Canada; Stay of Final Rules and Request for Comments

AGENCY: Immigration and Naturalization Service, Justice.

ACTION: Stay of final rule and request for comments.

SUMMARY: The purpose of this order is to stay indefinitely the final rules published at 43 FR 30268–69 on July 14, 1978, to allow for public participation in this rule making proceeding pursuant to a request of the Air Transport Association. The Service requests comments based on the text of the rules published at 43 FR 30268–69. Pull consideration will be given to all relevant representations received and the Service will reconsider the rules following an analysis of those representations.

DATES: Final rules stayed indefinitely. Interested persons are requested to submit relevant data, views and arguments concerning these stayed rules to the Commissioner of Immigration and Naturalization on or before September 26, 1978.

ADDRESSES: Please submit written representations, in duplicate, to the Commissioner of Immigration and Naturalization, Room 7100, 425 Eye Street NW., Washington, D.C. 20536.

FOR FURTHER INFORMATION CONTACT:


LEONEL J. CASTILLO,
Commissioner of Immigration and Naturalization.

[FR Doc. 78-21067 Filed 7-27-78; 8:45 am]

[1505–01]

Title 9—Animals and Animal Products

CHAPTER III—FOOD SAFETY AND QUALITY SERVICE, MEAT AND POULTRY PRODUCTS INSPECTION, DEPARTMENT OF AGRICULTURE

PART 318—ENTRY INTO OFFICIAL ESTABLISHMENTS, REINSPECTION AND PREPARATION OF PRODUCTS

Nitrates, Nitrites, and Ascorbates (or Isoascorbates) in Bacon

Correction

In FR Doc. 78–20721 appearing at page 32133 in the issue for Tuesday, July 25, 1978, on page 32137, first column, ninth line from the top, the word "nitrate" should read "nitrite".

[7590–01]

Title 10—Energy

CHAPTER I—NUCLEAR REGULATORY COMMISSION

CHANGE OF ADDRESS OF REGION II OFFICE

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is moving its Inspection and Enforcement Regional Office II to a new address in Atlanta, Ga. The new address is as follows: U.S. Nuclear Regulatory Commission, Region II, 101 Marietta Street, Suite 3100, Atlanta, Ga. 30303.

Because these amendments relate solely to corrections and minor matters, the Commission has found that good cause exists for omitting notice of proposed rulemaking, and public procedure thereon, as unnecessary, and for making the amendments effective on

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of Title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Parts 1, 20, and 73 are published as a document subject to codification.

PART 1—STATEMENT OF ORGANIZATION AND GENERAL INFORMATION

1. Paragraph 1.3(b) of 10 CFR Part 1 is amended by revising the address of NRC Regional Office II to read as follows:

§1.3 Location of principal offices and regional offices.

(b) · · · Region II, USNRC, 101 Marietta Street, Suite 3100, Atlanta, Ga. 30303.

PART 20—STANDARDS FOR PROTECTION AGAINST RADIATION

2. Appendix D of 10 CFR Part 20 is amended by revising the address of NRC Regional Office II to read as follows:

APPENDIX D—U.S. NUCLEAR REGULATORY COMMISSION INSPECTION AND ENFORCEMENT REGIONAL OFFICES

Region II, USNRC, Office of Inspection and Enforcement, 101 Marietta Street, Suite 3100, Atlanta, Ga. 30303.

PART 73—PHYSICAL PROTECTION OF PLANTS AND MATERIALS

3. Appendix A of 10 CFR Part 73 is amended by revising the address of NRC Regional Office II to read as follows:

FEDERAL REGISTER, VOL. 43, NO. 146—FRIDAY, JULY 28, 1978
PART 226—TRUTH IN LENDING

Official Staff Interpretations

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Official staff interpretation.

SUMMARY: The Board is publishing the following official staff interpretation of regulation Z regarding the truth in lending disclosures which must be made in connection with certain interim student credit transactions made under a federally insured program. The agency is taking this action in response to a request it has received for interpretation of this regulation.

EFFECTIVE DATE: On or after August 28, 1978.

FOR FURTHER INFORMATION CONTACT:


SUPPLEMENTARY INFORMATION: The official staff interpretation(s) published in FR Doc. 78-20886 appearing at page 30551 of the issue for Monday, July 17, 1978, paragraphs (2) and (3) of "Supplementary Information" should read as follows, with corrections in the code of Federal Regulations part number and the United States Code number:

"(2) An opportunity for public comment on an official staff interpretation may be provided upon request of interested parties and in accordance with 12 CFR Part 226.1(d)(2)(ii). As provided by 12 CFR Part 226.1(d)(3) every request for public comment must be in writing, should clearly identify the number of the official staff interpretation in question, should be addressed to the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551, and must be postmarked or received by the Secretary’s office before the effective date of the interpretation. The request must also state the reasons why an opportunity for public comment would be appropriate.

"(3) 15 U.S.C. 1691(b)."

§ 226.8(b) Under federally insured program providing credit to students for educ-
tional purposes, if student has option of receiving funds directly which may be used as the student sees fit, loan disclosures are appropriate.

§ 226.58. Federally Insured program providing credit to students for educational purposes, if student has option of receiving funds directly which may be used as the student sees fit, loan disclosures are appropriate.


This is in response to your letter of , in which you request an official staff interpretation of regulation Z regarding the . The Board’s procedures, is received and become effective .

If a credit is made to a student’s educational institution. You are concerned consists of a fund from which extend

funds received under the program is re-


FOR FURTHER INFORMATION CONTACT:

James P. Lawless, Assistant General Counsel, NOAA, Page Building 1, 3300 Whitehaven Street NW., Washington, D.C. 20235, 202-534-4245.

James P. Lawless, Assistant General Counsel, NOAA, Page Building 1, 3300 Whitehaven Street NW., Washington, D.C. 20235, 202-534-4245.

The purpose of the letter is to provide clarification on the applicability of Regulation Z regarding the use of funds received under the program.

Under the program, funds may be disbursed directly to the student or a credit may be made to the student’s account at the educational institution. If a credit is made, the student must sign an affidavit affirming that the funds will be used only for such expenses.

Under subsection 931.82(b) of the Higher Education Act of 1965, use of funds received under the program is restricted to expenses related to attendance at the educational institution. This restriction can be waived if the student signs an affidavit stating that the funds will be used only for such expenses.

Under section 931.82(b) of Regulation Z, the Board’s procedures, is received and become effective .

If a credit is made to a student’s educational institution, the transaction could be viewed as a credit sale rather than a loan, and credit sale disclosures rather than loan disclosures would be required. The staff believes that the applicable principles of law include the principles of the Convention on the Territorial Sea and the Contiguous Zone, and extended on the basis of such principles. In section 931.82 of the above regulations, procedures are set forth for establishment of a delimitation line when a lateral seaward boundary has not been clearly defined or fixed. The first sentence of subsection 931.82(b) reiterates the statutory provision that applicable principles of law are to be used, and was intended to provide examples of such principles.

Subsequent analysis of this language has raised some question as to whether NOAA has created a presumption in favor of the principles mentioned which go beyond the statutory language. NOAA definitely did not intend to establish a presumption in favor of any principle of law over another in this regard or to change the effect of the statute. In order to clarify this intent and to avoid the possibility that someone could interpret the regulations otherwise, NOAA is hereby correcting its regulations to reiterate the language of the statute. Any other reference in Subpart H of the regulations to “applicable principles of law” also means the same principles as in section 931.82(b)(3)(B)(ii) of the CZMA.

Because this constitutes only a clarification of what NOAA always intended in its regulations, which was to reiterate the terms of the statute, NOAA hereby finds for good cause, in accordance with 5 U.S.C. 553 (b) and (d), that notice and public procedure on such clarification is unnecessary, and that a 30-day delay prior to the effective date of the clarification is unnecessary. In consideration of the foregoing, part 931 should be changed as follows:

Delete that part of the first sentence of § 931.82(b) after the words “Associate Administrator” (beginning with the sixth line), and replace it with the following:

"** according to the applicable principles of law, including the principles of the Convention on the Territorial Sea and The Contiguous Zone."


T. P. Gleiter,
Assistant Administrator for Administration.

For purposes of determining such adjacency, section 308(b)(3)(B)(ii) of the Coastal Zone Management Act of 1972, as amended (CZMA), provides: "If no lateral seaward boundaries, or any portion thereof, have been clearly defined or fixed by an interstate compact, agreement, or judicial decision. lateral seaward boundaries shall be determined according to the applicable principles of law, including the principles of the Convention on the Territorial Sea and the Contiguous Zone, and extended on the basis of such principles."

In section 931.82 of the above regulations, procedures are set forth for establishment of a delimitation line when a lateral seaward boundary has not been clearly defined or fixed. The first sentence of subsection 931.82(b) reiterates the statutory provision that applicable principles of law are to be used, and was intended to provide examples of such principles. Subsequent analysis of this language has raised some question as to whether NOAA has created a presumption in favor of the principles mentioned which go beyond the statutory language. NOAA definitely did not intend to establish a presumption in favor of any principle of law over another in this regard or to change the effect of the statute. In order to clarify this intent and to avoid the possibility that someone could interpret the regulations otherwise, NOAA is hereby correcting its regulations to reiterate the language of the statute. Any other reference in Subpart H of the regulations to “applicable principles of law” also means the same principles as in section 938(b)(3)(B)(ii) of the CZMA.

Because this constitutes only a clarification of what NOAA always intended in its regulations, which was to reiterate the terms of the statute, NOAA hereby finds for good cause, in accordance with 5 U.S.C. 553 (b) and (d), that notice and public procedure on such clarification is unnecessary, and that a 30-day delay prior to the effective date of the clarification is unnecessary. In consideration of the foregoing, part 931 should be changed as follows:

Delete that part of the first sentence of § 931.82(b) after the words “Associate Administrator” (beginning with the sixth line), and replace it with the following:

"** according to the applicable principles of law, including the principles of the Convention on the Territorial Sea and The Contiguous Zone."

Exemption From Full Compliance With Labeling Requirements of Federal Hazardous Substances Act for Cyanoacrylate-Based Glue in Containers of 3 Grams or Less

AGENCY: Consumer Product Safety Commission.

ACTION: Final rule.

SUMMARY: This document partially exempts cyanoacrylate-based glue in packages of 3 grams or less from the size of labeling requirements of the Federal Hazardous Substances Act (FHSA). This exemption is being issued because the Commission has found that, because of the size of the package involved, full compliance with the labeling requirements applicable under the FHSA is impracticable and is not necessary for the adequate protection of the public health and safety.

DATES: This exemption is effective on July 28, 1978.

FOR FURTHER INFORMATION CONTACT:


SUPPLEMENTARY INFORMATION:

BACKGROUND

Section 2(f)(1)(A) of the Federal Hazardous Substances Act ("the Act" or "FHSA"), 15 U.S.C. 1201(1)(A), provides that the term "hazardous substance" includes any substance or mixture of substances which is an irritant, if such substance or mixture of substances may cause substantial personal injury or substantial illness during or as a proximate result of, any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children. Section 2(k) of the FHSA (15 U.S.C. 1201(O)) provides that a hazardous substance which is intended, or packaged in a form suitable, for use in the household or by children is misbrand-ed if it does not bear a label stating certain specified information. A Commission regulation, 16 CFR 1500.121, describes in detail the placement, conspicuousness, and contrast requirements for labeling under the FHSA. Section 1500.121(d) provides that except for labeling required to be on the main panel, which includes, i.e., (1) the signal word, (2) the statement of the principal hazard associated with the substance, and (3) instructions to read carefully any cautionary information that may be placed elsewhere on the label), the remainder of the information required under the FHSA may be placed on the label elsewhere on the main panel. Section 1500.121(d) also provides that the type size used for the remainder of the required information must bear a reasonable relationship to the printing on the package panel involved and may be no smaller than 10 point type unless the available label space requires reductions, in which case this size type may be reduced to no smaller than 6 point type. However, because of small label space, exemptions to the 6 point type requirement may be granted under section 3(c) of the Act and 16 CFR 1500.82, 1500.83. The Consumer Product Safety Commission may exempt the substance from the full labeling requirements, to the extent consistent with the adequate protection of public health and safety, if it finds that, because of the size of a package for a hazardous substance or because of the minor hazard presented to the public by the substance, or for other good and sufficient reason, full compliance with the labeling requirements is either impracticable or unnecessary for the adequate protection of the public health and safety. Under 16 CFR 1500.83(a), any person who believes that a particular hazardous substance intended or packaged in a form suitable for use in the household or by children should be exempted from a labeling requirement otherwise applicable under the Act may submit to the Commission a request for an exemption pursuant to section 3(c) of the Act. The request must present facts in support of the view that full compliance is impracticable or is not necessary for the protection of the public health.

On May 9, 1974, the Commission issued a notice announcing information that had been obtained by testing cyanoacrylate glues (39 FR 16511). This information indicated that cyanoacrylate-based glue is a "hazardous substance" within the meaning of that term under the Act because it is an "eye irritant." Therefore, any such glue is deemed "misbranded" under section 2(k) of the Act unless it is labeled in accordance with 16 CFR 1500.121.

The information available to the Commission shows that these glues can contact the eyes in situations such as when some glue squirts out when the container is shaken to get glue to flow, when the tube ruptures when it is squeezed, when glues squirt out when the surfaces to be glued are pressed together, and when the tubes are intentionally or accidentally misused by children. In each of these types of situations, it would appear that only a small amount of glue would be likely to contact the eye.

PETITION

On November 11, 1975, the Consumer Product Safety Commission received a petition from Wilhold Glues, Inc., of Santa Fe Springs, Calif., requesting an exemption from full compliance with the labeling requirements under the Federal Hazardous Substances Act for cyanoacrylate-based glue in 2-gram size tubes. The petition stated that the size of the package made it impracticable to show all of the labeling that was required by 16 CFR 1500.121 to be in at least 6 point type.

After considering this petition and the information obtained by the Commission's staff, the Commission concluded that an exemption for glues with a cyanoacrylate base sold in sizes of 2 grams or less should be granted (42 FR 54308; October 5, 1977).

The Commission's decision to propose this exemption was based principally on the preliminary findings that full label compliance is both impracticable, due to the size of the package, and unnecessary for the adequate protection of the public health.

The Commission believes that any risk to the public of injury caused by eye irritation associated with cyanoacrylate glues can be reduced sufficiently by placing the signal word, statement of hazard, and instructions to read additional warnings on the main label panel and by placing the additional warnings elsewhere on the immediate container, and on any outer package, accompanying leaflet, and display card in accordance with the placement, conspicuousness, and contrast requirements of 16 CFR 1500.121. Accordingly, the Commission proposed that this exemption be granted under the following conditions:

(1) The signal word (in this instance, either "WARNING" or "CAUTION") must appear on the main label panel of the product and must comply with the placement, conspicuousness, and contrast requirements of 16 CFR 1500.121.

(2) The statement of the principal hazard or hazards associated with the...
product, in this case "Eye Irritant" or similar wording descriptive of the hazard, must also appear on the main label panel of the product in accordance with the placement, conspicuousness, and contrast requirements of 16 CFR 1500.121. (These first two conditions merely restate requirements of § 1500.121(a), which is not affected by the exemption.)

(3) The main label panel must also bear instructions to read additional warnings, elsewhere on the label and on any outer package, accompanying leaflet, and display card. Thus, any statement of precautionary measures describing the action to be followed or avoided, instructions for first-aid treatment, and the statement "keep out of the reach of children" or its practical equivalent, all required by section 2(p)(1) of the Act, need not appear on the main label panel, but instructions to read these additional warnings must be placed on the main label panel along with the required signal word and statement of hazards or hazards, in accordance with 16 CFR 1500.121. (Except for the reference to the outer package, accompanying leaflet, and display card, this condition also restates a requirement of § 1500.121(a).)

(4) The remainder of the cautionary labeling required by the Act must appear elsewhere on the immediate container and on any outer package, accompanying leaflet, and display card. These additional warnings must comply with the size, placement, contrast, and conspicuousness requirements of 16 CFR 1500.121. "Keep out of the reach of children" or its practical equivalent, all required by section 2(p)(1) of the Act, need not appear on the main label panel, but instructions to read these additional warnings must be placed on the main label panel along with the required signal word and statement of hazards or hazards, in accordance with 16 CFR 1500.121. (Except for the reference to the outer package, accompanying leaflet, and display card, this condition also restates a requirement of § 1500.121(a).)

The Commission has evaluated this petition and has concluded that the petitioner's need for the exemption is the same for the tube containing 3 grams as for the tube containing 2 grams, since the same size tube is used to contain both amounts of glue. In addition, the additional gram of glue will not significantly increase the hazards associated with the use of cyanoacrylate-based glues. Accordingly, the Commission agrees with the comment.

CONCLUSION

After considering the petition, the comment received on the proposed petition, and information obtained by the Commission's staff, the Commission finds that, because of the size of the package involved and for the other good and sufficient reasons discussed above, full compliance with the labeling requirements otherwise applicable under the Federal Hazardous Substances Act for cyanoacrylate-based glues in packages containing 3 grams or less is impracticable and not necessary for the adequate protection of the public health and welfare and that the exemption set forth below is consistent with the adequate protection of the public health and safety.

Since this rule grants an exemption, the requirement of the Administrative Procedure Act that publication be made not less than 30 days before the effective date of the rule does not apply (5 U.S.C. 553(d)(1)), and this rule is therefore effective immediately.

Accordingly, pursuant to provisions of the Federal Hazardous Substances Act (Secs. 2(f), 2(p), 3(c), 10(a); 74 Stat. 372, 374, 375, 378, as amended 80 Stat. 1304, 1305, 83 Stat. 187-189; 15 U.S.C. 1261(f), 1261(p), 1262(c), 1269(a)), and under authority vested in the Commission by the Consumer Product Safety Act (sec. 30(a), Pub. L. 92-573, 86 Stat. 1231; 15 U.S.C. 2079(a)), the Commission amends subchapter C, chapter II, of title 16 of the Code of Federal Regulations by adding to § 1500.83 a new paragraph (a)(37), reading as follows: (The text of the introductory portion of § 1500.83(a), though unchanged, is included for context.)

§ 1500.83 Exceptions for small packages, minor hazards, and special circumstances.

(a) The following exemptions are granted for the labeling of hazardous substances under the provisions of § 1500.82:

(37) Glues with a cyanoacrylate base in packages containing 3 grams or less are exempt from the requirement of § 1500.121(d) that labeling which is permitted to appear elsewhere than on the main label panel must be in type size no smaller than 6 point type, provided that:

(i) The main panel of the immediate container bears both the proper signal word and a statement of the principal hazard or hazards associated with this product, as provided by § 1500.121 (a) and (c);

(ii) The main panel of the immediate container also bears an instruction to read carefully additional warnings elsewhere on the label and on any outer package, accompanying leaflet, and display card. The instruction to read additional warnings must comply with the size, placement, conspicuousness, and contrast requirements of § 1500.121; and

(iii) The remainder of the cautionary labeling required by the act that is not on the main label panel must appear elsewhere on the label in legible type and must appear on any outer package, accompanying leaflet, and display card. If there is no outer package, accompanying leaflet, or display card, then the remainder of the required cautionary labeling must be displayed on a tag or other suitable material that is securely affixed to the article so that the labeling will remain attached throughout the conditions of merchandising and distribution to the ultimate consumer.

COMMENT ON PROPOSAL

The Commission received one comment on the proposed exemption. This comment was from the original petitioner, Wilhold Glues, Inc. (Wilhold). Wilhold asked that the exemption apply to glues with a cyanoacrylate base packaged in containers of 3 grams or less, rather than the containers of 2 grams or less that were originally requested. Wilhold stated that this was necessary because since the original petition was submitted, the same size tube that had been used for 2 grams of glue was being extensively marketed with 3 grams of glue.


SADIE E. DUNN, Acting Secretary, Consumer Product Safety Commission.

FEDERAL REGISTER, VOL. 43, NO. 146—FRIDAY, JULY 28, 1978
Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER A—GENERAL

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

Redelegation of Grants Authority

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Commissioner of Food and Drugs is amending the regulations for delegations of authority by decentralizing the authority to approve or disapprove applications for grants and redelegating the authority to bureau level officials. The action, part of a decentralization effort to move operational functions out of the Office of the Commissioner, is being taken to increase the effectiveness of operations.


FOR FURTHER INFORMATION CONTACT:


SUPPLEMENTARY INFORMATION:

Section 5.25 (21 CFR 5.25) is being revised by deleting the delegation of authority and reference to the Associate and Deputy Associate Commissioner for Science. Approval authority for grant applications is being delegated to bureau directors, the Executive Director of Regional Operations, and the Director, National Center for Toxicological Research, and the authority to execute and issue notices of grant awards is extended to include the Chief of the Grants Management Branch of the new Office of Management and Operations.

Further redelegation of the authority delegated is not authorized. Authority delegated to a position by title may be exercised by a person officially designated to serve in such position in an acting capacity or on a temporary basis, unless prohibited by a restriction written into the document designating him as “acting,” or unless not legally permissible.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 701(a), 21 Stat. 1055 (21 U.S.C. 371(a))) and secs. 301, 307, 311, and 355 of the Public Health Service Act (42 U.S.C. 241, 2421, 243, and 263d) and under authority delegated to the Commissioner (21 CFR 5.1), part 5 is amended by revising §5.25 to read as follows:

§ 5.25 Grants.

(a) The directors of bureaus, the Executive Director of Regional Operations, and the Director of the National Center for Toxicological Research are authorized to approve or disapprove applications for grants under sections 301, 307, and 311 of the Public Health Service Act.

(b) The Director of the Bureau of Radiological Health is authorized to approve or disapprove applications for grants under section 356 of the Public Health Service Act.

(c) The Associate and Deputy Associate Commissioner for Management and Operations, the Director and Deputy Director of the Division of Contracts and Grants Management of the Office of Management and Operations, and the Chief of the Grants Management Branch of that Division and Office are authorized to sign and issue all notices of grant awards and amendments thereto and sign and issue notices of suspension and termination thereof.

Effective date. This regulation shall be effective July 28, 1978.


WILLIAM P. RANDOLPH,
Acting Associate Commissioner
for Regulatory Affairs.

(FR Doc. 78-20884 Filed 7-27-78; 8:45 am)

[4110-03]

PART 510—NEW ANIMAL DRUGS

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

Tyllosin

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The animal drug regulations are amended to reflect approval of two new animal drug applications (NADA's) providing for use of 10-gram-per-pound tyllosin premixes for making complete swine feeds. The applications were filed by Elanco Products Co. and Illini Feeds.

EFFECTIVE DATE: July 28, 1278.

FOR FURTHER INFORMATION CONTACT:

Jack C. Taylor, Bureau of Veterinary Medicine.

FEDERAL REGISTER, VOL. 43, NO. 146—FRIDAY, JULY 28, 1978
SUPPLEMENTARY INFORMATION: Jensen-Salsbery Laboratories, Division of Richardson-Merrell, Inc., 520 West 21st Street, Kansas City, Mo. 64141, filed an NADA (101-161V) providing for use of piperazine phosphate with thenium cloyslate tablets in weaned pups and adult dogs for removal of certain hookworms and ascarids.

In accordance with the freedom of information regulations and §514.11(e)(2)(i) (21 CFR 514.11(e)(2)(ii)) of the animal drug regulations, a summary of safety and effectiveness data and information submitted to support approval of this application is released publicly. The summary is available for public examination at the Office of the Hearing Clerk (HFC-20), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, from 9 a.m. to 4 p.m., Monday through Friday, except on Federal holidays. Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), part 520 is amended by adding new §520.1805, to read as follows:

§520.1805 Piperazine phosphate with thenium cloyslate tablets.

(a) Specifications. Each scored tablet contains the equivalent of 250 milligrams piperazine hexahydrate (as piperazine phosphate) and 125 milligrams thenium (as thenium cloyslate).

(b) Sponsor. See No. 011794 in §510.600(c) of this chapter.

(c) Conditions of use.—(1) Amount. Administer orally to dogs as follows:

<table>
<thead>
<tr>
<th>Number of tablets at each of the two doses</th>
<th>Animal weight (lb)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 or less</td>
<td>6 or less</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

(2) Indications for use. For removal of immature (fourth stage larvae) and adult hookworms (Ancyclostoma caninum, A. braziliense, and Uncinaria stenocephala) and ascarids (Toxocara canis) from weaned pups and adult dogs.

(3) Limitations. Do not use this product to treat dogs weighing less than 2 pounds, unweaned pups, or pups under 5 weeks of age. Maximum efficacy against hookworms necessitates two doses in 1 day of treatment. The interval between the doses should be not less than 4 hours or more than 24 hours. Administer the first dose in the morning before feeding. Do not permit dog to chew tablet. Feed the dog between doses. Do not feed milk or other fatty foods during treatment. Retreatment may be needed in 7 to 23 days as determined by laboratory fecal examinations or in animals kept in known contaminated quarters. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Effective date: July 28, 1978.

[4110-03]

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

Uredofos Tablets; Change of Sponsor

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The regulations are amended to reflect the change of sponsor for uredofos tablets from Affiliated Laboratories Division, Whitmoyer Laboratories, Inc., to Beecham Laboratories, Division of Beecham, Inc. A supplemental new animal drug application (NADA) filed by Beecham Laboratories provides for this change.


FOR FURTHER INFORMATION CONTACT:

Henry C. Hewitt, Bureau of Veterinary Medicine (HFV-112), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-3430.

FRED J. KINGMA, Acting Director, Bureau of Veterinary Medicine.
[FR Doc. 78-20725 Filed 7-21-78; 8:45 am]

[4110-03]

PART 540—PENICILLIN ANTIBIOTIC DRUGS FOR ANIMAL USE

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

Procarcin Penicillin G Aqueous Suspension (Injectable)

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The agency is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) providing revised labeling of injectable procaine penicillin G aqueous suspension in treating certain infections of cattle, sheep, swine, and horses. The application was filed by Pfizer, Inc., in compliance with the National Academy of Sciences—National Research Council Drug Efficacy Study Group (NAS/NRC) evaluation of the product. This document also amends the regulations by establishing a zero residue tolerance for penicillin and its salts in sheep.


FOR FURTHER INFORMATION CONTACT:

Myron C. Rosenberg, Bureau of Veterinary Medicine (HFV-125), Food and Drug Administration, Department of Health, Education and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-1783.

SUPPLEMENTARY INFORMATION:
Pfizer's product was one of several mentioned in the NAS/NRC evaluation published in the Federal Register of August 25, 1978 (35 FR 13644). In that document, the NAS/NRC concluded, and the Food and Drug Administration (FDA) concurred, that these products were probably effective for intramuscular use in treating infections in animals caused by pathogens sensitive to procaine penicillin. The NAS/NRC stated:

1. The dosage directions are inadequate. The dosage should be expressed as to provide a specific quantity of the drug per unit of body weight per unit of time for each animal species. The minimum allowable dosage should range from 3,000 to 10,000 units per pound body weight per day depending on the animal species. In some diseases, because of decreasing bacterial sensitivity, higher doses may be necessary.

2. Properly qualify disease entities as to those caused by pathogens sensitive to penicillin. If the disease claim cannot be so qualified the claim must be dropped.

3. The labeling should not recommend injection into open wounds, abscesses, and actinomycotic lesions, nor should the labeling recommend the dose if there is no response to previous injections.

4. The labeling should state the recommended procedure for treating hyper-sensitivity reactions to penicillin and also the occasional hypersensitivity to procaine.

5. The labeling should provide a precaution statement indicating the need for sensitivity testing preceding the use of penicillin in treating staphylococcal pathogens.

6. The revised labeling (package insert) provides a cautionary statement regarding untoward reactions that may occur in animals administered this drug and describes how they should be treated.

7. The revised labeling (package insert) provides a cautionary statement regarding the use of this product in treating staphylococcal pathogens.

The NADA was concerned only with the drug's effectiveness and safety to the animal being treated and did not take into account the safety of food derived from treated animals.

The evaluation was published to inform NADA holders of the findings of the NAS/NRC and FDA and to inform all interested persons that such articles may be marketed, provided they are the subject of approved NADA's and otherwise comply with the requirements of the Federal Food, Drug, and Cosmetic Act. NADA's that pertain to identical products and reflect those conditions of use set forth in this regulation do not require efficacy data as specified by §514.10(6)(i) or §514.16(4)(vi) of the animal drug regulations. In lieu of such data, approval may require bioequivalence or similar data as suggested in the guidelines for submitting NADA's for NAS/NRC-reviewed generic drugs. The guideline is available from the Hearing Clerk (HPA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857. Those conditions of use are identified in this regulation by a footnote.

Pfizer, Inc., 235 East 42d Street, New York, N.Y. 10017, submitted a supplemental NADA (65-110V) which corresponded to the above-mentioned NASA/NRC recommendations as follows:

1. and 2. The recommended daily dosage in large animal species is now given in the product labeling as 3,000 units per pound of body weight. The indications for use of this product in all small animals have been removed from the labeling.

3. Disease entities have been qualified as to causative pathogen and these are sensitive to penicillin. Many disease claims and several animal species have been deleted from the indications of use. Indications for the use of this drug in the treatment of antrax have been deleted from product labeling.

4. The labeling does not recommend injection into open wounds, abscesses, actinomycotic lesions nor does it suggest increasing the dose if there is no response to the previous dose. On the contrary the labeling warns against doses above those specifically recommended.

5. The revised labeling (package insert) provides a cautionary statement regarding untoward reactions that may occur in animals administered this drug and describes how they should be treated.

6. The revised labeling (package insert) provides a cautionary statement regarding the use of this product in treating staphylococcal infections.

A dosage of 3,000 units per pound of body weight meets NAS/NRC efficacy requirements for treatment of the cattle, sheep, swine, and horse diseases set forth in the indications for use in this regulation.

These claims deletions and modifications in indications for use have substantiated upgrading the NAS/NRC rating from probably effective to effective.

Although this drug has been indicated for use in sheep for many years, a residue tolerance for this species has never been listed in §556.510 (21 CFR 556.510). The FDA is currently reevaluating the tolerances for penicillins in all species. Pending completion of this evaluation, §556.510 is being amended to include sheep among those species for which a zero tolerance is now in effect. This action does not constitute a reevaluation or reaffirmation of the underlying human safety data.

In accordance with the freedom of information regulations and §514.11(e)(2)(ii) of the animal drug regulations (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness, data and information submitted to support approval of this application is released publicly. The summary is available for public examination at the Office of the Hearing Clerk HPA-305, at the above-named address from 9 a.m. to 4 p.m., Monday through Friday, except on Federal holidays.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(1), 82 Stat. 347 (21 U.S.C. 360b(1))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), Parts 540 and 556 are amended as follows:

1. In part 540, §540.274b is amended by adding new paragraph (c)(3) to read as follows:

§540.274b Procaine penicillin G aqueous suspension.

(c)(3) Specifications. The drug conforms to the requirements prescribed
PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

MONENSIN, BACITRACIN, BACITRACIN METHYLENE DISALICYLATE, ROXARSONE

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document amends the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Elanco Products Co., providing for the use of currently approved premixes in the preparation of a complete broiler feed containing a combination of monensin with bacitracin methylene disalicylate and roxarsone.


FOR FURTHER INFORMATION CONTACT:

Lonnie W. Luther, Bureau of Veterinary Medicine (HFV-147), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-445-4517.

SUPPLEMENTARY INFORMATION:

Elanco Products Co., a Division of Eli Lilly & Co., 740 South Alabama Street, Indianapolis, Ind. 46206, filed a supplemental NADA (95-735V) proposing label revision of its 20-, 30-, 45-, and 72-milligrams per pound monensin premixes. The revision permits use of finished feeds subsequently manufactured from these premixes for increased rate of weight gain in pasture cattle. Approval of this application does not constitute reaffirmation of the safety of residues resulting from use of this drug.

11.3 grams per ton monensin (ingestion of monensin, bacitracin methylene disalicylate, and roxarsone for use as an aid in the preparation of a complete broiler feed containing 90 to 110 grams per ton monensin sodium, 25 grams per ton bacitracin methylene disalicylate, and 11.3 to 22.7 grams per ton roxarsone for use as an aid in the prevention of certain forms of coccidiosis, for increased rate of weight gain, and for improved feed efficiency. This application is approved without reaffirmation of the underlying human safety data for use of the individual drug components: monensin sodium, bacitracin methylene disalicylate, and roxarsone in broiler feeds.

* * * * *

Effective date. This amendment is effective July 28, 1978.

(21 U.S.C. 360b(i)).


FRED J. KINGMA,
Acting Director, Bureau of Veterinary Medicine.

[FR Doc. 78-20718 Filed 7-27-78; 8:45 am]
In accordance with the freedom of information regulations and §514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)) of the animal drug regulations, a summary of safety and effectiveness data and information submitted to support approval of this application is released publicly. The summary is available for public examination at the office of the Hearing Clerk (HPA-305), Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, from 9 a.m. to 4 p.m., Monday through Friday, except on Federal holidays.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), part 558 is amended as follows:

1. In §558.76, by adding new paragraph (e)(3)(ix) to read as follows:

§558.76 Bacitracin methylene disalicylate.

(e) * * *
(3) * * *
(ix) Monensin and roxarsone in accordance with §558.355.

In §558.358, by adding new paragraph (f)(1)(xii) to read as follows:

§558.355 Monensin.

(f) * * *
(1) * * *
(xii) Amount per ton. Monensin, 90 to 110 grams, plus bacitracin methylene disalicylate, 28 grams, and roxarsone, 11.3 to 22.7 grams.

(a) Indications for use. As an aid in the prevention of coccidiosis caused by E. necatrix, E. tenella, E. acervulina, E. brunetti, E. maxima, and E. mivati; for increased rate of weight gain and for improved feed efficiency.

(b) Limitations. Do not feed to laying chickens; feed continuously as sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic; as monensin sodium provided by No. 000986 in §510.600 of this chapter; as bacitracin methylene disalicylate provided by No. 046573 in §510.600 of this chapter; as roxarsone provided by No. 011801 in §510.600 of this chapter.

Effective date. This regulation is effective July 28, 1978.


FRED J. KINGMA, Acting Director, Bureau of Veterinary Medicine.

[FR Doc. 78-20722 Filed 7-27-78; 8:45 a.m.]

PART 556—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

Decoquinate

AGENCY: Food and drug Administration.

ACTION: Final rule.

SUMMARY: The animal drug regulations are amended to reflect approval of a supplemental new animal drug application (NADA) filed by Hess & Clark, Division of Rhodia, Inc., providing for the use of higher concentration decoquinate-containing feed supplements for the preparation of approved decoquinate-containing cattle feeds.


FOR FURTHER INFORMATION CONTACT:

Adriano R. Gabuten, Bureau of Veterinary Medicine (HFV-140), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4913.

SUPPLEMENTARY INFORMATION:

Hess & Clark, Division of Rhodia, Inc., Ashland, OFF 44805, filed a supplemental NADA (39-417V) providing for the use of decoquinate-containing feed supplements containing 0.05 to 0.5 percent decoquinate for the preparation of cattle feed to be fed at the rate of 22.7 milligrams per 100 pounds of body weight per day. In addition, §555.195 (21 CFR 555.195) is amended to include approved concentrations for complete feeds.

Approval of this supplement does not involve reevaluation of the original application or reaffirmation of the drug’s safety and effectiveness.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), §555.195 is amended in the table in paragraph (g)(2) by revising the "Limitations" column to read as follows:

§555.195 Decoquinate.

<table>
<thead>
<tr>
<th>Decoquinate Combination 1</th>
<th>Indications for use</th>
<th>Limitations</th>
<th>Sponsor</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Administer as a complete feed containing 0.0015 pct to 0.003 pct decoquinate, or as a supplement containing 0.05 pct to 0.5 pct decoquinate. Feed for at least 28 days during periods of coccidiosis or when it is likely to be a hazard. Do not feed to breeding animals or cows producing milk for food. Complete feed should be consumed within 7 days of manufacture, supplements within 2 months.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1In grams per ton.

Effective date: This regulation is effective July 28, 1978.


FRED J. KINGMA, Acting Director, Bureau of Veterinary Medicine.
PART 1914—AREAS ELIGIBLE FOR THE SALE OF INSURANCE

Suspension of Community Eligibility

AGENCY: Federal Insurance Administration, HUD.

ACTION: Final rule.

SUMMARY: This rule lists communities where the sale of flood insurance, as authorized under the National Flood Insurance Program (NFIP), will be suspended because of noncompliance with the flood plain management requirements of the program.

EFFECTIVE DATES: The third date ("Susp.") listed in the fourth column.

FOR FURTHER INFORMATION CONTACT:

Mr. Richard Krimm, Assistant Administrator, Office of Flood Insurance Program, Room 5270, 451 Seventh Street, SW., Washington, D.C. 20410, 202-755-5651 or toll-free line 800-424-8872.

SUPPLEMENTARY INFORMATION:

The National Flood Insurance Program (NFIP), administered by the Federal Insurance Administration, enables property owners to purchase flood insurance at rates made reasonable through a Federal subsidy. In return, communities agree to adopt and administer local flood plain management measures aimed at protecting lives and new construction from future flooding. Section 1315 of the National Flood Insurance Act of 1968, as amended (42 U.S.C. 4022) prohibits flood insurance coverage as authorized under the National Flood Insurance Program (42 U.S.C. 4001–4128) unless an appropriate public body shall have adopted adequate flood plain management measures with effective enforcement measures. The communities listed in this notice no longer meet that statutory requirement for compliance, with program regulations (24 CFR pt. 1909 et seq.). Accordingly, the communities are suspended on the effective date in the fifth column, so that as of that date subsidized flood insurance is no longer available in the community.

In addition, the Federal Insurance Administration has identified the special flood hazard areas in these communities by publishing a flood hazard boundary map. The date of the flood map, if one has been published, is indicated in the sixth column of the table. Section 202(a) of the Flood Disaster Protection Act of 1973 (Pub. L. 93–234), as amended, provides that no direct Federal financial assistance (except assistance pursuant to the Disaster Relief Act of 1974 not in connection with a flood) may be legally provided for construction or acquisition of buildings in the identified special flood hazard area of communities not participating in the NFIP, with respect to which a year has elapsed since publication of a flood insurance map. This prohibition against certain types of Federal assistance becomes effective for the communities listed on the date shown in the last column.

The Federal Insurance Administrator finds that delayed effective dates would be contrary to the public interest. The Administrator also finds that notice and public procedure under 5 U.S.C. 553(b) are impracticable and unnecessary.

In each entry, a complete chronology of effective dates appears for each listed community.

Section 1914.6 is amended by adding in alphabetical sequence new entries to the table.

§ 1914.6 List of suspended communities.

<table>
<thead>
<tr>
<th>State</th>
<th>County</th>
<th>Location</th>
<th>Community</th>
<th>Effective dates of authorization/cancellation of sale of flood insurance in community</th>
<th>Hazard area identified</th>
<th>Date of Suspension</th>
</tr>
</thead>
<tbody>
<tr>
<td>State</td>
<td>County</td>
<td>Location</td>
<td>Community No.</td>
<td>Effective dates of authorization/cancellation of sale of flood insurance in community</td>
<td>Hazard area identified</td>
<td>Date</td>
</tr>
<tr>
<td>-------</td>
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</tr>
</tbody>
</table>


Gloria M. Jimenez, Federal Insurance Administrator.

[FR Doc. 78-19411 Filed 7-27-78; 8:45 am]

FEDERAL REGISTER, VOL. 43, NO. 146—FRIDAY, JULY 28, 1978
PART I—INCOME TAX; TAXABLE YEARS BEGINNING AFTER DECEMBER 31, 1953

Dividend Treatment for Certain Distributions by Controlled Foreign Corporations and Limitation of the Definition of Foreign Base Company Sales Income With Respect to Certain Agricultural Commodities

AGENCY: Internal Revenue Service, Treasury.

ACTION: Final regulations.

SUMMARY: This document provides final regulations relating to dividend treatment for certain distributions by controlled foreign corporations and limitation on the definition of foreign base company sales income with respect to certain agricultural commodities. The regulations provide necessary guidance to the public for compliance with the law.

EFFECTIVE DATES: The regulations are effective for taxable years of controlled foreign corporations beginning after December 31, 1975, and for taxable years of United States shareholders within which or with which such taxable years of controlled foreign corporations end.

FOR FURTHER INFORMATION CONTACT:


SUPPLEMENTARY INFORMATION:

BACKGROUND

On May 14, 1976, the Federal Register published proposed amendments to the Income Tax Regulations (26 CFR Part 1) under sections 851 and 954 of the Internal Revenue Code of 1954 (41 FR 19970). The amendments were proposed to conform the regulations to section 602 (a)(2) and (b) of the Tax Reduction Act of 1975 (88 Stat. 58). A public hearing was held on August 12, 1976. After consideration of all comments regarding the proposed amendments, those amendments are adopted as revised by this Treasury decision. In addition, this Treasury decision deletes the statutory material under sections 851 and 954.

COFFEE AND BANANAS

The proposed rules under §1.954-3 list coffee and bananas as agricultural commodities grown in the United States in commercially marketable quantities. Information was submitted by interested persons indicating that the amount of coffee and bananas produced in the United States is insignificant by comparison to the total world production of the two commodities. After consideration of this information, it was decided to provide in these final regulations that coffee and bananas are agricultural commodities not considered grown in the United States in commercially marketable quantities.

CRUDE RUBBER

As proposed, the rules under §1.954-3 do not classify crude rubber either as a commodity grown or not grown in the United States in commercially marketable quantities. It was submitted the crude rubber should be listed as an agricultural commodity not grown in the United States in commercially marketable quantities. It was concluded that crude rubber should be so listed.

DRAFTING INFORMATION

The principal author of this regulation was William E. Mantle of the Legislation and Regulations Division of the Office of Chief Counsel, Internal Revenue Service. However, personnel from other offices of the Internal Revenue Service and Treasury Department participated in developing the regulation, both on matters of substance and style.

ADOPTION OF AMENDMENTS TO THE REGULATIONS

Accordingly, the amendments to 26 CFR Part 1 published as a notice of proposed rulemaking in the Federal Register on May 14, 1976 (41 FR 19970), are hereby adopted as proposed subject to the following changes:

Paragraph 1. Paragraph 1 of the appendix to the notice of proposed rulemaking is revised to read as follows: “Section 1.851 is deleted.”

Paragraph 2. Paragraph 1.954-3 is deleted.

Paragraph 3. Section 1.954-3(a)(1)(i), as set forth in paragraph 3 of the appendix to the notice of proposed rulemaking, is revised as follows:

1. Inferior subdivision (a) is revised by deleting the third sentence and substituting in lieu thereof the following sentence: “Bananas, black pepper, cacao, coconut, coffee, crude rubber, and tea shall not be considered grown in the United States in commercially marketable quantities.”

2. Inferior subdivision (b) is revised by deleting “Bananas” and “Coffee” from the list of crops in table I.

This Treasury decision is issued under the authority contained in section 7805 of the Internal Revenue Code of 1954 (78 Stat. 917; 26 U.S.C. 7805).

Approved: July 17, 1978.

Donald C. Lubick,
Assistant Secretary of the Treasury.

TREASURY DECISION

Paragraph 1. Section 1.851 is deleted.

Paragraph 2. Paragraph (b) of §1.851-2 is amended by redesignating paragraph (b) as subparagraph (1) of paragraph (b), by adding a caption to redesignated subparagraph (1), by redesignating subparagraphs (1) and (2) of existing paragraph (b) as subdivisions (1) and (2) of redesignated subparagraphs (1), and by adding a new subparagraph (1) to paragraph (b). The redesignated and revised provisions read as follows:

§1.851-2 Limitations.

General rule. (1) Gross income requirement—(1) General rule. Section 851(b)(2) and (3) provides that (i) at least 50 percent of the corporation’s gross income for the taxable year must be derived from dividends, interest, and gains from the sale or other disposition of stocks or securities, and (ii) less than 50 percent of its gross income must have been derived from the sale or other disposition of stock or securities held for less than three months.

(2) Special rules—(i) For purposes of section 851(b)(2), there shall be treated as dividends amounts which are included in gross income for the taxable year under section 951(a)(1)(A)(i) to the extent that (a) a distribution out of a foreign corporation’s earnings and profits of the taxable year is not included in gross income by reason of section 959 (a)(1), and (b) the earnings and profits are attributable to the amounts which were so included in gross income under section 951(a)(1)(A)(i). For allocation of distributions to earnings and profits of foreign corporations, see §1.959-3. The provisions of this subparagraph shall apply with respect to taxable years of controlled foreign corporations beginning after December 31, 1975, and to taxable years of United States share-
RULES AND REGULATIONS

Livestock and Products

<table>
<thead>
<tr>
<th>Livestock and Products</th>
<th>Crops</th>
</tr>
</thead>
</table>
| Beef \(\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\times\time...
foreign corporations carrying on life insurance business in the United States.


FOR FURTHER INFORMATION, CONTACT:

Mr. Seymour Fieckowski, Office of Tax Analysis, U.S. Treasury Department, Washington, D.C. 20220, 202-569-5282, not a toll-free call.

SUPPLEMENTARY INFORMATION:

This proclamation modifies the proclamation made by the Secretary of the Treasury March 14, 1978, announcing the percentage to be used to compute the income tax liability of foreign corporations carrying on life insurance business in the United States. The Secretary issues a proclamation each year announcing this percentage. A modification of the earlier proclamation is being issued because further analysis of the data available for the year 1978 has revealed that the appropriate percentage is different from the percentage announced in the earlier proclamation.

PROCLAMATION: For purposes of computing the 1977 income tax of foreign corporations carrying on a life insurance business, a percentage of 15.4 shall be used in determining the “minimum figure” under section 818. The same percentage shall be used for purposes of computing the estimated tax and the installment payments of estimated tax for the taxable year 1978. No additions to tax shall be made because of any underpayment of estimated tax for the taxable year 1978 which results solely from the use of this percentage.

This proclamation is issued without notice and public procedure because the public cannot effectively participate in the determination of the percentage. It is computed from information contained in income tax returns that are not open to the public. The proclamation was not published prior to its effective date because the percentage is computed on the basis of data which were not then available.


ROBERT H. MUNDHEIM,
General Counsel.

[FR Doc. 78-20359 Filed 7-27-78; 8:45 am]

RULES AND REGULATIONS

[3810-70]

Title 32—National Defense

CHAPTER I—OFFICE OF THE SECRETARY OF DEFENSE

PART 357—DEFENSE CONTRACT AUDIT AGENCY

AGENCY: Office of the Secretary of Defense.

ACTION: Final rule—DOD Charter directive 5105.38.

SUMMARY: The Secretary of Defense has assigned functions and responsibilities to the Director, Defense Contract Audit Agency (DCAA), and has delegated to his specific authorities. This directive serves as the instrument that authorizes the Director, DCAA, to carry out his charter.

EFFECTIVE DATE: June 8, 1978.

FOR FURTHER INFORMATION CONTACT:

Mr. Arthur H. Ehlers, Director, Organizational and Management Planning, Office of the Deputy Assistant Secretary of Defense (Administration), telephone 202-695-4278.

Accordingly, a new part 357 of chapter I, title 32 of the Code of Federal Regulations is established, reading as set forth below.


MAURICE W. ROCHE,
Director, Correspondence and Directorate, Defense Contract Audit Agency, Headquarters Services, Department of Defense.

Sec. 357.1 Purpose.
357.2 Mission.
357.3 Organization and management.
357.4 Responsibilities and functions.
357.5 Authority.
357.6 Relationships.
357.7 Administration.
357.8 Delegations of authority.

AUTHORITY: 10 U.S.C. Chapter 4.

§ 357.1 Purpose.

Pursuant to authority vested in the Secretary of Defense under the provisions of title 10, United States Code, this part establishes the Defense Contract Audit Agency (hereafter referred to as "DCAA") with responsibilities, functions, authorities, and relationships as outlined below.

§ 357.2 Mission.

DCAA shall: (a) Perform all necessary contract audit for the Department of Defense and provide accounting and financial advisory services regarding contracts and subcontracts to all Department of Defense components responsible for procurement and contract administration. These services will be provided in connection with negotiation, administration, and settlement of contracts and subcontracts.

(b) Provide contract audit service to other Government agencies as appropriate.

§ 357.3 Organization and management.

(a) DCAA is established as a separate agency of the Department of Defense under the direction, authority, and control of the Assistant Secretary of Defense (Comptroller). It shall consist of a Director and such subordinate organizational elements as are established by the Director within resources authorized by the Secretary of Defense.

(b) No separate contract audit organization independent of the DCAA shall be established in the Department of Defense.

§ 357.4 Responsibilities and functions.

The Director, DCAA shall: (a) Organize, direct, and manage the DCAA and all resources assigned to the DCAA.

(b) Assist in achieving the objective of prudent contracting by providing DOD officials responsible for procurement and contract administration with financial information and advice on proposed or existing contracts and contractors, as appropriate.

(c) Audit, examine and/or review contractors' and subcontractors' accounts, records, documents, and other evidence; systems of internal control; accounting, costing, and general business practices and procedures; to the extent and in whatever manner is considered necessary to permit proper performance of the other functions described in (d) through (l) below.

(d) Examine reimbursement vouchers received directly from contractors, under cost-type contracts, transmitting these vouchers approved-for payment to the cognizant disbursing officer and issuing DCAA Form 1, "Notice of Contract Costs Suspended and/or Disapproved," with a copy to the cognizant contracting officer, with respect to costs claimed but not considered allowable. Where the contractor disagrees with a suspension or disallowance action by DCAA, and the difference cannot be resolved, the contractor may appeal it to the Administrative Contracting Officer (ACO) who will make his determination in writing. In addition, the contracting officer may direct the issuance of DCAA Form 1, "Notice of Contract Costs Suspended and/or Disappro
proved," with respect to any cost which he has reason to believe should be suspended or disapproved.

(e) Provide advice and recommendations to procurement and contract administration personnel on:
   (1) Acceptability of costs incurred under redeterminable, incentive and similar type contracts.
   (2) Acceptability of incurred costs and estimates of cost to be incurred as represented by contractors incident to the award, negotiation, modification, change, administration, termination, or settlement of contracts.

(3) Adequacy of financial or accounting aspects of contract provisions.

(4) Adequacy of contractors' accounting and financial management systems, adequacy of contractors' estimating procedures and adequacy of property controls.

(f) Assist responsible procurement or contract administration activities in their surveys of the purchasing-procurement systems of major contractors.

(g) Direct audit reports to the Government management level having authority and responsibility to take action on the audit findings and recommendations.

(h) Cooperate with other appropriate Department of Defense components on reviews, audits, analyses, or inquiries involving contractors' financial position or financial and accounting policies, procedures, or practices.

(i) Establish and maintain liaison auditors as appropriate at major procuring and contract administration offices.

(j) Review General Accounting Office reports and proposed responses thereto which involve significant contract or contractor activities for the purpose of assuring the validity of appropriate pertinent facts contained therein.

(k) In an advisory capacity, attend and participate, as appropriate, in contract negotiation and other meetings which contract cost matters, audit reports, or related financial matters are under consideration.

(1) Provide assistance, as requested in the development of procurement policies and regulations.

(m) Perform such other functions as the Assistant Secretary of Defense (Comptroller) may from time to time prescribe.

§ 357.5 Authority.

The Director, DCAA, is specifically delegated authority to:

(a) Have free and unrestricted access to and direct communication with all elements of the Department of Defense and other executive departments and agencies as necessary.

(b) Establish Defense Contract Audit Agency facilities using appropriate established physical facilities and services of other DOD components whenever practicable to achieve maximum efficiency and economy.

(c) Obtain such information, consistent with the policies and criteria of DOD Directive 5,600.19, and assistance from DOD components as he deems necessary.

(d) Exercise the administrative authorities contained in 357.8 of this Part.

§ 357.6 Relationships.

(a) In the performance of his functions, the Director, DCAA shall:

(b) Maintain and coordinate liaison with other components of the DOD, other agencies of the executive branch, and the General Accounting Office for the exchange of information and programs in the field of assigned responsibilities.

(c) Make full use of established facilities in the Office of the Secretary of Defense, other DOD components, and other governmental agencies rather than unnecessarily duplicating such facilities.

(d) The military departments and other DOD components shall provide support, within their respective fields of responsibility, to the Director, DCAA to assist in carrying out the assigned responsibilities and functions of the Agency. Programming, budgeting and financing for such support will be in accordance with policies and procedures prescribed by the Assistant Secretary of Defense (Comptroller).

(e) Procurement and contract administration activities of the DOD components shall utilize audit services of the DCAA to the extent appropriate in connection with the negotiation, administration, and settlement of contract payments and prices which are based on cost (incurred or estimated), or on cost analysis.

§ 357.7 Administration.

(a) The Director, DCAA, shall be a civilian selected by the Secretary of Defense.

(b) The appointment of other personnel to the Agency will be subject to the approval of the director, DCAA.

(c) DCAA will be authorized such personnel, facilities, funds, and other administrative support as the Secretary of Defense deems necessary.

§ 357.8 Delegations of authority.

Pursuant to the authority vested in the Secretary of Defense, and subject to his direction, authority, and control, and in accordance with DOD policies, directives, and instructions, the Director, DCAA, or, in the absence of the Director the person acting for him, is hereby delegated authority as required in the administration and operation of DCAA to:

See footnote 1.

(a) Exercise the powers vested in the Secretary of Defense by 5 U.S.C. 301, 302(b) and 3101 pertaining to the employment, direction and general administration of DCAA civilian personnel.

(b) Fix rates of pay for wage board employees exempted from Civil Service classification by 5 U.S.C. 5102(o)(7) on the basis of prevailing rates for comparable jobs in the locality where each installation is located.

(c) Establish advisory committees and employ persons, to the extent accountant to the provisions of 10 U.S.C. 173, 5 U.S.C. 3109(b), the Federal Advisory Committee Act, and the Agreement between the Department of Defense (DOD) and the Civil Service Commission on employment of experts and consultants, dated March 14, 1975.

(d) Administer oaths of office incident to entrance into the executive branch of the Federal Government or its subordinate agencies of the executive branch.

(e) Establish a DCAA incentive awards board and pay cash awards to, and incur necessary expenses for the honorary recognition of civilian employees of the Government whose suggestions, inventions, accomplishments or other personal efforts, including special acts or services, benefit or affect DCAA or its subordinate activities in accordance with the provisions of 5 U.S.C. 4503 and Civil Service Regulations.

(f) In accordance with the provisions of 5 U.S.C. 7532; Executive Order 10450, dated April 27, 1953, as amended; and DOD directive 5128.7, "Departments of Defense Civilian Applicant and Employee Security Program," September 2, 1966:

(1) Designate any position in DCAA as a "sensitive" position;

(2) Authorize, in case of an emergency, the appointment of a person to a sensitive position in the Agency for a limited period of time for whom a full field investigation or other appropriate investigation, including the National Agency Check, has not been completed; and

(3) Authorize the suspension, but not to terminate the services of an employee in the interest of national security in positions within DCAA.

(g) Clear DCAA personnel and such other individuals as may be appropriate for access to classified Defense material and information in accordance with the provisions of DOD directive 5210.8, "Policy on Investigation and Clearance of DOD Personnel for Access to Classified Defense Information," February 15, 1962, and of Ex-
Executive Order 11652, dated March 8, 1972, as amended.

(b) Act as agent for the collection and payment of employment taxes imposed by chapter 21 of the Internal Revenue Code of 1954 and, as such agent, make all determinations and certifications required or provided for under section 3122 of the Internal Revenue Code of 1954 and section 205(p) (1) and (2) of the Social Security Act, as amended (42 U.S.C. 405(p) (1) and (2)) with respect to DCAA employees.

(i) Authorize and approve overtime work for DCAA civilian officers and employees in accordance with the provisions of the Federal Personnel Manual Supplement 990-1, Section 550-11.

(j) Authorize and approve.

(1) Travel for DCAA civilian officers and employees in accordance with Joint Travel Regulations, Volume 2, DOD Civilian Personnel;

(2) Temporary duty travel only for military personnel assigned or detailed to DCAA in accordance with Joint Travel Regulations, Volume 1, Members of Uniformed Services; and

(3) Invitational travel to persons serving without compensation whose professional services are required in a capacity that is directly related to, or in connection with DCAA activities, pursuant to the provisions of 5 U.S.C. 5703.

(k) Approve the expenditure of funds available for travel by military personnel assigned or detailed to DCAA for expenses incident to attendance at meetings of technical, scientific, professional or other highly specialized technical services are required in a capacity that is directly related to, or in connection with DCAA activities, pursuant to the provisions of 5 U.S.C. 5703.

(l) Develop, establish, and maintain an active and continuing records management program, pursuant to the provisions of section 506(b) of the Federal Records Act of 1950 (44 U.S.C. 3102), the Freedom of Information Act program (5 U.S.C. 552) and the Privacy Act program (5 U.S.C. 552a).

(m) Establish and use imprest funds for making small purchases of material and services other than personal for DCAA when it is determined more advantageous and consistent with the best interests of the Government, in accordance with the provisions of DOD Instruction 5100.71, "Delegation of Authority and Regulations Relating to Cash Held at Personal Risk Including Imprest Funds," March 5, 1973, and the Joint Regulation of the General Services Administration/Treasury Department/General Accounting Office entitled "For Small Purchases Utilizing Imprest Funds.

(n) Authorize the publication of advertisements, notices or proposals in newspapers, magazines or other public periodicals as required for the effective administration and operation of DCAA (44 U.S.C. 3702).

(o) Establish and maintain appropriate property accounts for DCAA and appoint boards of survey, approve reports of survey, relieve personal liability, and drop accountability for DCAA property contained in the authorized property accounts that has been lost, damaged, stolen, destroyed or otherwise rendered unserviceable, in accordance with applicable laws and regulations.


(q) Establish and maintain, for the functions assigned, an appropriate publications system for the promulgation of common supply and service regulations, instructions, and reference documents, and changes thereto, pursuant to the policies and procedures prescribed in DOD Directive 5025.1, "Department of Defense Directive System," November 18, 1977.

(r) Enter into support and service agreements with the military departments, other DOD agencies, or other Government agencies as required for the effective performance of responsibilities and functions assigned to DCAA.

The Director, Defense Contract Audit Agency, may redelegating these authorities, as appropriate, and in writing, except as otherwise specifically indicated above or as otherwise provided by law or regulation.

This delegation of authorities is effective immediately.

[3810-70]

(DOD Directive 5105.41)

PART 358—DEFENSE ADVANCED RESEARCH PROJECTS AGENCY AGENCY: Office of the Secretary of Defense.


SUMMARY: The Secretary of Defense has assigned functions and responsibilities to the Director, Defense Advanced Research Projects Agency (DARPA), and has delegated to him specific authorities. This Directive serves as the instrument that authorizes the Director, DARPA, to carry out his charter.

EFFECTIVE DATE: June 8, 1978.

FOR FURTHER INFORMATION CONTACT:

Mr. Arthur H. Ehlers, Director for Organizational and Management Planning, Office of the Deputy Assistant Secretary of Defense, Administration, telephone 202-693-4278.

Accordingly, a new Part 358 of Title 32, Chapter I, of the Code of Federal Regulations is established, reading as set forth below.


MAURICE W. ROGEL.

Director, Correspondence and Directives, Washington Headquarters Services, Department of Defense.

Sec.

358.1 Purpose.

358.2 Mission.

358.3 Organization and management.

358.4 Responsibilities and functions.

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358.7 Administration.

358.8 Delegations of authority.

Authority: 10 U.S.C. Chapter 4.

§358.1 Purpose.

Pursuant to the authority vested in the Secretary of Defense under the provisions of title 10, United States Code, this Part establishes the Defense Advanced Research Projects Agency (hereafter referred to as "DARPA") with responsibilities, functions, authorities and relationships as outlined below.

§358.2 Mission.

DARPA shall manage and direct the conduct of selected advanced basic and applied research and development projects for the Department of Defense.

§358.3 Organization and management.

DARPA is established as a separate agency of the Department of Defense under the staff and operational direction of the Under Secretary of Defense for Research and Engineering. It shall consist of a Director and such subordinate organizational elements as are established by the Director within resources authorized by the Secretary of Defense.

§358.4 Responsibilities and functions.

The Director, DARPA shall:

(a) Organize, direct, and manage the DARPA and all resources assigned to the DARPA.
(b) Provide guidance and assistance, as appropriate, to all DOD Components and other U.S. Government activities on matters pertaining to the projects assigned to the DARPA.

c) Recommend to the Secretary of Defense, through the Under Secretary of Defense for Research and Engineering, the assignment of research projects to DARPA.

(d) Arrange for the performance of and supervise the work connected with DARPA projects assigned to the Military Departments, other U.S. Government activities, individuals, private business entities, educational institutions, or research institutions, giving consideration to the primary functions of the Military Departments.

e) Engage in assigned advanced research projects.

(f) Keep the Under Secretary of Defense for Research and Engineering, the Military Departments, the Joint Chiefs of Staff, and other DOD Agencies informed, as appropriate, of significant new developments, breakthroughs, and technological advances within assigned projects and on the status of such projects in order to facilitate early operational assignment.

(g) Prepare and submit to the Assistant Secretary of Defense (Comptroller), in accordance with established procedures, the DARPA annual program-bulletin estimates, to include the assignment of appropriation program priorities.

(h) Perform such other functions as may be assigned by the Under Secretary of Defense for Research and Engineering.

§358.5 Authority.

The Director, DARPA, is specifically delegated authority to:

(a) Place funded work orders with the Military Departments and other DOD Components, or directly with subordinate echelons of the Military Departments, after clearance with the Secretary of the Military Department concerned.

(b) Authorize the allocation, as appropriate, of funds made available to DARPA for assigned advanced projects.

(c) Establish for DARPA, the Military Departments, and other research and development activities, such procedures required in connection with work being performed for DARPA consistent with policies and instructions governing the Department of Defense.

(d) Acquire or construct, through a Military Department or other U.S. Government agency, such research, development, and test facilities and equipment required to carry out his assignments and that may be approved by the Secretary of Defense in accordance with applicable statutes and DOD Directives.

(e) Exercise the administrative authorities contained in §358.8 of this Part.

§358.6 Relationships.

(a) In the performance of his functions, the Director, DARPA, shall:

1. Coordinate actions, as appropriate, with the other Components of DOD having collateral or related functions in the field of his assigned responsibility.

2. Maintain active liaison for the exchange of information and advice in the field of his assigned responsibility with all DOD Components, non-DOD research and development institutions (including private business entities), educational institutions, and other U.S. Government activities.

3. Make full use of established facilities in the Office of the Secretary of Defense, other DOD Components, and other Governmental agencies rather than unnecessarily duplicating such facilities.

(b) Officials of all DOD Components will provide support, within their respective fields of responsibility, to the Director, DARPA, as may be necessary to carry out the assigned responsibilities and functions of his Agency.

§358.7 Administration.

(a) The Director, DARPA, shall be a civilian selected by the Secretary of Defense.

(b) DARPA shall be authorized such personnel, facilities, funds, and other administrative support as the Secretary of Defense and other Governmental agencies may provide, within their respective fields of responsibility.

(c) The Military Departments shall assign personnel to DARPA in accordance with approved authorizations and procedures for assignment to joint duty.

(d) Administrative support required for DARPA will be provided by the Director, Washington Headquarters Services, and other DOD Components, as appropriate.

§358.8 Delegations of authority.

Pursuant to the authority vested in the Secretary of Defense, and subject to his direction, authority, and control, and in accordance with DOD policies, directives, and instructions, the Director, DARPA, or, in the absence of the Director the person acting for him, is hereby delegated authority as required in the administration and operation of DARPA to:


(b) Authorize and approve overtime work for DARPA civilian officers and employees in accordance with the provisions of the Federal Personnel Manual Supplement 690-1, section 550.111.

(c) Authorize and approve:

1. Travel for DARPA civilian officers and employees in accordance with the Joint Travel Regulations, volume 2, Department of Defense, Civilian Personnel;

2. Temporary duty travel only for military personnel assigned or detailed to DARPA in accordance with the Joint Travel Regulations, volume 2, Department of Defense, Civilian Personnel;

3. Invitational travel for persons serving without compensation whose consultative, advisory, or special functions are required in a capacity that is directly related to, or in connection with, DARPA activities, pursuant to the provisions of United States Code 5703.

(d) Approve the expenditure of funds available for travel by military personnel assigned or detailed to DARPA for expenses incident to attendance at meetings of technical, scientific, professional, or other similar organizations in such instances where the approval of the Secretary of Defense or his designee is required by law (37 U.S.C. 412). This authority cannot be redelegated.

(e) Develop, establish, and maintain an active and continuing Records Management Program, pursuant to the provisions of Section 506(b) of the Federal Records Act of 1950 (44 U.S.C. 3102), the Freedom of Information Act Program (5 U.S.C. 552) and the Privacy Act Program (5 U.S.C. 552a).

(f) Enter into and administer contracts, through a Military Department or other U.S. Government department or agency, as appropriate, for research and development, supplies, equipment, and services required to accomplish the mission of DARPA. To the extent that any law or Executive Order specifically limits the exercise of such authority to persons at a higher level in the Department of Defense, such authority will be exercised by the appropriate Under Secretary or Assistant Secretary of Defense.

(g) Establish and use Imprest Funds for making small purchases of material and services, other than personal, when it is determined more advantageous and consistent with the best interest of the Government, in accordance with the provisions of DOD Instruction 5100.71, "Delegations of Authority and Regulations Relating to Cash Held at Personal Risk Including Imprest Funds," March 5, 1973 and the Joint Regulation of the General
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Services Administration/Treasury Department/General Accounting Office, entitled "For Small Purchases Utilizing Imprest Funds.""

(h) Authorize the publication of advertisements, notices, or proposals in public periodicals as required for the effective administration and operation of DARPA (44 U.S.C. 3702).


(j) Establish and maintain, for the functions assigned, an appropriate publications system for the promulgation of regulations, instructions, and reference documents, and changes thereto, pursuant to the policies and procedures prescribed in DOD Directive 5025.1, November 18, 1971.

(k) In coordination with the Deputy Assistant Secretary of Defense (Administration), enter into interservice support agreements in accordance with DOD Directive 4000.19, "Basic Policies and Principles for Interservice, Interdepartmental and Interagency Support," March 27, 1972.

(l) Establish and maintain appropriate Property Accounts for DARPA and appoint Boards of Survey, approve reports of survey, relieve personal liability, and drop accountability for DARPA property contained in the authorized Property Accounts that have been lost, damaged, stolen, destroyed, or otherwise rendered unserviceable, in accordance with applicable laws and regulations.

The Director, DARPA, may delegate these authorities, as appropriate, and in writing, except as otherwised specifically indicated above or as otherwise provided by law or regulation. These delegations of authority are effective immediately.

[FR Doc. 76-20382 Filed 7-27-76; 8:45 am]

[3810-70]

[DOD Directive 5105.22]

PART 359—DEFENSE LOGISTICS AGENCY

AGENCY: Office of the Secretary of Defense.


SUMMARY: The Secretary of Defense has assigned functions and responsibilities to the Director, Defense Logistics Agency (DLA), and has delegated to him specific authorities. This Director serves as the instrument that authorizes the Director, DLA, to carry out his charter.

EFFECTIVE DATE: June 8, 1978.

FOR FURTHER INFORMATION CONTACT:

Mr. Arthur H. Ehlers, Director for Organizational and Management Planning, Office of the Deputy Assistant Secretary of Defense, Administration, telephone 202-695-4278.

Accordingly, a new Part 359 of Chapter I, Title 32 of the Code of Federal Regulations is established, reading as set forth below.


MAURICE W. ROCHE,
Director, Correspondence and Directives, Washington Headquarters Services, Department of Defense.

Sec. 359.1 Purpose.

Pursuant to authority vested in the Secretary of Defense under the provisions of title 10, United States Code, this Part establishes the Defense Logistics Agency (hereafter referred to as "DLA") with responsibilities, functions, authorities, and relationships as outlined below.

§359.2 Mission.

DLA shall:

(a) Function as an integral element of the defense military logistics system and, as such, direct its efforts and operations toward logistics support of the mission of the military departments and the unified and specified commands under all conditions of peace and war.

(b) Provide effective and economical support to the Military Departments, other DOD Components, Federal civil agencies, foreign governments, and others as authorized, for assigned:

(1) Materiel commodities and items of supply (hereafter referenced as "items"), which are determined, through application of approved DOD criteria, to be susceptible of integrated management by a single agency for all of the military departments or as otherwise assigned.

(2) Materiel commodities directly associated with the supply management function and other support services as directed by the Secretary of Defense.

(c) Administer the operation of DOD programs as assigned.

§359.3 Organization and management.

(a) DLA is established as a separate agency of the Department of Defense under the direction, authority and control of the Assistant Secretary of Defense (Manpower, Reserve Affairs and Logistics), (hereafter referred to as "ASD(MRA&L)"). DLA activities involving acquisition policy and related matters will be closely coordinated with, and generally monitored by, the Under Secretary of Defense for Research and Engineering.

(b) DLA shall consist of a Director and such subordinate organizational elements as are established by the Director within resources authorized by the Secretary of Defense.

§359.4 Responsibilities.

The Director, DLA shall be responsible for:

(a) Organizing, directing, and managing the DLA and all resources assigned to the DLA.

(b) Providing responsible, effective, and economical support to:

(1) The military departments and other DOD components.

(2) Federal civil agencies.

(3) Foreign governments, and others, as authorized.

(c) Monitoring DOD supply relationships with the General Services Administration (GSA).

(d) The management (including organization, direction, procurement, administration, supervision, and control) of assigned items, services, and programs.

(e) A wholesale distribution system for assigned items.

(f) Providing assigned contract administration service in support of the military departments, other DOD components, Federal civil agencies, and when authorized, to foreign governments and others.

(g) Systems analysis and design, procedural development, and maintenance for supply and service systems.

§359.5 Functions.

The Director, DLA shall perform the following functions:

(a) Coordinated Procurement. (1) Administer the DOD Coordinated Procurement Program.

(2) Recommend criteria and maintain procedures for coordinated procurement assignments of all DOD components.

(3) Make recommendations on new coordinated procurement assignments
and changes to existing assignments for all DOD components.

(4) Review and evaluate the operation of the DOD Coordinated Procurement Program, and make changes as required and as authorized, to improve the effectiveness of the operation.

(5) Conduct coordinated procurement as assignee for designated commodities.

(b) Cataloging. (1) Administer the Federal catalog system.

(2) Develop, review, and control the operating procedures, rules, and regulations for the Federal catalog system pertaining to item classification, identification, Federal stock number assignment, and central file maintenance. Based upon analysis of Federal catalog system operation, recommend to the ASD(MRA&L) new and revised policies to improve the system.

(3) Develop and maintain the central, single, official record of Federal catalog data of supply in the Federal catalog system, including all identification and classification data and those elements of management data appropriately contained therein.

(4) Ensure the exclusive use of Federal catalog data in the preparation, publication, distribution, and maintenance of the DOD sections of the Federal catalog, and that the publication of Identification and management data lists is fully synchronized.

(5) Furnish to the military departments, Defense Supply Centers, civil agencies, NATO countries, and other friendly foreign governments such Federal catalog data lists as are required and requested for item identification, classification, and maintenance of the Federal catalog system. This includes such management data as are centrally recorded and utilized by the military departments and civil agencies for the publication of management data lists.

(6) Prepare and publish on a centralized basis, for all DOD users, identification and cross-reference lists in a standard DOD format.

(7) Operate as the single submitting activity in the Federal supply groups and classes assigned to DLA, and prepare item identification for NATO and other friendly foreign governments, as assigned.

(8) Represent the DOD, as required, in negotiations with Federal civil agencies, NATO, and other friendly foreign governments, industry, and other non-defense activities, in matters concerning the administration of the Federal catalog system.

(c) Excess and Surplus Disposal (Personal Property). (1) Administer the DOD Excess, Surplus, and Foreign Excess Personal Property Disposal Program in CONUS and overseas in accordance with DOD policy.

(2) Represent the DOD as required in negotiations with other Federal departments and agencies on matters of mutual interest in the disposal of excess, surplus, and foreign excess personal property.

(3) Develop, review and prescribe techniques, systems and procedures for preparation and disposal of excess, surplus, and personal property, including foreign excess. Recommend to the ASD(MRA&L) as appropriate, revisions to DOD policies.

(4) In coordination with the military departments, develop and establish workload, performance and cost standards for all CONUS activities that are reimbursed from surplus sales proceeds. Exercise supervision of the program level of individual disposal activities, activity program within established standards. Assist in establishment of the reimbursable obligation authority required for the disposal activity program of each DOD component, by recommending program levels based upon individual activity program changes thereto when appropriate, as a result of analyses carried out during the year.

(5) Maintain a reporting system for DOD worldwide excess and surplus personal property, including foreign excess, and prepare reports as required. Recommend to the Assistant Secretary of Defense (Comptroller) any necessary refinements to the specificity of the expenses authorized to be reimbursed from proceeds of surplus sales.

(6) Direct, manage and operate defense surplus sales offices.

(7) Administer a consolidated holding activity for CONUS with authority to determine the disposal activities required and resolve differences.

(d) Utilization (Personal Property and Retail Interservice Support). (1) Administer the Defense Materiel Utilization Program in CONUS and overseas in accordance with DOD policy.

(2) Develop systems and procedures for, and recommend to the ASD(MRA&L) assignments of responsibility to the military departments to assure the cross-utilization of assets in order to minimize new procurement, stockage and transportation costs.

(3) Review and evaluate the operation of assigned utilization responsibilities and make changes as required to improve the effectiveness of operations.

(4) Administer the Defense Retail Interservice Logistic Support Program, in coordination with military departments and other DOD components, as prescribed by DOD policies.

(5) Prepare and disseminate reports, on operation of the Defense Materiel Utilization Program and the Defense Retail Interservice Logistic Support Program, as required.

(e) Systems Analysis and Design. (1) Conduct analyses, as directed by the Secretary of Defense, of the supply and service systems of the military departments in order to recommend improvements in integrated management techniques.

(2) Design and implement improved supply and service systems for the management responsibilities assigned to DLA.

(3) Develop plans, systems, and procedures to assure a close and responsive relationship between DLA operations and the war plans and logistics requirements of the Joint Chiefs of Staff and the military departments.

(4) Design and implement DLA systems to insure effectiveness, reliability and survivability in time of war or emergencies.

(5) Review and evaluate the operation of the supply and service systems assigned to DLA and make changes, as required, to improve the effectiveness of operations.

(6) Perform analysis, design, maintenance, and surveillance of standard DOD data systems.

(1) Item Entry Control. (1) Administer the DOD Item Entry Control Program.

(2) Provide DOD-wide counsel and leadership in the development of techniques and systems to prevent the entry of unnecessary items into the DOD supply system; foster industry cooperation; and coordinate and monitor the direction and progress of the program to insure expeditious and effective DOD-wide implementation.

(3) Manage and conduct the DLA portion of the DOD Item Entry Control Program.

(g) Contract Administration Services. Within CONUS and overseas, as directed, provide assigned contract administration services to the military departments and other DOD components, Federal civil agencies and, when authorized, to foreign governments and others. Among the more significant functions performed are the following:

(1) Industrial Security. Administer the DOD Industrial Security Program. Establish procedures, requirements, and practices to insure effective protection of classified information (including foreign classified information) in the hands of contractors located within the United States, including Alaska and Hawaii, its possessions, trust territories, and Puerto Rico, and such other areas as are specifically authorized by the Secretary of Defense.

(2) Contract Administration. Perform contract administration, including plant clearance, utilization, and disposal of contract inventories, ad-
Administer the DOD-wide program for Equipment Reutilization Screening.

(2) Recommend changes as required to serve, as necessary.

(3) Production. Conduct preaward surveys and surveillance of contractors' production control and industrial resources, and arrange for packaging and transportation support.

(4) Quality Assurance. Evaluate contractors' quality and reliability programs for conformance with contractual provisions, inspection and testing for acceptance or rejection of supplies and services in accordance with the quality and reliability provisions of the contracts.

(5) Engineering Liaison. Provide engineering liaison and assistance to system/project managers and purchasing offices.

(6) Management Data. Provide management information to inventory managers including contract shipments, fund status and contractual disbursements.

(h) DOD/GSA Supply Relationships. (1) Monitor supply support arrangements between GSA and DOD concerning procurement, storage and distribution of material within the United States or overseas.

(2) Review and evaluate performance by GSA under approved arrangements and, if possible, pursuant to the Liberalization Act of 1978, steps to assure efficient use of GSA services.

(3) Recommend to the ASDMRA&L action on proposals to support Federal civil agencies with DLA-assigned or controlled items and inventory managers including contract shipments, fund status and contractual disbursements.

(4) Maintain and implement criteria for assignment of supply management responsibility between DLA and GSA in Federal supply groups, classes, and items designated for integrated management within DOD; recommend to the ASDMRA&L changes in criteria as required.

(i) Industrial Plant Equipment. (1) Administer the DOD Industrial Plant Equipment (IPE) Program to ensure the reutilization of available assets.

(2) Maintain and control a reserve of IPE to meet peacetime and mobilization needs; rebuild items in the reserve, as necessary.

(3) Review and evaluate the operation of the DOD IPE Program and recommend changes as required to improve the effectiveness of operations.

(j) Automatic Data-Processing Equipment Reutilization Screening. Administer the DOD-wide program for redistribution/reutilization of excess Government owned and rented automated data-processing equipment.

(k) Warehousing Cross Performance Measurement. Administer the DOD warehousing gross performance measurement system.


(2) Receive, store, retrieve, and disseminate information on current research and exploratory development work.

(m) Centralized Referral System for Displaced DOD Employees. (1) Serve as the operating agency for the nationwide centralized referral system developed and deployed by DOD.

(2) Coordinate the DOD referral and placement responsibilities within Zone 3 (Chicago and St. Louis Civil Service Regions).

(n) Automation of the Career Program for Civilian Procurement Personnel. Administer the automated phases of the DOD Civilian Procurement Career Development Program.

(o) Defense Automatic Addressing System. Administer or assure that the automatic addressing system for logistics management data.

(p) Civil Preparedness Materiel Support. Administer assigned logistics operations contingent to the National Civil Defense Program within the military departments and services and establish by the Director of the Defense Civil Preparedness Agency.

(q) Materiel Management. (1) Item Management Classification. (1) Under the Army Materiel Classifications Program established by the DOD and in coordination with the military departments, establish and maintain procedures for the coding and classification of items to be placed or maintained under integrated management.

(2) Warehousing Cross Performance Measurement. Administer or assure that the DOD warehousing gross performance measurement system are contained in the Army Materiel Classifications Program established by the DOD and in coordination with the military departments, establish and maintain procedures for the coding and classification of items to be placed or maintained under integrated management.

(r) Assurance of Quality and Reliability. Take appropriate action to assure the quality and reliability of materiel procured by DLA and/or stored and maintained in the DLA distribution system.

(s) Industrial Mobilization Planning. (1) Conduct industrial mobilization planning for logistics management data.

(t) Management Data. Provide management information to inventory managers including contract shipments, fund status and contractual disbursements.

(u) Authorized Procurement. Administer direct procurement of assigned or otherwise designated items and services to meet the needs of the military departments and other authorized customers.

(v) Recommend to the appropriate action to assure the quality and reliability of materiel procured by DLA and/or stored and maintained in the DLA distribution system.

(w) Review and evaluate performance by GSA under approved arrangements and, if possible, pursuant to the Liberalization Act of 1978, steps to assure efficient use of GSA services.

(x) Maintain and implement criteria for assignment of supply management responsibility between DLA and GSA in Federal supply groups, classes, and items designated for integrated management within DOD; recommend to the ASDMRA&L changes in criteria as required.

(y) Industrial Plant Equipment. (1) Administer the DOD Industrial Plant Equipment (IPE) Program to ensure the reutilization of available assets.

(z) Maintain and control a reserve of IPE to meet peacetime and mobilization needs; rebuild items in the reserve, as necessary.

(1) Review and evaluate the operation of the DOD IPE Program and recommend changes as required to improve the effectiveness of operations.

(m) Automatic Data-Processing Equipment Reutilization Screening. Administer the DOD-wide program for redistribution/reutilization of excess Government owned and rented automated data-processing equipment.

(n) Warehousing Cross Performance Measurement. Administer the DOD warehousing gross performance measurement system.

(o) Technical (RDT&E) Report Services. (1) Receive, store, announce, retrieve, and provide secondary distribution of scientific and technical documents.

(p) Centralized Referral System for Displaced DOD Employees. (1) Serve as the operating agency for the nationwide centralized referral system developed and deployed by DOD.

(q) Automation of the Career Program for Civilian Procurement Personnel. Administer the automated phases of the DOD Civilian Procurement Career Development Program.

(r) Defense Automatic Addressing System. Administer or assure that the automatic addressing system for logistics management data.

(s) Civil Preparedness Materiel Support. Administer assigned logistics operations contingent to the National Civil Defense Program within the military departments and services and establish by the Director of the Defense Civil Preparedness Agency.

(t) Materiel Management. (1) Item Management Classification. (1) Under the Army Materiel Classifications Program established by the DOD and in coordination with the military departments, establish and maintain procedures for the coding and classification of items to be placed or maintained under integrated management.

(2) Warehousing Cross Performance Measurement. Administer or assure that the DOD warehousing gross performance measurement system are contained in the Army Materiel Classifications Program established by the DOD and in coordination with the military departments, establish and maintain procedures for the coding and classification of items to be placed or maintained under integrated management.

(3) Assurance of Quality and Reliability. Take appropriate action to assure the quality and reliability of materiel procured by DLA and/or stored and maintained in the DLA distribution system.

(4) Review and evaluate performance by GSA under approved arrangements and, if possible, pursuant to the Liberalization Act of 1978, steps to assure efficient use of GSA services.

(5) Maintain and implement criteria for assignment of supply management responsibility between DLA and GSA in Federal supply groups, classes, and items designated for integrated management within DOD; recommend to the ASDMRA&L changes in criteria as required.

(6) Industrial Plant Equipment. (1) Administer the DOD Industrial Plant Equipment (IPE) Program to ensure the reutilization of available assets.

(2) Maintain and control a reserve of IPE to meet peacetime and mobilization needs; rebuild items in the reserve, as necessary.

(3) Review and evaluate the operation of the DOD IPE Program and recommend changes as required to improve the effectiveness of operations.

(4) Automatic Data-Processing Equipment Reutilization Screening. Administer the DOD-wide program for redistribution/reutilization of excess Government owned and rented automated data-processing equipment.

(5) Warehousing Cross Performance Measurement. Administer the DOD warehousing gross performance measurement system.


(2) Receive, store, retrieve, and disseminate information on current research and exploratory development work.

(3) Centralized Referral System for Displaced DOD Employees. (1) Serve as the operating agency for the nationwide centralized referral system developed and deployed by DOD.

(4) Automation of the Career Program for Civilian Procurement Personnel. Administer the automated phases of the DOD Civilian Procurement Career Development Program.

(5) Defense Automatic Addressing System. Administer or assure that the automatic addressing system for logistics management data.

(6) Civil Preparedness Materiel Support. Administer assigned logistics operations contingent to the National Civil Defense Program within the military departments and services and establish by the Director of the Defense Civil Preparedness Agency.

(7) Materiel Management. (1) Item Management Classification. (1) Under the Army Materiel Classifications Program established by the DOD and in coordination with the military departments, establish and maintain procedures for the coding and classification of items to be placed or maintained under integrated management.

(2) Warehousing Cross Performance Measurement. Administer or assure that the DOD warehousing gross performance measurement system are contained in the Army Materiel Classifications Program established by the DOD and in coordination with the military departments, establish and maintain procedures for the coding and classification of items to be placed or maintained under integrated management.

(3) Assurance of Quality and Reliability. Take appropriate action to assure the quality and reliability of materiel procured by DLA and/or stored and maintained in the DLA distribution system.

(8) Review and evaluate performance by GSA under approved arrangements and, if possible, pursuant to the Liberalization Act of 1978, steps to assure efficient use of GSA services.

(9) Maintain and implement criteria for assignment of supply management responsibility between DLA and GSA in Federal supply groups, classes, and items designated for integrated management within DOD; recommend to the ASDMRA&L changes in criteria as required.

(10) Industrial Plant Equipment. (1) Administer the DOD Industrial Plant Equipment (IPE) Program to ensure the reutilization of available assets.

(11) Maintain and control a reserve of IPE to meet peacetime and mobilization needs; rebuild items in the reserve, as necessary.

(12) Review and evaluate the operation of the DOD IPE Program and recommend changes as required to improve the effectiveness of operations.
(5) Research and Development, and Engineering Support. (1) Recommend to the military departments, or to the Under Secretary of Defense for Research and Engineering, as appropriate, any new or changed research, development, and engineering projects considered desirable, to: (A) Improve materials, items, and methods within the commodity jurisdictions assigned; and (B) Promote the elimination of undesirable duplication.

(ii) Arrange through the appropriate military department and the Under Secretary of Defense for Research and Engineering for support required by DLA in the performance of its mission.

(9) Transportation. Arrange for transportation of DLA-owned material for initial distribution of stocks from supplier to point of storage, from point of storage or supplier direct to consumer, and for redistribution between storage points.

(10) Maintenance and Manufacturing. (i) Manage, control, and operate assigned maintenance and manufacturing facilities.

(ii) Develop programs, schedules, and technical guidance; and provide or arrange for the maintenance, manufacture, modification, conversion, re-manufacture, reconstitution, or assembly of DLA-owned material and items authorized for return to DLA from users for repair at facilities of the military departments, commercial contractors, or those assigned to DLA.

(iii) Develop technical maintenance standards for DLA-owned items, and items authorized for return from users, in coordination with the using military departments.

(iv) When requested by the using military departments and other DOD components, provide technical manuals for the operation and maintenance of items assigned to DLA.

(11) Provisioning. (i) Participate as a supporting inventory manager in the provisioning processes of the military departments.

(ii) Establish and maintain, in coordination with the military departments, defective procedures for provisioning supply support of the military departments and uniform provisioning of procedures and technical documentation requirements for incorporation into DLA contracts requiring provisioning.

(12) Technical Logistics Data and Information. (i) Develop, administer, and maintain, as assigned, documentation requirements governing the preparation of technical data.

(ii) Acquire, process, interchange, identify, store, and issue technical data and information adequate to support mission requirements.

(v) Value Engineering. (1) Initiate value engineering-type projects and studies to seek the lowest overall cost for DLA-managed/procured items, consistent with requirements for performance, reliability and maintainability.

(2) Coordinate findings with military departments, as applicable, to obtain agreement with respect to technical and engineering aspects.

(3) Make decisions with respect to value engineering changes for DLA-managed items, subject to the right of appeal to the Secretary of Defense by the military departments affected.

(g) Establish appropriate liaison with other DOD components and other agencies of the executive branch.

(h) Establish new DLA facilities or recommend to the Assistant Secretary for Research and Development the takeover or use of existing facilities of the military departments by DLA, as deemed necessary for improved effectiveness and economy.

(i) Provide membership on the Defense Acquisition Regulatory Council and participate with the Secretaries of the military departments in the development and promulgation of the DAR.

(j) Exercise the administrative authorities contained in §359.9 of this part.

§ 359.7 Relationships.

(a) In the performance of his functions, the Director, DLA, shall:

(1) Maintain close working relationships with weapon systems managers of the military departments to ensure integration of effort and exchange of technical programs and reference data.

(2) Make use of established facilities and services in the DOD or other governmental agencies wherever practicable to achieve maximum efficiency and economy.

(b) The Joint Chiefs of Staff, the military departments, and other DOD components shall provide support and logistical planning information, within their respective fields of responsibility, to the Director, DLA, to carry out assigned responsibilities and functions of DLA.

(c) The relationship between commanders of unified commands and overseas elements of the DLA is defined in §359.10.

§ 359.8 Administration.

(a) The Director shall be selected by the Secretary of Defense.

(b) When the Director and the Deputy Director are both military officers, they will normally be selected from different military departments.

(c) DLA will be authorized such personnel, facilities, funds, and other ad-

\[\text{\footnote{See footnote 1.}}\]
ministrative support as the Secretary of Defense deems necessary.

(d) The military departments will assign military personnel to DLA in accordance with approved authorizations and procedures for assignment to joint duty.

(e) Programming, budgeting, funding, auditing, accounting, pricing, and reporting activities of DLA will be in accordance with policy and procedures established by the Office of the Secretary of Defense. DLA will utilize appropriated funds to finance the operating costs of the Agency; a stock fund to finance all inventories procured for resale; and, when appropriate, an industrial fund for financing industrial-commercial type operations.

§ 359.9 Delegations of Authority.

Pursuant to the authority vested in the Secretary of Defense, and subject to his direction, authority, and control, and in accordance with DOD policies, directives, and instructions, the Director, DLA, or in the absence of the Director, the person acting for him, is hereby delegated authority as required in the administration and operation of DLA to:

(a) Exercise the powers vested in the Secretary of Defense by 5 U.S.C. 301, 302(b) and 501 pertaining to the employment, direction and general administration of DLA civilian personnel.

(b) Fix rates of pay for wage board employees exempted from civil service classification by 5 U.S.C. 5102(c)(7) on the basis of prevailing rates for comparable jobs in the locality where each installation is located.

(c) Establish advisory committees and employ part-time advisors, as approved by the Secretary of Defense for the performance of DLA functions pursuant to the provisions of 10 U.S.C. 173, 5 U.S.C. 3109(b), the Federal Advisory Committee Act, and the Agreement between the Department of Defense (DOD) and the Civil Service Commission on employment of experts and consultants, dated March 14, 1975.

(d) Administer oaths of office incident to entrance into the executive branch of the Federal Government or any other oath required by law in connection with employment therein, in accordance with the provisions of 5 U.S.C. 2903, and designate in writing, as may be necessary, officers and employees of DLA to perform this function.

(e) Establish a DLA incentive awards board and pay cash awards to, and incur necessary expenses for the honorary recognition of civilian employees of the government whose suggestions, inventions, superior accomplishments or other personal efforts, including special acts or services, benefit or affect DLA or its subordinate activities in accordance with the provisions of 5 U.S.C. 4503 and civil service regulations.

(f) In accordance with the provisions of 5 U.S.C. 7382, Executive Order 10450, dated April 27, 1953, as amended; and DOD Directive 5210.7, "Department of Defense Civilian Applicant and Employee Security Program," September 2, 1966:

(1) Designation in DLA as a "sensitive" position;

(2) Authorize, in case of an emergency, the appointment of a person to a sensitive position in the Agency for a limited period of time for whom a full field investigation, including the national agency check, has not been completed; and

(3) Authorize the suspension, but not the removal of an employee in the interest of national security in positions within DLA.

(g) Clear DLA personnel and such other individuals as may be appropriate for access to classified Defense materials, in accordance with the provisions of DOD Directive 5210.8, "Policy on Investigation and Clearance of DOD Personnel for Access to Classified Defense Information," February 15, 1962, and of Executive Order 11650, dated March 8, 1972, as amended.

(h) Act as agent for the collection and payment of employment taxes imposed by chapter 21 of the Internal Revenue Code of 1954 and, as such agent, install and maintain tax withholding and certifications required or provided for under section 3122 of the Internal Revenue Code of 1954 and section 205(p) (1) and (2) of the Social Security Act, as amended (42 U.S.C. 405(p) (1) and (2)) with respect to DLA employees.

(i) Authorize and approve overtime work for DLA civilian officers and employees in accordance with the provisions of the Federal Personnel Manual Supplement 390-1, section 550.111.

(j) Authorize and approve:

(1) Travel for DLA civilian officers and employees in accordance with Joint Travel Regulations, Volume 2, DOD Civilian Personnel;

(2) Temporary duty travel only for military personnel assigned or detailed to DLA in accordance with Joint Travel Regulations, Volume 1, Members of Uniformed Services; and

(3) Invitational travel to persons serving without compensation whose consultive, advisory or other highly specialized technical services are required in a capacity that is directly related to DOD's function in connection with DLA activities, pursuant to the provisions of 5 U.S.C. 5703.

(k) Approve the expenditure of funds available for travel by military personnel assigned or detailed to DLA for expenses incident to attendance at meetings of technical, scientific, professional or other similar organizations in such instances where the approval of the Secretary of Defense or his designee is required by law (37 U.S.C. 412). This authority cannot be redelegated.

(l) Develop, establish and maintain an active and continuing Records Management Program in accordance with the provisions of section 508(b) of the Federal Records Act of 1950 (44 U.S.C. 3102), the Freedom of Information Act Program (5 U.S.C. 552) and the Privacy Act Program (5 U.S.C. 552a).

(m) Expend and use imprest funds for making small purchases of material and services other than personal for DLA when it is determined more advantageous and consistent with the best interests of the Government, in accordance with the provisions of DOD Instruction 5100.71, "Delegation of Authority and Regulations Relating to Cash Held at Personal Risk Including Imprest Funds," March 5, 1973, and the Joint Regulation of the General Services Administration/Treasury Department/General Accounting Office, entitled "For Small Purchases Utilizing Imprest Funds."

(n) Authorize the publication of advertisements, notices of proposals in newspapers, magazines or other public periodicals as required for the effective administration and operation of DLA (44 U.S.C. 3702).

(o) Establish and maintain an appropriate publications system for the promulgation of common supply and service regulations, instructions, and reference documents, and changes thereto, pursuant to the policies and procedures prescribed in DOD Directive 5055.1, "Department of Defense Directive System," November 18, 1977.

(p) Enter into interservice support agreements in accordance with DOD Directive 4000.19, "Basic Policies and
Principles for Interservice, Interdepartmental and Interagency Support,” March 27, 1972.

(6) Comply with physical security requirements promulgated by the commander of the unified command or component commander, as appropriate.

(7) Provide for the management and direction of DLA overseas activities including budgeting, inspection, and audit functions, personnel support and internal administration.

(b) The commander of a unified command and is authorized to, and as appropriate, will:

(1) Exercise directive authority in the field of logistics over DLA elements within his geographic area of responsibility to ensure effectiveness and economy in operations, and the prevention or elimination of unnecessary duplication of facilities and overlapping of functions. This authority is defined as that required to ensure the coordination, as necessary, of:

(i) Acquisition, storage, movement, distribution, maintenance, evacuation and disposition of material.

(ii) Movement and evacuation of personnel.

(iii) Acquisition or construction, maintenance, operation and disposition of facilities.

(iv) Acquisition or furnishing of services.

The commander will exercise such authority, after prior coordination directly with the Director, DLA, or through the JCS, as appropriate.

(2) In the event of a major emergency which necessitates use of all available forces, assume temporary operational control of all DLA elements in his area of responsibility. The determination of the existence of such an emergency is the responsibility of the commander concerned who, on assuming temporary operational control of DLA elements, shall immediately advise the following of the nature and estimated duration of employment:

(i) The JCS.

(ii) The appropriate operational commander.

(iii) The Director, DLA.

(3) Exercise administrative direction over DLA elements in their area of responsibility in a manner consistent with, and comparable to that which he exercises over assigned forces and elements of other DOD components within his command. This will include, without being limited to, matters relating to status of forces agreements and other agreements with host nations, standards for dress and conduct, general theatre regulations applicable to all U.S. Forces, and war and emergency plans.

(4) Provide, in accordance with existing DOD policy for interservice support, guidance on support between DLA overseas elements and service components.

(5) Advise the Director, DLA, of any recommended changes to, or dissatisfaction with, the type, adequacy and responsiveness of logistic support provided by DLA to and within his command. Unresolved issues between the Director, DLA, and a commander of a unified command will be referred to the JCS for resolution or forwarding, if applicable, to the ASD(MRA&L) for final determination when a negotiated resolution cannot be achieved.

(c) Commanders of component commands will:

(1) Exercise such responsibilities and authorities pertinent to DLA elements as may be assigned or otherwise delegated to them by the commander of their unified command.

(2) Provide for the physical security and administrative and logistic support of DLA elements as agreed to by DLA and component commands concerned under host/tenant agreements.

§ 359.10 Relationship between commanders of unified commands and overseas elements of the defense logistics agency.

When the Secretary of Defense assigns mission responsibilities to the Director, Defense Logistics Agency (DLA) for the performance of integrated management functions outside of CONUS, command relationships and interfaces pertinent to DLA elements assigned overseas will be in consonance with the following:

(a) The Director, DLA, will:

(1) Ensure that DLA-assigned missions are carried out and coordinated in a manner fully responsive to, and in accordance with, the requirements of all unified and component commands concerned.

(2) Coordinate matters of significant mutual command and management interest with the unified commander and/or the Joint Chiefs of Staff (JCS), as may be appropriate. Unresolved issues between the Director, DLA, and a commander of a unified command will be referred to the JCS for resolution or forwarding to the ASD(MRA&L) for final determination when a negotiated resolution cannot be achieved.

(3) Except as otherwise provided herein, exercise operational command over DLA-assigned elements.

(4) Develop and promulgate necessary plans, policies and procedures for the efficient operation of DLA overseas activities.

(5) Develop resource requirements for DLA overseas activities and, in coordination with the applicable unified commands, establish/deseattle DLA elements as dictated by mission requirements and objectives.

(6) Comply with physical security requirements promulgated by the commander of the unified command or component commander, as appropriate.

(7) Provide for the management and direction of DLA overseas activities including budgeting, inspection, and audit functions, personnel support and internal administration.

(b) The commander of a unified command and is authorized to, and as appropriate, will:

(1) Exercise directive authority in the field of logistics over DLA elements within his geographic area of responsibility to ensure effectiveness and economy in operations, and the prevention or elimination of unnecessary duplication of facilities and overlapping of functions. This authority is defined as that required to ensure the coordination, as necessary, of:

(i) Acquisition, storage, movement, distribution, maintenance, evacuation and disposition of material.

(ii) Movement and evacuation of personnel.

(iii) Acquisition or construction, maintenance, operation and disposition of facilities.

(iv) Acquisition or furnishing of services.

The commander will exercise such authority, after prior coordination directly with the Director, DLA, or through the JCS, as appropriate.

(2) In the event of a major emergency which necessitates use of all available forces, assume temporary operational control of all DLA elements in his area of responsibility. The determination of the existence of such an emergency is the responsibility of the commander concerned who, on assuming temporary operational control of DLA elements, shall immediately advise the following of the nature and estimated duration of employment:

(i) The JCS.

(ii) The appropriate operational commander.

(iii) The Director, DLA.

(3) Exercise administrative direction over DLA elements in their area of responsibility in a manner consistent with, and comparable to that which he exercises over assigned forces and elements of other DOD components within his command. This will include, without being limited to, matters relating to status of forces agreements and other agreements with host nations, standards for dress and conduct, general theatre regulations applicable to all U.S. Forces, and war and emergency plans.

(4) Provide, in accordance with existing DOD policy for interservice support, guidance on support between DLA overseas elements and service components.

(5) Advise the Director, DLA, of any recommended changes to, or dissatisfaction with, the type, adequacy and responsiveness of logistic support provided by DLA to and within his command. Unresolved issues between the Director, DLA, and a commander of a unified command will be referred to the JCS for resolution or forwarding, if applicable, to the ASD(MRA&L) for final determination when a negotiated resolution cannot be achieved.

(c) Commanders of component commands will:

(1) Exercise such responsibilities and authorities pertinent to DLA elements as may be assigned or otherwise delegated to them by the commander of their unified command.

(2) Provide for the physical security and administrative and logistic support of DLA elements as agreed to by DLA and component commands concerned under host/tenant agreements.

[6560-01]

Title 40—Protection of Environment

CHAPTER I—ENVIRONMENTAL PROTECTION AGENCY

SUBCHAPTER D—WATER PROGRAMS

[FR 933-1]

PART 118—DETERMINATION OF HARMFUL QUANTITIES FOR HAZARDOUS SUBSTANCES

Intention To Reinstate Effective Date

AGENCY: Environmental Protection Agency.

ACTION: Notice regarding effective date and guidance.

SUMMARY: On March 13, 1978, EPA published regulations under the Clean Water Act to control the discharge of hazardous substances (43 FR 10474). The regulations apply in part to discharges from facilities holding permits under the national pollution discharge elimination system (NPDES) of the act. On June 5, 1978, EPA deferred for 60 days the regulations' effective date for discharges subject to NPDES permits (43 FR 24309). On June 8, 1978, the District Court for the Western District of Louisiana enjoined EPA from enforcing and implementing the regulations pending a final determination on the merits or until further order of the court. EPA has received a number of inquiries regarding the relationship between the court injunction and EPA's 60 day deferral for NPDES-permitted discharges. EPA's
intent is to reinstate this 60-day deferral period whenever the court's injunction is terminated, in order to allow permittees sufficient time to test their effluents and submit permit applications. EPA will publish notice in the Federal Register stating the new effective date for NPDES-permitted discharges whenever the injunction is terminated.

Guidance regarding testing and reporting procedures to be used in NPDES permit applications with respect to hazardous substances is now being developed. Copies of this guidance may be obtained by requesting it in writing from Edward A. Kramer at the address listed below.


FOR FURTHER INFORMATION CONTACT:


JEFFERY G. MILLER,
Acting Assistant Administrator for Enforcement
(FR Doc. 78-21024 Filed 7-27-78; 8:45 am)

[6820-24] Title 41—Public Contracts and Property Management

CHAPTER 101—FEDERAL PROPERTY MANAGEMENT REGULATIONS

SUBCHAPTER E—SUPPLY AND PROCUREMENT

(FPMMR Amendment E-220)

PART 101-26—PROCUREMENT SOURCES AND PROGRAMS

Submitting Requisitions to GSA

AGENCY: Final rule.

ACTION: General Services Administration.

SUMMARY: This regulation changes the Federal Property Management Regulations (FPMR) to require that Federal agencies submit requisitions for security equipment, certain types of data processing tape, and tabulating machine cards to the GSA regional office supporting the geographic area in which the requisitioning agency is located rather than to selected GSA regions as is presently required. This change will simplify the requisitioning process by providing that agencies submit requisitions for these items to the same GSA regional office from which they normally order other items.


FOR FURTHER INFORMATION CONTACT:
Mr. John T. Tait, Director, Regulations and Management Control Division, Office of the Executive Director, Federal Supply Service, General Services Administration, Washington, D.C. 20405, 703-557-1914.

The table of contents for part 101-29 is amended to revise the following entries:

101-26.507-1 Submission of requisitions.
101-26.507-1 Requisitioning data processing tape available through Federal Supply Schedule contracts.
101-26.508-3 Consolidation of requisitions.
101-26.507-3 Consolidation of requisitions.

Authority: Sec. 205(c), 63 Stat. 390; 40 U.S.C. 466(c).

Subpart 101-26.5—GSA Procurement Programs

1. Section 101-26.507-1 is revised as follows:

§ 101-26.507-1 Submission of requisitions. Requisitions for security equipment covered by the latest edition of Federal specifications AA-F-357, AA-F-358, AA-F-363, AA-S-1518, and AA-D-600, and interim Federal specifications AA-F-00364 and AA-C-001697 shall be submitted in FEDSTRIP format to the GSA regional office supporting the geographic area in which the requisitioner is located. GSA will consolidate requisitions for these items from all regions for procurement on a definite quantity basis.

2. Section 101-26.507-2 is revised as follows:

§ 101-26.507-2 Procurement time schedule. Requisitions for security equipment will be consolidated by GSA on January 31, April 30, July 31, and October 31 of each year. The consolidated requisitions will be used in executing definite quantity contracts. To ensure inclusion in the invitation for bids, requisitions shall be submitted to GSA on or before January 1, April 1, July 1, or October 1 as appropriate. Requisitions received after any of these dates normally will be carried over to the subsequent consolidation date. Approximately 150 calendar days following the consolidation date should be allowed for initial delivery. Requisitions shall include a required delivery date which reflects anticipated receipt under the time schedule.

3. Section 101-25.507-3 is revised as follows:


To ensure that a readily available source exists to meet unforeseen demands for security equipment, indefinite quantity Federal Supply Schedule contracts will remain in effect to satisfy urgent requirements which are not appropriate for consolidated procurement and do not exceed the maximum order limitations. Items of security equipment are available through Federal Supply Schedule, FSC group 71, part XI, sections A and B, for agencies to order direct from GSA. These sources may also be used by Government contractors and subcontractors (at any tier) meeting the requirements of § 1-5.902 and 101-26.407, as applicable, for purchases within the specified maximum order limitation.

4. Section 101-26.508-1 is revised as follows:

§ 101-26.508-1 Requisitioning data processing tape available through Federal Supply Schedule contracts.

Federal Supply Schedules, FSC group 70, part XI, and FSC group 58, part V, section C, include contracts to satisfy Government requirements for those types of EDP tape and instrumentation tape (wide and intermediate band) which are most widely used. Federal agencies located within the 48 contiguous United States, Washington, D.C., and Hawaii (the only EDP tape only for Hawaii) shall procure these tapes in accordance with the provisions of the current schedules and this § 101-26.508-1. Orders not exceeding the maximum order limitations of the Federal Supply Schedules and prepared directly by activities located outside the geographical areas referenced above shall, to the extent possible, be consolidated and submitted in FEDSTRIP format to the GSA regional office supporting the geographic area in which the requisitioner is located.

5. Section 101-26.508-2 is amended to revise paragraphs (a), (b), and (d) as follows:

§ 101-26.508-2 Requisitioning data processing tape not available from Federal Supply Schedule contracts.

(a) Requisitions for types of EDP tape and instrumentation tape (wide and intermediate band) covered by Federal Supply Schedule contracts which exceed the maximum order limitations of the schedule shall be submitted to the GSA regional office supporting the geographic area in which the requisitioner is located.
(b) Requisitions for all types of EDP tape and instrumentation tape (wide and intermediate band) not covered by Federal Supply Schedule contracts shall be submitted to GSA for purchase action when the dollar value of the requisitions exceeds, or is estimated to exceed, $2,500 for EDP tape and $5,000 for instrumentation tape. However, regardless of the amount involved (including requisitions estimated to be less than the dollar limitations referenced above), purchase action shall not be taken by GSA or an agency unless a waiver of the requirement for using items of tape available from Federal Supply Schedule contracts has been furnished in accordance with §101-26.100-2. Requests for waivers shall be submitted to the Commissioner, Federal Supply Service (F), General Services Administration, Washington, D.C. 20406. The requests shall fully describe the type of tape required and state the reasons Federal Supply Schedule items will not adequately serve the agency's needs. GSA will notify the requesting agency in writing of the action taken on the requests. To reduce leadtime, requisitions may be submitted in FEDSTRIP format with the requests for waivers. Requisitions for which a waiver has first been obtained shall be submitted with a copy of the waiver to the GSA regional office supporting the geographic area in which the requisitioner is located. GSA will either arrange for procurement of the items or authorize the requesting agency to procure them.

(d) When an agency submitting a purchase request in accordance with this §101-26.508-2 has a need for scheduled deliveries, minimum or maximum order quantities, or other special arrangements, GSA will develop specific provisions to accommodate the needs. The provisions will be based on information furnished by the agency concerned and will be included in solicitations for offers and resultant contracts.

6. Section 101-26.508-3 is revised as follows:

§101-26.508-3 Consolidation of requisitions.

To the maximum extent feasible, agencies shall develop procedures which will permit planned consolidated requisitioning of EDP tape and instrumentation tape (wide and intermediate band) on an agencywide basis. When agencywide consolidation is not feasible, consideration shall be given to the consolidation of individual requisitions for small quantities at any agency level. This will enable the Government to benefit from lower prices generally obtainable through large volume procurements.

7. Section 101-26.509-1 is revised as follows:


Federal Supply Schedule, FSC group 75, part VIII, includes contracts for tabulating cards applicable to electrical and mechanical contact tabulating machines, including aperture cards and copy cards. Federal agencies shall procure these cards in accordance with the provisions of the current schedule. On the maximum order limitation of the Federal Supply Schedule and prepared directly by activities located outside the geographic delivery areas specified in the schedule shall be submitted in FEDSTRIP format to the GSA regional office supporting the geographic area in which the requisitioner is located.

8. Section 101-26.509-2 is amended to revise paragraphs (a) and (b) as follows:


(a) Requisitions for tabulating machine cards covered by Federal Supply Schedule contracts which exceed the maximum order limitation of the schedule shall be forwarded in FEDSTRIP format to the GSA regional office supporting the geographic area in which the requisitioner is located.

(b) Requisitions for tabulating machine cards not covered by Federal Supply Schedule contracts shall be submitted to GSA for purchase action if the dollar value of the cards exceeds or is estimated to exceed $2,500. However, regardless of the amount involved (including requisitions estimated to be $2,500 or less), purchase action shall not be taken by GSA or an agency unless a waiver of the requirement for the use of tabulating cards available from Federal Supply Schedule contracts has been furnished in accordance with §101-26.100-2. Requests for waivers shall be submitted to the Commissioner, Federal Supply Service (F), General Services Administration, Washington, D.C. 20406. The requests shall fully describe the items required and state the reasons the tabulating machine cards covered by the Federal Supply Schedule contracts will not adequately serve the end-use purpose. GSA will notify the requesting agency in writing of the action taken on the waiver request. To reduce leadtime, requisitions may be submitted in FEDSTRIP format with the requests for waivers. A requisition for items for which a waiver has first been obtained shall be submitted with a copy of the waiver to the GSA regional office supporting the geographic area in which the requisitioner is located. GSA will either arrange for procurement of the items or authorize the requesting agency to procure them.

9. Section 101-26.509-3 is revised as follows:

§101-26.509-3 Consolidation of requisitions.

To the maximum extent feasible, agencies shall consolidate their requisitions for tabulating machine cards on an agencywide basis. If agencywide consolidation is not feasible, consideration shall be given to the consolidation of requisitions at any agency level when the Government will benefit from lower prices through large-volume procurement.

(Sec. 205(c), 63 Stat. 390; 40 U.S.C. 486(c).)


ROBERT T. GRIFFIN,
Acting Administrator
of General Services.

[FR Doc. 78-20932 Filed 7-27-78; 8:45 am]

[6820-24]

(FPMR Amendment E-227)

PART 101-26—PROCUREMENT SOURCES AND PROGRAMS

Procurement of Automobiles

AGENCY: General Services Administration.

ACTION: Final rule.

SUMMARY: This regulation changes the identification of the various categories of vehicles available through the GSA motor vehicle procurement program; includes a reference to the GSA Handbook, Discrepancies or Deficiencies in GSA or DOD Shipments, Material, or Billings; prescribes the use of GSA Form 6817, Instructions to Consignee Receiving New Motor Vehicles Purchased by General Services Administration; and includes minor editorial and procedural changes. This regulation has been developed to update the provisions relating to procurement of new motor vehicles.


FOR FURTHER INFORMATION CONTACT:

Mr. John J. Tait, Director, Regulations and Management Control Division, Office of the Executive Director, Federal Supply Service, General Services Administration, Washington, D.C. 20406, 703-557-1914.

The table of contents for part 101-26 is amended to revise the following entry:

FEDERAL REGISTER, VOL. 43, NO. 146—FRIDAY, JULY 28, 1978
101-26.501-3 Submission of orders.

Subpart 101-26.5—GSA Procurement Programs

1. Section 101-26.500 is revised as follows:

§ 101-26.500 Scope and applicability of subpart.

(a) This subpart prescribes policies and procedures relating to GSA procurement programs other than the GSA stock and the Federal supply schedule programs. Also excluded are the policies and procedures relating to the procurement of automatic data processing equipment and services set forth in part 101-36.

(b) The policies and procedures in this subpart 101-26.5 are applicable to executive agencies except as otherwise specifically indicated. Federal agencies other than executive agencies may participate in these programs and are encouraged to do so.

2. Section 101-26.501 is amended to revise the introductory material in paragraph (a) and revise paragraph (b) and subparagraph (d)(2), as follows:


(a) With respect to the procurement of new sedans, station wagons, and light trucks other than those to be used for law enforcement, it shall be the policy to procure standard vehicles (unless other than standard vehicles are specifically required) as follows:

Sedans, class IA-small, class IB-subcompact, or class II-compact; station wagons, class IB-subcompact or class II-compact vehicles, as described in Federal standard Nos. 292 and 307. (Federal standard Nos. 122, 292, and 307 as used in this section mean the latest editions and include any interim standard being used temporarily as a replacement.)

(b) Requisitions submitted to GSA for motor vehicles shall be in conformance with the requirements of subpart 101-38.13.

(d) • • • (2) Additional systems or equipment requested to be purchased by GSA will be construed to have been determined essential for the effective operation of the vehicle involved by the agency head or a designee. When systems or equipment other than those listed in Federal standards are requested, these systems or equipment shall be considered and treated as deviations under § 101-26.501-3(b).

3. Section 101-26.501-1 is amended to revise the introductory paragraph and paragraph (a) as follows:


Except as provided for the Department of Defense (DOD) in paragraph (a) of this section, each executive agency shall submit to GSA for procurement its orders for purchase in the United States of all new passenger motor vehicles (FSC 2310), trucks or truck tractors (FSC 2320), trailers (FSC 2330) van type (with payload of not less than 5,000 nor more than 50,000 pounds), and firefighting trailers (FSC 4210). Specifically included are sedans, station wagons, carryalls, ambulances, buses, and trucks, including trucks with specialized mounted equipment, truck chassis with special purpose bodies, and all van-type trailers (with payload of not less than 5,000 nor more than 50,000 pounds).

(a) DOD shall submit to GSA for procurement its orders for purchase in the United States of all commercial-type passenger motor vehicles (FSC 2310), including buses and trucks (FSC 2320) up to 10,000 pounds gross vehicle weight (GVW) except the following:

(1) Buses, convertible to ambulances;

(2) Trucks, convertible to ambulances; and

(3) Trucks, 4 x 4, dump, 9,000 GVW with cut-down cab.

4. Section 101-26.501-2(a) is revised as follows:


(a) To achieve maximum benefits and economies, GSA makes monthly consolidated purchases of all motor vehicle types plus four volume procurements each year as follows:

(1) One volume procurement of sedan and station wagons of the types covered by Federal standard No. 122 and related specifications for civilian agencies and for DOD activities; and

(2) Three volume procurements of light trucks of the types covered by Federal standard No. 397 for civilian agencies and of similar types covered by military specifications for DOD activities.

5. Section 101-26.501-3 is amended to revise the introductory paragraph and paragraph (c) as follows:

§ 101-26.501-3 Submission of orders.

Orders for all motor vehicles shall be submitted on GSA Form 1781, Motor Vehicle Requisition—Delivery Order—Invoice, or DD Form 448, Military Interdepartmental Purchase Request (MIPR), to the General Services Administration (FY), Washington, D.C. 20408, and shall contain required FEDSTRIP data for mechanized processing. The Department of Defense shall ensure that appropriate MIL-STRIP data are entered on DD Form 448.

6. Section 101-26.501-4 is amended to revise paragraph (a) and subparagraph (b)(3) as follows:

FEDERAL REGISTER, VOL. 43, NO. 145—FRIDAY, JULY 28, 1978
§ 101-26.501-4 Procurement time schedules.

(a) Volume consolidated purchases. Requisitions covering vehicle types included in Federal standard No. 122 or Federal standard No. 307 received before the consolidation dates shown in the time schedule of this paragraph (a) will be consolidated for volume procurement unless there is included a statement justifying the need for delivery earlier than the delivery times indicated in § 101-26.501-4(d). Requisitions containing a statement of justification will be handled on a monthly basis in accordance with § 101-26.501-4(d)(1).

(b) * * *(3) With respect to categories (i) and (ii) of § 101-26.501-4(c)(1), no assurance can be given as to price and time of delivery of vehicles on requisitions received by GSA after the 15th of April. This is because of the industry practice of closing out the production of the current year's model and retooling for new models. Agencies should bear this in mind when preparing their requirements. Agencies submitting requisitions for sedans also be used to report all noncompliance with specifications or other requirements of the purchase order.

(c) GSA Form 6317, Instructions to Consignee Receiving New Motor Vehicles Purchased by General Services Administration. This form is furnished to each consignee with copies of GSA form 1781, Motor Vehicle Requisition—Delivery Order—Invoice. Personnel responsible for receipt and operation of Government motor vehicles should be familiar with the instructions and information contained in GSA form 6317.

7. Section 101-26.501-6 is amended to revise paragraph (b) and add a new paragraph (c) as follows:

§ 101-26.501-6 Forms used in connection with delivery of vehicles.

(b) Standard Form 368, Quality Deficiency Report (Category II). GSA is constantly striving to improve customer service and the quality of motor vehicles for which it contracts. To inform contractors of the deficiencies noted during the life of the vehicles, Standard form 368 shall be prepared by the consignee and sent to GSA describing details of vehicle deficiency and action taken for correction. Procedures for documenting and reporting quality deficiencies are set forth in the GSA Handbook. Discrepancies or Deficiencies in GSA of DOD Shipments, Material, or Billings (FPMR 101-26.8). Standard form 368 replaced GSA form 1718, Unsatisfactory Equipment Report, for reporting deficiencies and repetitive failures of motor vehicles. Agencies are urged to report all deficiencies to GSA irrespective of satisfactory corrective action taken by the manufacturer's authorized dealer. If the dealer refuses to take corrective action on any vehicle within its warranty period, the report shall so state and include an explanation of the circumstances. Standard form 368 shall also be used to report all noncompliance with specifications or other requirements of the purchase order.

(c) 6317, Instructions to Consignee Receiving New Motor Vehicles Purchased by General Services Administration. This form is furnished to each consignee with copies of GSA form 1781, Motor Vehicle Requisition—Delivery Order—Invoice. Personnel responsible for receipt and operation of Government motor vehicles should be familiar with the instructions and information contained in GSA form 6317.

8. Section 101-26.501-7 is revised as follows:


GSA will not solicit trade-in bids when purchasing new motor vehicles for replacement purposes under the consolidated purchase program because experience has shown that suppliers (manufacturers) are unwilling to accept used vehicles in part payment for new ones. Accordingly, used vehicles that are being replaced will be disposed of by sale as set forth in part 101-46.

Subpart 101-26.49—Illustrations of Forms

eligible for return to GSA for credit and provides revised policy on the granting of credit to stock items returned to GSA with packing or packaging deficiencies.

2. Effective date. This regulation is effective upon publication in the Federal Register.

3. Expiration date. This regulation expires December 31, 1978, unless revised or superseded sooner.

4. Background. a. The costs incurred in returning items to GSA and placing them in stock have increased significantly in the past several years. When the item dollar value of items returned is relatively low, these costs frequently exceed the value of the items returned. This results in a net loss to the Government. To reduce these losses, it is necessary to eliminate the return of items when it is uneconomical for them to be returned to stock. This can be accomplished by revising FMPR 101-27.502(a) to increase the minimum line item dollar value required for items to be eligible for return to GSA for credit.

b. When material is returned to GSA for credit with packing or packaging deficiencies which were not the fault of GSA, GSA frequency must repack or repackag the material before it can be reissued. The costs associated with repacking or repackaging material can be considerable. These costs are presently absorbed by GSA although it is appropriate that they be borne by the agency returning the material. Accordingly, a decision has been made to revise FMPR 101-27.505-2 to include a provision that will allow a reduction in the credit granted for material returned to GSA with significant packing or packaging deficiencies. A sampling of the cost involved in correcting these deficiencies indicates that a 60 percent credit would be sufficient for GSA to recover the cost.

c. Criteria for return of stock items to GSA for credit. When an agency determines that it has no current or future requirements for GSA stock items in that agency's possession, the items may be eligible for return to GSA for credit if the dollar value per line item (based on the current GSA selling price) is at least:

a) $50 for hand tools, FSC 51; and measuring tools, FSC 52; or
b) $50 for:
   (1) Household furniture, FSC 7105; office furniture, FSC 7110; cabinets, lockers, bins, and shelving, FSC 7125; miscellaneous furniture and equipment; FSC 7125;
   (2) Cleaning and polishing compounds and preparations, FSC 7930; and
   (3) Paints, varnishes, and related products, FSC 800; preservatives and seal ing compounds, FSC 8930; and adhesives, FSC 8940; and

c) $100 for items in all other Federal supply groups and classes except for standard forms, FSC 7540; and boxes, cartons, and crates, FSC 8115, which are not returnable and shall be considered excess and processed in accordance with part 101-43.

d. Credit for stock items returned with deficiencies. a. After acceptance by GSA of items with deficiencies which were not the fault of GSA, credit will be granted for the items at a percentage of the current GSA selling price in accordance with the following:

(1) Sixty percent for items which involve limited expenses or effort to restore to serviceability (specifically, a deficiency in packing or packaging which restricts the

issue or requires repacking or repackaging) (condition code 5);

(2) Thirty percent when it is economically feasible to repair, overhaul, or recondition the items for return to serviceable condition (condition code 4);

(3) Thirty percent when these items require additional parts or components to complete the end item prior to issue (condition code 1).

b. No credit will be given for material returned to GSA which does not meet the above criteria or which was returned to GSA without prior approval.

c. Agency comments. Comments concerning the effect or impact of this regulation on agency operations or programs should be submitted to the General Services Administration (FAP), Washington, D.C. 20409, no later than August 31, 1978, for consideration and possible incorporation into a permanent regulation.

7. Effect on other directives. This regulation supersedes FMPR 101-27.502(a) and 101-27.505-2.

ROBERT T. GRIFFITH,
Acting Administrator
General Services.


[6820-35]

Title 45—Public Welfare

CHAPTER XVI—LEGAL SERVICES CORPORATION

PART 1606—PROCEDURES GOVERNING TERMINATION OF FINANCIAL ASSISTANCE AND DENIAL OF RE-FUNDING

AGENCY: Legal Services Corporation.

ACTION: Final regulation.

SUMMARY: The Legal Services Corporation issues a final regulation establishing procedures to insure a fair hearing before any application for refunding will be denied or financial assistance terminated. This regulation is required by the Legal Services Corporation Act, as amended.


FOR FURTHER INFORMATION CONTACT:

Stephen S. Walters, 202-376-5113

SUPPLEMENTARY INFORMATION: Section 1011 of the Legal Services Corporation Act, 42 U.S.C. 2996j, requires the Corporation to establish procedures to insure that no application for refunding will be denied and financial assistance will not be terminated unless the recipient has been afforded an opportunity for a fair hearing. A temporary regulation, published on April 30, 1976 (41 FR 18081), is now in effect. A proposed final regulation was published for comment on January 25, 1977 (42 FR 45864), and a revised version was published for comment on January 3, 1978 (43 FR 16), following final amendment of the Legal Services Corporation Act. Full consideration of written comments, and extended discussion with interested persons, preceded the decision made by the Board of Directors of the Corporation on July 6, 1978 to adopt the following regulation.

There is little functional difference between a decision to deny refunding and a decision to terminate a recipient's grant or contract. Both are serious actions to be taken only as necessary to achieve the purpose of the Act. In the vast majority of cases, the Corporation will seek to ensure that service will continue to the community affected without regard to whether financial assistance has been terminated or refunding denied. The single difference between the two types of action is the equitable consideration that, having made a grant or contract to a particular recipient, the Corporation should not be permitted to terminate on the basis of a rule, regulation, guideline, or instruction that did not exist at the time financial assistance was extended. That principle is reflected in section 1606.4 of the regulation.

Section 1606.3, enumerating the grounds for denial of refunding, has been revised to provide more specificity than existed in previous drafts. The final version is designed to provide a satisfactory balance between the need for fairness to recipients and the need to protect the Corporation's ability to meet its statutory responsibilities and to respond to anticipated contingencies.

Section 1606.11, dealing with burden of proof, has been revised. The final version assigns to the corporation the burden of proving any disputed fact relied upon as a basis for denying refunding. In addition, the "substantial basis" language in section 1606.11(b) indicates that, even if the Corporation proves its case, refunding should not be denied for an insubstantial or trivial reason. Consistent with that meaning of section 1606.11(b), section 1616.13 gives the presiding officer authority to recommend continuation of funding if the grounds for denying it—though proven—are unreasonable, insubstantial, or trivial. The same discretion is conferred on the President of the Corporation by title 42, section 2996j-8.

Accordingly, 45 CFR Part 1606 is revised to read as follows:

FEDERAL REGISTER, VOL. 43, NO. 146—FRIDAY, JULY 28, 1978
PART 1606—PROCEDURES GOVERNING TERMINATION OF FINANCIAL ASSISTANCE AND DENIAL OF REFUNDING

Sec. 1606.1 Purpose. 1606.2 Definitions. 1606.3 Grounds for Denial of Refunding. 1606.4 Grounds for Termination. 1606.5 Preliminary Determination. 1606.6 Informal Conference. 1606.7 Initiation of Proceedings. 1606.8 Presiding Officer. 1606.9 Pre-hearing Conference. 1606.10 Conduct of Hearing. 1606.11 Obligations of the Corporation. 1606.12 Briefs and Argument. 1606.13 Recommended Decisions. 1606.14 Final Decision. 1606.15 Time Extension and Waiver. 1606.16 Right to Counsel. 1606.17 Reimbursement. 1606.18 Interim Funding. 1606.19 Termination Funding. 1606.20 Notice.

Authority: Sec. 1606(b)(1) and (3), 1007(a)(1), 1007(a)(3), 1007(a)(9), 1606.1142 U.S.C. 2996a(x)(1) and (3), 2996a(x)(3), 2996a(2a)x(3), 2996g(x)(3), 2996f(x)(2a), 2996g(x)(2a).

§ 1606.1 Purpose.

By affording a recipient the opportunity for a timely, full, and fair hearing that will provide an informed deliberation by the Corporation when there is reason to believe a grant or contract should be terminated or refunding denied, this part seeks to avoid unnecessary disruption in the delivery of legal assistance to eligible clients.

§ 1606.2 Definitions.

(a) “Termination” means a decision that financial assistance to a recipient will be permanently terminated in whole or in part prior to expiration of the recipient’s current grant or contract.

(b) “Denial of refunding” means a decision that, after expiration of its current grant or contract, a recipient:

1. Will not be provided with financial assistance; or
2. Will have its annual level of financial support reduced to an extent that is not required either by a change of law or by a reduction in the Corporation’s appropriation that is apportioned among all recipients of the same class proportion to their current level of funding, and is either more than 10 percent or more than $20,000 below the recipient’s annual level of financial assistance under its current grant or contract; or
3. Will be provided with financial assistance subject to a new condition or restriction that is not generally applicable to all recipients of the same class, and that would significantly reduce the ability of a recipient to maintain the quality and quantity of its current legal assistance to eligible clients.

(c) “Director of a recipient” means the person who has overall day-to-day responsibility for management of operations by the recipient.

(d) “Presiding Officer” means the person appointed by the President to recommend a decision that a grant or contract should be terminated or denied, or that refunding should be granted or denied.

§ 1606.3 Grounds for denial or refunding.

Refunding may be denied when (a) Denial is required by, or will implement, a provision of law, a Corporation rule, regulation, guideline, or instruction that is generally applicable to all recipients of the same class, or a funding policy, standard, or criterion approved by the Board; or

(b) There has been substantial failure by a recipient to comply with a provision of law, or a rule, regulation, or guideline issued by the Corporation, or a term or condition of a current or prior grant from or contract with the Corporation. In the absence of unusual circumstances, refunding shall not be denied for this cause unless the Corporation has given the recipient notice of such failure and an opportunity to take effective corrective action; or

(c) There had been substantial failure by a recipient to use its resources to provide economical and effective legal assistance of high quality as measured by generally accepted professional standards, the provisions of the act, or a rule, regulation or guideline issued by the Corporation. In the absence of unusual circumstances, refunding shall not be denied for this cause unless the Corporation has given the recipient notice of such failure and an opportunity to take effective corrective action.

§ 1606.4 Grounds for termination.

A grant or contract may be terminated on any of the grounds and under the circumstances stated in § 1606.3, except that termination shall not be based on a Corporation rule, regulation, guideline, or instruction that was not in effect when the current grant was made or when the current contract was entered into.

§ 1606.5 Preliminary determination.

(a) When there is reason to believe that a grant or contract should be terminated or that refunding should be denied, the Corporation shall serve a written preliminary determination upon the recipient, which shall state the grounds for the proposed action, shall identify, with reasonable specificity, any facts or documents relied upon as justification for that action.

(b) The preliminary determination shall advise the recipient that it may, within 10 days of receipt of the preliminary determination, make written request for

(1) a hearing under this part, or

(2) an informal conference under § 1606.6 of this part, with a subsequent right as there provided to request a hearing.

(c) The preliminary determination shall also advise the recipient of its right to receive interim, and to request termination, funding, under § 1606.18 or § 1606.19 of this part.

(d) If the recipient advises the Corporation that it will not request review, or if it fails to request review within the time prescribed in § 1606.5(b) or § 1606.6, the preliminary determination shall become final.

§ 1606.6 Informal conference.

On timely request by the recipient, the Corporation employee who made the preliminary determination shall promptly conduct an informal conference with the recipient at a time and place designated by the employee. The parties thereto shall exchange views, seek to narrow the issues, and explore the possibilities of settlement or compromise. At the conclusion of the conference, which may be adjourned for deliberation or consultation, the Corporation employee may, in writing, modify, withdraw, or affirm the preliminary determination. The recipient may, within 5 days thereafter, make written request for a hearing under§ 1606.9 through § 1606.15 of this part.

§ 1606.7 Initiation of proceedings.

Within 10 days after receipt of a request for a hearing made under § 1606.5(b) or § 1606.5, the Corporation shall notify the recipient in writing of

(a) The name of the presiding officer, and of the attorney who will represent the Corporation; (b) The date, time and place scheduled for a prehearing conference, if any should be requested or ordered; and (c) The date, time and place scheduled for the hearing.

§ 1606.8 Presiding officer.

(a) The presiding officer shall be appointed by the President, and shall be a person who is familiar with legal services and supportive of the purposes of the Act, who is independent, and who is not an employee of the Corporation.

(b) Within 5 days of receipt of the notice required under § 1606.7, the recipient shall notify the Corporation if it objects to the presiding officer on the ground that the person does not satisfy the criteria stated in § 1606.8(a), or is personally biased. The notice shall state the specific facts and documents that the recipient contends
support its objection, and, if a pre-hearing conference has not been scheduled, shall request a pre-hearing conference for the purpose of presenting the objection. At the pre-hearing conference, the recipient and the Corporation may question the presiding officer for a reasonable period of time on matters relevant to the recipient's objection.

(c) The recipient shall, within 5 days following the pre-hearing conference, notify the Corporation of any further facts that it contends support its objections. The President shall, within 10 days following the pre-hearing conference, either sustain the objection and appoint a new hearing officer or overrule the objection.

(d) No objection to the appointment of a presiding officer may be made unless presented in the manner specified by this section.

§1606.9 Pre-hearing conference.

(a) A pre-hearing conference may be ordered by the presiding officer, and shall be ordered if requested by either the recipient or the Corporation. The matters to be considered at the conference shall include:

(1) Proposals to define and narrow the issues;
(2) Efforts to stipulate the facts, in whole or in part;
(3) The probable number, identity, and order of presentation of exhibits and witnesses;
(4) On the agreement of the parties, the possibility of presenting the case on written submission or oral argument;
(5) The desirability of advance submission of some or all of the direct testimony in writing;
(6) Any necessary variation in the date, time and place of the hearing;
(7) Discussion of settlement; and
(8) Such other matters as may be appropriate.

(b) In advance of the pre-hearing conference, the presiding officer may require a party to submit a written statement discussing any matter described in subparagraph (a). After the pre-hearing conference, the presiding officer may establish the procedures, consistent with this part, to be followed at the hearing.

(c) The presiding officer may, at the pre-hearing conference or at any subsequent appropriate time prior to completion of the hearing, require the Corporation or the recipient, on sufficient notice, to produce a relevant document in its possession, to make a report not unduly burdensome to prepare, or to produce a person in its employ to testify, if any might offer a relevant and substantial addition to the accuracy or completeness of the record. With the consent of the presiding officer, a party may make a written submission before the hearing.

§1606.10 Conduct of hearing.

(a) The hearing shall be scheduled to commence at the earliest appropriate date, ordinarily not later than 45 days after the notice required by §1606.7, and, whenever practical, shall be held at a place convenient to the recipient and the community it serves. A hearing affecting more than one community or recipient shall be held in a single centrally located place unless the presiding officer determines that an additional hearing place is required.

(b) The presiding officer shall preside, conduct a full and fair hearing, avoid delay, maintain order, and insure that a record sufficient for full evaluation of the issues is made. The hearing shall be open to the public unless, for good cause and in the interests of Justice, the presiding officer shall determine otherwise.

(c) The presiding officer may allow any interested person or organization to participate in the hearing if such participation will not broaden the issues unduly or cause delay, and will aid in proper determination of the issues.

(1) A person or organization wishing to participate in a hearing shall request permission from the presiding officer, stating the reason for the request, and the nature of the evidence or argument to be offered; and shall notify the Corporation and the recipient of its request.

(2) The presiding officer shall notify the Corporation, the recipient, and the person or organization requesting participation under this paragraph.

(d) The Corporation and the recipient may present its case by oral or documentary evidence, conduct examination and cross-examination of witnesses, examine any document submitted by another party, and submit rebuttal evidence.

(e) If a party fails, without good cause, to produce a person or document required under §1606.9(c), the presiding officer may make an adverse finding on the fact or issue with respect to which production was required.

(f) Technical rules of evidence shall not apply. The presiding officer shall make any procedure or evidentiary ruling that may help to insure full disclosure of the facts, to maintain order, or to avoid delay. Irrelevant, immaterial, repetitious or unduly prejudicial matter may be excluded.

(g) Official notice may be taken of published policies, rules, regulations, guidelines, and instructions of the Corporation, of any matter of which judicial notice may be taken in a Federal court, or of any other matter whose existence, authenticity, or accuracy is not open to serious question.

(h) A stenographic or electronic sound record, or a summary of the hearing shall be made in a manner determined by the presiding officer, and a copy shall be made available to a party upon payment of its cost.

§1606.11 Burden of proof.

At a hearing under §1606.10:

(a) The Corporation shall have the obligation of proving, by a preponderance of the evidence, the existence of any disputed fact relied upon as justification for termination or denial of refunding; and

(b) On all other issues, the Corporation shall have the obligation of establishing a substantial basis for terminating the grant or contract or denying refunding.

§1606.12 Briefs and argument.

(a) Within 10 days after the close of the hearing, each party may, and, upon request of the presiding officer, shall, submit to the presiding officer, with service upon all other parties, proposed findings of fact and argument on matters of law or policy.

(b) The presiding officer may direct or permit oral argument at the close of the hearing or after submission of briefs.

§1606.13 Recommended decision.

(a) As soon as practicable after the hearing, and normally within 20 days after its conclusion, the presiding officer shall issue a written recommended decision.

(1) Continuing the recipient's current grant or contract, or granting refunding subject to any modification or condition that may be deemed necessary on the basis of information added at the hearing; or

(2) Terminating financial assistance to the recipient as of a particular date, or denying refunding.

(b) The recommended decision shall contain findings of the significant and relevant facts and shall state the reasons for the decision. Findings of fact shall be based solely on the evidence adduced at the hearing or on matters of which official notice was taken.

§1606.14 Final decision.

(a) If neither the Corporation nor the recipient requests review by the President, a recommended decision shall become final 10 days after receipt by a recipient.

(b) The recipient or the Corporation may seek review by the President of a
RULERS AND REGULATIONS

§ 1606.18 Interim funding.
Failure by the Corporation to meet a time requirement of this part shall not entitle a recipient to continuation of its grant or contract or to refunding. Pending a final determination under this part, the Corporation shall provide the recipient with interim funding necessary to maintain its current level of legal assistance activities under the act.

§ 1606.19 Termination funding.
After a final determination to terminate a recipient's grant or contract or to deny refunding, and without regard to whether a hearing has occurred, the Corporation may authorize temporary funding if necessary to enable a recipient to close or transfer current matters in a manner consistent with the recipient's professional responsibility to its present clients.

§ 1606.20 Notice.
A notice required to be sent to a recipient under this part shall be sent to the director of the recipient, and may be sent to the chairperson of its governing body.

Alice Daniel,
General Counsel,
Legal Services Corporation.

[FR Doc. 78-21010 Filed 7-27-78; 8:45 am]

[6820-35]

PART 1607—GOVERNING BODIES

Amendments to the Regulations

AGENCY: Legal Services Corporation.
ACTION: Final regulation.
SUMMARY: These regulations require that at least one-third of the members of a recipient's governing board be eligible clients. These amendments implement the new statutory requirement in the Legal Services Corporation Act Amendments of 1977. Although the statute provides only that eligible clients on a program board may be representatives of their communities, the regulation makes that requirement mandatory. The new regulations attempt to insure that programs will be accountable to the communities they serve.

DATE: Effective date: August 28, 1978.
FOR FURTHER INFORMATION CONTACT:
Stephen S. Walters, 202-376-5113.
SUPPLEMENTARY INFORMATION: Section 11 of the Legal Services Corporation Act Amendments of 1977, Pub. L. 95-222, amended section 1007(c) of the act to require that at least one-third of a recipient's governing body consist of "persons who are, when selected, eligible clients who may also be representatives of associations or organizations of eligible clients." The effective date of this provision was delayed until July 1, 1978, "to afford local boards time, if needed to comply * * *." Sen. Rep. No. 95-172, 95th Cong., 1st sess. (1977), at 8.

The amendments to part 1607 implement the new statutory requirement. The Amendment follows the approach of the current regulation by requiring that most members of a program board be selected by appropriate associations or groups. That requirement is at the heart of the Corporation's attempt to insure that programs will be accountable to the communities that they serve. Although the statute provides only that eligible clients on a program board may be representatives of their communities, the regulation makes that requirement mandatory.

The regulation contains a new section 1607.14 concerning compliance with the board composition requirements. Immediate compliance is required, but recipients may apply for an extension of time in which to comply with the new statutory language. This approach should help to avoid disruption of programs that have recently restructured their boards to comply with the current regulation or for which immediate compliance would otherwise be unduly burdensome. Given the importance of the issue, however, extensions should not be granted lightly, and all recipients must be in compliance by July 1, 1979.

The regulation was published for comment on May 22, 1978 (43 FR 21904). All comments received were considered by the Regulations Committee of the Corporation at its meeting on July 5, 1978.

Following is the complete regulation, as amended. The comment that appeared in the June 23, 1978 (41 FR 25891), final publication of part 1607 remains in effect.

Accordingly, 45 CFR Part 1607 is revised to read as follows:

Sec. 1607.1 Purpose.
1607.2 Definition.
1607.3 Composition.
1607.4 Functions of a governing body.
1607.5 Waiver.
1607.6 Compensation.
1607.7 Compliance.

Authority: Sec. 1007(c); 42 U.S.C. 2996f(c).

§ 1607.1 Purpose.

This part is designed to insure that the governing body of a recipient will be well qualified to guide a recipient in its efforts to provide high-quality legal
assistance to those who otherwise would be unable to obtain adequate legal counsel, and to insure that the recipient is accountable to its clients.

§ 1607.2 Definition.

"Eligible client," as used in this part, means a person eligible to receive legal assistance under the act, without regard to whether the person is receiving assistance at the time of selection for membership on a governing body.

§ 1607.3 Composition.

(a) A recipient shall be incorporated in a State in which it provides legal assistance, and shall have a governing body by which a majority of its staff are attorneys. The governing body shall be accountable to its governing body, and for the operation of a recipient, but shall be accountable to the recipient's governing body, to continue such nonattorney majority.

(b) The President may waive the requirements of this part upon application of a recipient that demonstrates that it cannot comply with them because of:

1. The nature of the population or area served; or

2. Special circumstances, including, but not limited to, conflicting requirements of the recipient's major funding source.

(c) A recipient seeking a waiver shall demonstrate that it has made diligent efforts to comply with the requirements of this part.

§ 1607.4 Functions of a governing body.

(a) A governing body shall have at least four meetings a year. Timely and effective prior public notice of all meetings shall be given, and all meetings shall be public except for those concerned with matters properly discussed in executive session.

(b) A governing body shall establish and enforce broad policies governing the operation of a recipient, but shall not interfere with any attorney's professional responsibilities to clients.

§ 1607.5 Waiver.

(a) Upon application, the President shall waive the requirements of this part to permit a recipient that was funded under section 222(a)(3) of the Economic Opportunity Act of 1964 and, on July 25, 1974, had a majority of persons who were not attorneys on its governing body, to continue such nonattorney majority.

(b) The President may waive the requirements of this part upon application of a recipient that demonstrates that it cannot comply with them because of:

1. The nature of the population or area served; or

2. Special circumstances, including, but not limited to, conflicting requirements of the recipient's major funding source.

(c) A recipient seeking a waiver shall demonstrate that it has made diligent efforts to comply with the requirements of this part.

§ 1607.6 Compensation.

While serving on the governing body of a recipient, no member shall receive compensation from the recipient, but a member may receive payment for normal travel and other out-of-pocket expenses required for fulfillment of the obligations of membership.

§ 1607.7 Compliance.

(a) A recipient whose current governing body does not satisfy the requirements of this part shall submit a plan for achieving compliance to the relevant Regional Director immediately.

(b) The President may, upon application, extend the time in which a recipient must comply with the requirements of section 1607.3 (d) and (e). The application shall state:

1. The current composition of the recipient's governing body, and the date upon which the composition was achieved;

2. The date upon which the term of each current member of the recipient's governing body will expire;

3. The recipient's plan for complying with the requirements of section 1607.3 (d) and (e) with all possible speed; and

4. The reasons why complying immediately would be unduly burdensome to the recipient.

(c) An application for an extension of time under subsection (b) must be received by the Corporation no later than 30 days after the effective date of the regulation. A copy of the application shall also be sent to the National Clients Council, which shall transmit its comments on the application, if any, to the Corporation. An extension may be granted for no more than 6 months, and no more than two extensions may be granted to any recipient.

In no event may the time for compliance be extended beyond July 1, 1979.

ALICE DANIEL,
General Counsel,
Legal Services Corporation.

FEDERAL REGISTER, VOL 43, NO. 146—FRIDAY, JULY 28, 1978

FEDERAL REGISTER, Vol. 43, No. 146—Friday, July 28, 1978
§ 1608.1 Purpose.

This part is designed to ensure that the Corporation’s resources will be used to provide high quality legal assistance and not to support or promote political activities or interests. The part should be construed and applied so as to further this purpose without infringing upon the constitutional rights of employees or the professional responsibilities of attorneys to their clients.

§ 1608.2 Definition.

“Legal assistance activities,” as used in this part, means any activity,

(a) Carried out during an employee’s working hours;

(b) Using resources provided by the Corporation or by a recipient; or

(c) That, in fact, provides legal advice, or representation to an eligible client.

§ 1608.3 Prohibitions applicable to the Corporation and to recipients.

(a) Neither the Corporation nor any recipient shall use any political test or qualification in making any decision, taking any action, or performing any function under the act.

(b) Neither the Corporation nor any recipient shall contribute or make available Corporation funds, or any personnel or equipment

(1) To any political party or association;

(2) To the campaign of any candidate for public or party office;

(3) For use in advocating or opposing any ballot measure, initiative, or referendum.

§ 1608.4 Prohibitions applicable to all employees.

(a) No employee shall intentionally identify the Corporation or a recipient with any partisan or nonpartisan political activity, or with the campaign of any candidate for public or party office.

(b) No employee shall use any Corporation funds for activities prohibited to attorneys under section 1608.6; nor shall an employee intentionally identify or encourage others to identify the Corporation or a recipient with such activities.

§ 1608.5 Prohibitions applicable to Corporation employees and to staff attorneys.

While employed under the act, no Corporation employee and no staff attorney shall, at any time,

(a) Use official authority or influence for the purpose of interfering with or affecting the result of an election or nomination for office, whether partisan or nonpartisan;

(b) Directly or indirectly coerce, attempt to coerce, command or advise an employee of the Corporation or of any recipient to pay, lend, or contribute anything of value to a political party, committee, organization, agency or person for political purposes; or

(c) Be a candidate for partisan elective public office.

§ 1608.6 Prohibitions applicable to attorneys and to staff attorneys.

While engaged in legal assistance activities supported under the act, no attorney shall engage in

(1) Any political activity,

(2) Any activity to provide voters with transportation to the polls, or to provide similar assistance in connection with an election, or

(3) Any voter registration activity.

§ 1608.7 Attorney-client relationship.

Nothing in this Part is intended to prohibit an attorney or staff attorney from providing any form of legal assistance to an eligible client, or to interfere with the fulfillment of any attorney’s professional responsibilities to a client.

§ 1608.8 Enforcement.

This part shall be enforced according to the procedures set forth in §1612.5.

Alice Daniel,
General Counsel,
Legal Services Corporation.

[FR Doc. 78-21011 Filed 7-27-78; 8:45 am]

[6820-35]

PART 1612—RESTRICTIONS ON CERTAIN ACTIVITIES

Amendments to the Regulations

AGENCY: Legal Services Corporation.

ACTION: Final regulation.

SUMMARY: The current regulations restrict the availability of Corporation funds which are used to influence legislation. This rule clarifies and revises the restrictions. One of the effects of the new regulations is to restrict the use of Corporation funds for activities designed to influence the outcome of State proposals by initiative petition. The rule is being adopted to reflect the new language in the Legal Services Corporation Act Amendments of 1977.

DATES: Effective date: August 28, 1978.

ADDRESS: Legal Services Corporation, 733 15th Street NW., Suite 700, Washington, D.C. 20005

FOR FURTHER INFORMATION CONTACT:

Stephen S. Walters, 202-376-5113.

SUPPLEMENTARY INFORMATION:

Section 9(c) of the Legal Services Corporation Act Amendments of 1977, Pub. L. 95-222, expanded the prohibition in section 1007(a)(5) of the Act regarding legislative representation to include activities designed to influence the outcome of State proposals by initiative petition, expanded the exceptions to the prohibition to include lobbying regarding measures directly affecting the activities of the recipient or the Corporation, and clarified the restriction on soliciting clients for purposes of legislative representation to include only activities that violate the Code of Professional Responsibility. Section 1612.4(a) of the regulations has been revised to include the new language. In addition, section 1612.5(a) has been revised to reflect the fact that the Corporation has prescribed procedures governing suspension and termination proceedings. Thus, it is no longer necessary to rely on OEO regulations for enforcement of part 1612.

It bears emphasis that the new exception for matters “directly affecting” a recipient does not permit lobbying on poor people’s issues generally. To the contrary, an amendment in the House bill that would have permitted such lobbying was dropped in conference. The exception extends only to appropriations or other measures directed to the Corporation, or the recipient or its employees, as opposed to eligible clients. See Conf. Rep. 95-825, 95th Cong., 1st Sess. (1977), at 13.

The amendment to this regulation was published in the Federal Register on March 17, 1978 (43 FR 11241). Following is the complete regulation, as amended. The comment that appeared in the May 5, 1976 final publication of part 1612 remains in effect (41 FR 18514).

Accordingly, 45 CFR Part 1612 is revised to read as follows:

Sec. 1612.1 Definition.

1612.2 Public demonstrations and other activities.

1612.3 Attorney-client relationship.

1612.4 Legislative and administrative representation.

1612.5 Enforcement.

Authority: 1005(b)(6), 1006(g), 1011, 1006(e), Public Law 95-355, 88 Stat. 378, 1031, 12 U.S.C. 2903(d)(1), 2906(c)(3), 2906(e)(3).

§ 1612.1 Definition.

“Legal assistance activities,” as used in this part, means any activity

(a) Carried out during an employee's working hours;

(b) Using resources provided by the Corporation or by a recipient; or
§1612.2 Public demonstrations and other activities.

(a) While carrying out legal assistance activities under the Act no employee shall:
   (1) Knowingly participate in any public demonstration, picketing, boycott, or strike, except as permitted by law in connection with the employee's own employment situation; or
   (2) Intentionally exhort, direct, or coerce others to engage in such activities, or otherwise usurp or invade the rightful authority of a client to determine what course of action to follow.

(b) While employed under the Act, no employee shall, at any time:
   (1) Knowingly participate in any
      (i) Rioting or civil disturbance;
      (ii) Activity in violation of an outstanding injunction of any court of competent jurisdiction; or
      (iii) Any other illegal activity that is inconsistent with an employee's responsibilities under the Act, Corporation regulations, or the Code of Professional Responsibility; or
   (2) Intentionally exhort, direct, or coerce others to engage in such activities, or otherwise usurp or invade the rightful authority of a client to determine what course of action to follow.

§1612.3 Attorney-client relationship.

Nothing in this part shall prohibit an attorney from
   (a) Informing and advising a client about legal alternatives to litigation or the lawful conduct thereof;
   (b) Attending a public demonstration, picketing, boycott, or strike for the purpose of providing legal assistance to a client; or
   (c) Fulfilling the professional responsibilities of an attorney to a client.

§1612.4 Legislative and administrative representation.

(a) No funds made available to a recipient by the Corporation shall be used, directly or indirectly, to support activities intended to influence the issuance, amendment, or revocation of any executive or administrative order or regulation of a Federal, State or local agency, or to influence the passage or defeat of any legislation by the Congress of the United States or by any State or local legislative body or State proposals by initiative petition.
   (1) An employee may engage in such activities in response to a request from a governmental agency or a legislative body, committee, or member made to the employee or to a recipient; and
   (2) An employee may engage in such activities on behalf of an eligible client of a recipient, if the client may be affected by a particular legislative or administrative measure but no employee shall solicit a client in violation of professional responsibilities for the purpose of making such representation possible; and,
   (3) An employee may engage in such activities if a governmental agency, legislative body, committee, or member thereof is considering a measure directly affecting the activities under the Act of the recipient or the Corporation.

(b) Nothing in this section is intended to prohibit an employee from
   (1) Communicating with a governmental agency for the purpose of obtaining information, clarification, or interpretation of the agency's rules, regulations, practices, or policies; or
   (2) Informing a client about a new or proposed statute, executive order, or administrative regulation; or
   (3) Communicating with the Corporation for any purpose.

§1612.5 Enforcement.

(a) The Corporation shall have authority in accordance with the procedures set forth in part 1606 and part 1623 of these regulations:
   (1) To suspend or terminate the employment of an employee of the Corporation who violates the provisions of this part; and
   (2) To suspend or terminate financial assistance to a recipient who fails to insure that its employees refrain from activities prescribed by the Act or by this part.

(b) A recipient shall
   (1) Advise employees about their responsibilities under this part; and
   (2) Establish procedures, consistent with the notice and hearing requirements of section 1011 of the Act, for determining whether an employee has violated a provision of this part; and shall establish a policy for determining the appropriate sanction to be imposed for a violation, including
      (i) Administrative reprimand if a violation is found to be minor and unintentional, or otherwise affected by mitigating circumstances;
      (ii) Suspension and termination of employment; and
      (iii) Other sanctions appropriate for the enforcement of this regulation; and
   (3) Consult the General Counsel of the Corporation before suspending or terminating the employment of any person for violation of this part.

ALICE DANIEL,
General Counsel, Legal Services Corporation.
§ 1613.1 Purpose.
This part is designed to insure that Corporation funds will not be used to provide legal assistance with respect to criminal proceedings unless such assistance is required as part of an attorney’s responsibilities as a member of the bar.

§ 1613.2 Definition.
“Criminal proceeding” means the adversary judicial process prosecuted by a public officer and initiated by a formal complaint, information, or indictment charging a person with an offense denominated “criminal” by applicable law and punishable by death, imprisonment, or a jail sentence. A misdemeanor or lesser offense tried in the bar.

§ 1613.3 Prohibition.
Corporation funds shall not be used to provide legal assistance with respect to a criminal proceeding, unless authorized by this part.

§ 1613.4 Authorized representation.
Legal assistance may be provided with respect to a criminal proceeding.
(a) Pursuant to a court appointment made under a statute or a court rule or practice of equal applicability to all attorneys in the jurisdiction, if authorized by the recipient after a determination that it is consistent with the recipient’s primary responsibility to provide legal assistance to eligible clients in civil matters; or
(b) When professional responsibility requires representation in a criminal proceeding arising out of a transaction with respect to which the client is being, or has been, represented by a recipient.

ALICE DANIEL, General Counsel, Legal Services Corporation.
[FR Doc. 78-20784 Filed 7-27-78; 8:45 am]

[6730-01]
Title 46—Shipping
CHAPTER IV—FEDERAL MARITIME COMMISSION
[General Order 4; Docket No. 77-63]
PART 510—LICENSING OF INDEPENDENT OCEAN FREIGHT FORWARDERS
Surety Bond
AGENCY: Federal Maritime Commission.
ACTION: Final rule.
SUMMARY: This rule increases the amount of the surety bond required for Commission licensed independent ocean freight forwarders engaged in the business of forwarding in the United States export trade from $10,000 to $30,000. The rule further provides for return of the application for failure to submit such required bond within a specified period. The rule also deletes as provisions rendered obsolete or unnecessary by the passage of time. The changes are designed to add a greater degree of protection to the shipping public in the event of a forwarder default.

DATES: To become effective September 1, 1978.

FOR FURTHER INFORMATION CONTACT:
Francis C. Hurney, Secretary, Federal Maritime Commission, Room 11101, 1100 L Street NW, Washington, D.C. 20573, 202-523-5725.

SUPPLEMENTAL INFORMATION: This proceeding was instituted by Notice of Proposed Rulemaking published in the Federal Register on October 21, 1977 (42 FR 56139-56140) to: (1) Amend § 510.5(g)(3) of the Commission’s General Order (46 CFR 510.5(g)(3)), by raising the amount of the surety bond required for Commission licensed independent ocean freight forwarders engaged in carrying on the business of forwarding in the export commerce of the United States from $10,000 to $50,000; (2) provide for the return of an application for a forwarding license to the applicant for failure to submit surety bond in the required amount; and (3) make other modifications to § 510.5.

In its notice the commission explained that while the bonding requirement was intended to offer some degree of protection to the shipping public, the present amount of the bond does not reasonably afford the degree of protection originally intended. In this regard, it was noted that inflationary spiral since 1963, the date of the original $10,000 bond, requires that more financial protection be afforded shipper clients of freight forwarders. This, the Commission pointed out, is demonstrated by the fact that freight rates, the moneys received by forwarders from shippers to be paid to carriers, have doubled and tripled since the original bond was established. The Commission also noted that to obtain such a bond would require the applicant to demonstrate a substantial degree of financial responsibility and that the surety companies would require a higher degree of financial responsibility from the forwarder.

In addition to increasing the amount of the required surety bond, the Commission also proposed to amend the existing provisions of § 510.5 by: (1) Providing for the return of the application to the applicant for failure to submit required bond; (2) establishing a time period within which existing licenses would be required to file the increased bond; (3) eliminating those provisions pertaining to “grandfather” rights of forwarders and temporary bonding which have been rendered unnecessary by the passage of time; and (4) redesignating certain provisions and making other editorial revisions necessitated by the above changes.

The stated reason for additional amendment (1) above, was to terminate the existing procedure of issuing a notice of intent to deny an application and affording the applicant an opportunity for hearing where such applicant has failed to file the required bond.

This Commission also proposed to amend the existing provisions of § 510.5 because the filing of a bond by an applicant prior to licensing is mandatory under General Order 4 and section 44 of the Shipping Act, 1916, to require a hearing under circumstances where no bond has been furnished is unnecessary and time consuming.

Comments to the proposed rule were received from 134 parties, 122 forwarders, four forwarder associations, two congressmen, two shippers, one insurance association, one Government agency, one surety company, and one group of ocean freight agents. The Commission’s Bureau of Hearing Counsel replied to the comments and answers to Hearing Counsel’s replies were also submitted.

All of the comments address the proposal to raise the amount of the bond from $10,000 to $50,000. Most of these oppose the proposed increase in the amount of bond. Those opposed, including Hearing Counsel, agree, however, that some change in the present bonding requirement is necessary and a variety of alternatives is suggested.

Several reasons are advanced by those commentators supporting the proposed increase; the increased bond would better protect the shipping public, help “professionalize” an industry in which, at present, an individual may enter with relatively little capital, reduce malpractices and deter undercapitalized individuals from entering the field.

Those opposing changes in the present bonding requirement take the position that the increase would impose a severe burden on small forwarders; that small forwarders would be forced from the business, leaving the field entirely in the hands of large forwarders. Several of these parties, including an insurance association and the Small Business Administration, submit that forwarders will be unable to: (1)
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Afford the premium on such a bond; and/or (2) establish to the bonding companies that a small forwarder has sufficient financial strength to be eligible to receive a bond of the proposed size. While many of those opposing the Commission proposal believe that the present bond is sufficient, some argue that no bond should be required.

A large number of comments was received favoring some change in the present bond, but opposing the proposed increase to $50,000. This group, which includes hearing counsel, states that small forwarders will be unable to secure a $50,000 bond due to the size of their forwarding operations and inability to pledge the required collateral, thus leaving small forwarders from the trade, leaving ocean freight forwarding entirely in the hands of a limited number of large forwarders.

Many of these parties urge that the size of the bond be based upon the volume of the forwarder's business. Other comments suggest that recently licensed forwarders, or those licensed in the future, should be required to maintain a large bond while forwarders with several years of experience be permitted to operate under the current bond requirements.

Certain of the commentators in favor of some change recommend that the amount of the bond be raised to $20,000; hearing counsel suggest $25,000. Some suggest that the public would be better served by rigorous Commission enforcement of existing regulations governing the conduct of forwarders in addition to imposing stricter requirements on forwarders seeking a Commission license. Several parties believe that the amount of credit extended by carriers to forwarders should be limited and that the bond requirement be replaced by a yearly license fee.

Hearing counsel suggest the initiation of a further rulemaking proceeding to strengthen the Commission's regulation of the forwarding industry by establishing experience requirements for new forwarders and requiring financial data reporting by existing forwarders in order to identify those with potential problems.

Finally, one commentator suggests that the Commission give consideration to allowing the submission of security other than a bond. In this regard, it is noted that while section 44(e) of the Shipping Act, 1916, provides for a bond, "or other security," § 510.5(g)(3), of Commission general order 4, allows only for the filling of a surety bond.

In this proceeding the Commission must weigh the consequences of the following alternatives. An increase in the amount of the forwarder bond to $50,000 could impose hardship on small forwarders and be detrimental to the interests of the shipping public and possibly reduce the number of forwarders with a corresponding lessening of competition. Conversely, requiring a $50,000 bond could enhance the level of protection to the shipping public by holding forwarders to a higher degree of financial responsibility.

After carefully considering and evaluating all arguments advanced in support of these conflicting propositions, we have decided to increase the amount of the forwarder bond to $50,000. This not only should act to temper the fears of those who believe the existing $10,000 bond is inadequate to protect the shipping public, but also appears to be within the range which many of those opposing an increase to $50,000 would find reasonable.

No comments were made on the remaining proposed amendments to § 510.5 and subject to one minor change in redesignated paragraph (h)(2), will be adopted as proposed.

Hearing counsel have suggested various changes in the Commission's freight forwarder regulations which are outside the scope of this rulemaking and, accordingly, are not addressed here. However, these comments will be considered for possible inclusion in any future rulemaking.

§ 510.5 (Amended)

Therefore, pursuant to sections 43 and 44 of the Shipping Act, 1916 (46 U.S.C. 841a, 841b); and section 4 of the Administrative Procedure Act (5 U.S.C. 553), § 510.5, Title 46 CFR, is hereby amended as follows:

1. Paragraphs (g)(1) and (g)(2) are deleted.

2. Paragraph (g)(3) is redesignated paragraph (g)(1) and revised as follows:

In the present bond is sufficient, some argue that no bond should be required.

3. New paragraph (g)(3) is added as follows:

(1) No license shall be issued to a person to whom this paragraph is applicable unless such person has filed with the Commission a surety bond in the amount of $30,000 on form FMC-59 as set forth below.

(2) Every licensee shall file with the Commission on or before December 1, 1978, a surety bond in the amount of $30,000 on form FMC-59 as set forth below; otherwise such license issued to the licensee shall be revoked in accordance with § 510.9.

(3) The phrase "for failure to prosecute its application in accordance with this section" has been deleted from final paragraph (h)(2) as unnecessary.

(4) Paragraph (h)(1) is deleted.

(5) Paragraph (h)(2) is redesignated as paragraph (h)(1) and revised as follows:

(6) Paragraph (h)(3) is redesignated as paragraph (h)(2) and revised as follows:

Bakke dissents on this point. He does not find the proposed $50,000 figure to be unreasonable and would hold to that amount.

The phrase "for failure to prosecute its application in accordance with this section" has been deleted from final paragraph (h)(2) as unnecessary.

(1) No license shall be issued to a person to whom this paragraph is applicable unless such person has filed with the Commission a surety bond in the amount of $50,000 on form FMC-59 as set forth below.

(2) Every licensee shall file with the Commission on or before December 1, 1978, a surety bond in the amount of $30,000 on form FMC-59 as set forth below; otherwise such license issued to the licensee shall be revoked in accordance with § 510.9.

(3) The phrase "for failure to prosecute its application in accordance with this section" has been deleted from final paragraph (h)(2) as unnecessary.

(4) Paragraph (h)(1) is deleted.

(5) Paragraph (h)(2) is redesignated as paragraph (h)(1) and revised as follows:

(6) Paragraph (h)(3) is redesignated as paragraph (h)(2) and revised as follows:

By order of the Federal Maritime Commission.

FRANCIS C. HURNEY,
Secretary.

(F.R. Doc. 78-20367 Filed 7-27-78; 8:45 a.m.)

FEDERAL REGISTER, VOL. 43, NO. 146—FRIDAY, JULY 28, 1978
Title 47—Telecommunication
CHAPTER I—FEDERAL COMMUNICATIONS COMMISSION
PART 1—PRACTICE AND PROCEDURE
PART 81—STATIONS ON LAND IN THE MARITIME SERVICES AND ALASKA-PUBLIC FIXED STATIONS
PART 83—STATIONS ON SHIPBOARD IN THE MARITIME SERVICES
PART 87—AVIATION SERVICES
PART 89—PUBLIC SAFETY RADIO SERVICES
PART 91—INDUSTRIAL RADIO SERVICES
PART 93—LAND TRANSPORTATION RADIO SERVICES
PART 94—PRIVATE OPERATIONAL FIXED MICROWAVE SERVICE
PART 95—PERSONAL RADIO SERVICE

Permitting Corporate Officers or Duly Authorized Employees of Corporations To Sign Applications, Amendments Thereto, and Related Statements of Fact Required by the Commission; Correction

AGENCY: Federal Communications Commission.

ACTION: Order.

SUMMARY: As a result of its continuing study of reregulation of broadcasting, the Commission initiated the restructurings of part 73 of its rules into a more concise and orderly form by beginning the transfer to subpart H of all rules the subject matter of which is common to AM, FM, and TV broadcasting but are repeated in each of the present subparts for those services. Revisions are made in the rules where needed. Rules which are unique to a particular service will remain in their respective subparts.

EFFECTIVE DATE: August 1, 1978.


FOR FURTHER INFORMATION CONTACT:
Phil Cross, Steve Crane, or John Reiser, Broadcast Bureau, 202-632-9600.

SUPPLEMENTARY INFORMATION:
Adopted: July 12, 1978.


Order. In the matter of reregulation of radio and television broadcasting.

By the Commission:

1. As a result of its continuing study concerning the reregulation of radio and TV, the Commission has under consideration the matter of amending certain provisions of its broadcasting rules as described herein.

2. In the public notice in which the broadcast reregulation study and the formation of the reregulation staff were announced, the Commission stated that one of the staff's goals would be a simpler, more readily understandable set of rules, organized in a manner to more clearly identify those regulations which apply to the various types and classes of broadcast stations.

3. As the reregulation work has progressed, reviewing rules, determining their validity with relation to the present state of the art, and deciding whether they should be retained, modified, or deleted. Also, thought has been given to the optimum form the broadcast rule book should take.

4. In developing a reorganized and reformatted rule book, we have concluded that a basic purpose thereof is to facilitate a better understanding of our rules by broadcasters and practitioners through simple and quick access to them. The first step to easy access was the development and the adoption of the alphabetical index (FCC 76-1042, adopted November 9, 1976). It is an alphabetical index of rule titles in part 73, volume III, and provides ready reference to most, but not absolutely all, of the subject matter in the rules, inasmuch as a rule title, while it is indicative, may not be all-inclusive of the subject matter therein. A complete alphabetical index of all subject matter in our rules is to be an integral and continuing part of this overall reorganization and rewriting (where needed) which begins with this order.

5. The FCC rules and regulations are grouped into 11 volumes and sold by the Superintendent of Documents, Washington, D.C. volume III, parts 73 and 74, "Radio Broadcast Services," contain the bulk of the broadcast rules. Other rules exclusively applicable to broadcasting are contained in volume I, part I, subpart D, "Broadcast Applications and Proceedings." Also, rules applicable to broadcasting, and to other communications services as well, are found in volume I, subpart G, "Schedule of Fees Filed with the Commission" (suspended January 1, 1977, pending further Commission action), subpart H, "Ex Parte Presentations"; subpart I, "Procedures Implementing the National Environmental Policy Act of 1969"; part J, "Commercial Radio Operators"; and part K, "Construction, Marking and Lighting of Antenna Structures."

6. We are looking toward a rule book setting forth, in part 73 of volume III, all rules applicable to the broadcast services. Rules in volume I which are applicable exclusively to broadcasting would be removed therefrom and condensed into part 73, volume III. Rules which are applicable to other communications services, as well as to broadcasting, would be left in volume I, but restated in pertinent part and in condensed form and added to the broadcast services rule book in part 73, volume III. Thus, volume I would be

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undisturbed except for removal of subpart D, "Broadcast Applications and Procedures."

7. Part 73, volume III, is presently subdivided into subparts A, "Standard Broadcast Stations" (to be changed to "AM Broadcast Stations") in this title and throughout the rules as review and revision proceed; B, "FM Broadcast Stations and Radio Astronomy Observatories"; C, "Noncommercial Educational FM Broadcast Stations"; E, "Television Broadcast Stations" (to be changed to "TV Broadcast Stations" as revision take place); F, "Interruption, we seek most Stations"; G, "Emergency Broadcast System"; and H, "Rules Applicable in Common to Broadcast Stations". Subparts F and G will remain as they are for now. Subpart H will be expanded to include all rules applying in common to AM, FM, and TV stations. (See par. 5, below.) Thought is being given to adding subpart D for rules exclusively applicable to noncommercial educational AM, FM, and TV stations. An alternate plan being considered is the inclusion of rules exclusively applicable to noncommercial educational stations in the subparts for the separate AM, FM, and TV services. They could be included as separate subdivisions of the AM, FM, and TV subparts, or as separate subparagaphs in subpart H sections (i.e., "Commercial applicability" and "Noncommercial educational applicability."). In the immediate future, testing the alternatives as the reformatting and reorganization progresses, and our findings, will dictate our final decision.

8. Part 73, volume III, as presently structured, includes, in the separate subparts, rules which are applicable to that particular service only, as well as approximately 215 rules which apply in common to all broadcast stations.
May be selected by the station licensee determining the station carrier frequency or method used for measuring the frequency of each main transmitter used. It also makes it clear that the actual process of measurement of the FM stereo broadcast signal analysis work. Low power portable transmitters are frequently used in making these measurements. The term "portable transmitter" as used in connection with special field tests, is only defined in the AM subpart of the rule in §73.12. Since these portable facilities, more correctly called "Portable Test Stations," are used for field tests in all broadcast services, the definition "Portable Test Station" is set forth in subpart H as §73.1530.

(c) The part 73 alphabetical index is revised to reflect the rule changes described below.

13. We conclude that, for the reasons set forth above, adoption of these revisions will serve the public interest and inasmuch as these amendments impose no additional burdens and raise no issue upon which comments would serve any useful purpose, prior notice of rulemaking, effective date provisions and public procedure therefore are unnecessary pursuant to the Administrative Procedure and Judicial Review Act provisions of 5 U.S.C. (b)(3)(B).

14. Therefore, it is ordered, That pursuant to Sections 40 and 303(r) of the Communications Act of 1934, as amended, the Commission's rules and regulations are amended as set forth below, effective August 1, 1978.

(Sees. 4, 303, 48 stat., as amended, 1065, 1082; 47 U.S.C. 154, 303.)

FEDERAL COMMUNICATIONS COMMISSION, WILLIAM J. FUGARICO, Secretary.

1. In part 73, the title headnote of subpart A is changed to the following:

Subpart A—AM Broadcast Stations

2. Section 73.1 and headnote are amended to read as follows:

§73.1 AM broadcast station (Definition).

The term "AM broadcast station" means a broadcast station licensed for the dissemination of radio communications intended to be received by the public and operated on a channel in the band 535–1605 kilohertz (kHz). The term "AM broadcast" is synonymous with the term "standard broadcast" as contained elsewhere in this chapter.

3. Section 73.2 and headnote are amended to read as follows:

§73.2 AM broadcast band (Definition).

The term "AM broadcast band" means the band of frequencies extending from 535 to 1605 kHz.

4. Section 73.3 and headnote are amended to read as follows:

§73.3 AM broadcast channel (Definition).

The term "AM broadcast channel" means the band of frequencies occupied by the carrier and two sidebands of a broadcast signal with the carrier frequency at the center. Channels shall be designated by their assigned carrier frequencies. The 107 carrier frequencies assigned to AM broadcast stations shall begin at 540 kHz and be in successive steps of 10 kHz.

5. Section 73.10 headnote and text are amended to read as follows:

§73.10 Experimental period (Definition).

The term "experimental period" in reference to AM station operation means that time between 12 midnight local time and local sunrise.

6. Section 73.12 is amended to read as follows:

§73.12 Portable transmitters.

See §73.1530.

7. Section 73.17 is amended to read as follows:

§73.17 Cross reference to rules in other parts.

See §73.1030.

8. Section 73.18 is amended to read as follows:

§73.18 Notification of filing of applications.

See §73.1030.

9. The headnote of section 73.21 is amended to read as follows:

§73.21 Classes of AM broadcast channels and stations.

10. Section 73.32 is amended to read as follows:

§73.32 Special experimental authorizations.

See §73.1510 and §73.1520.

11. Section 73.34 is amended to read as follows:

§73.34 Normal license period.

See §73.1030.

12. Section 73.60 is amended to read as follows:

§73.60 Frequency measurements.

See §73.1540.

13. Section 73.72, the headnote and text are amended to read as follows:

§73.72 Operating during the experimental period.

(a) An AM station may operate during the experimental period on its assigned frequency and with its authorized power for the routine testing and maintenance of its transmitting system, and for conducting experimental operations under an experimental authori-
zation; provided no interference is caused to other stations maintaining a regular operating schedule within such period.

(b) No station licensed for “daytime” or “specified hours” of operation may broadcast any regular or scheduled program during this period.

(c) The licensee of an AM station shall operate or refrain from operating its station during the experimental period as directed by the FCC to facilitate frequency measurements or for the determination of interference.

14. Section 73.95 is amended to read as follows:

§ 73.95 Equipment tests.

See §73.1610.

15. Section 73.96 is amended to read as follows:

§ 73.96 Program tests.

See §73.1620.

16. The undesignated headnote immediately preceding §73.181 is changed to read as follows:

AM TECHNICAL STANDARDS

17. The undesignated headnote, “Administrative Procedures,” preceding section 73.214 is deleted in its entirety.

18. Section 73.214 is amended to read as follows:

§ 73.214 Cross reference to rules in other parts.

See §73.1010.

19. Section 73.215 is amended to read as follows:

§ 73.215 Notification of filing of applications.

See §73.1030.

20. Section 73.216 is amended to read as follows:

§ 73.216 Equipment tests.

See §73.1610.

21. Section 73.217 is amended to read as follows:

§ 73.217 Program tests.

See §73.1620.

22. Section 73.218 is amended to read as follows:

§ 73.218 Normal license period.

See §73.1020.

23. Section 73.219 is amended to read as follows:

§ 73.219 Frequency measurements.

See §73.1540.

24. Section 73.220 is amended to read as follows:

§ 73.220 Experimental operation.

See §73.1510 and §73.1520.

25. The undesignated headnote, “FM Technical Standards,” following §73.265 in the “Contents—Part 73” is relocated to follow §73.301 and precede §73.310.

26. The undesignated headnote, “Administrative Procedures,” preceding §73.514 is deleted in its entirety.

27. Section 73.514 is amended to read as follows:

§ 73.514 Cross reference to rules in other parts.

See §73.1010.

28. Section 73.515 is amended to read as follows:

§ 73.515 Notification of filing of applications.

See §73.1030.

29. Section 73.516 is amended to read as follows:

§ 73.516 Equipment tests.

See §73.1610.

30. Section 73.517 is amended to read as follows:

§ 73.517 Program tests.

See §73.1620.

31. Section 73.518 is amended to read as follows:

§ 73.518 Normal license period.

See §73.1020.

32. The undesignated headnote, “Equipment,” preceding §73.550 is relocated to precede §73.540.

33. Section 73.552 is amended to read as follows:

§ 73.552 Frequency measurements.

See §73.1540.

34. Section 73.556 is amended to read as follows:

§ 73.556 Experimental operation.

See §73.1510 and §73.1520.

35. Section 73.557 is amended to read as follows:

§ 73.557 Cross reference to rules in other parts.

See §73.1010.

36. Section 73.562 is amended to read as follows:

§ 73.562 Notification of filing of applications.

See §73.1030.

37. Section 73.568 is amended to read as follows:

§ 73.568 Equipment tests.

See §73.1610.

38. Section 73.569 is amended to read as follows:

§ 73.569 Program tests.

See §73.1620.

39. Section 73.570 is amended to read as follows:

§ 73.570 Normal license period.

See §73.1020.

40. Section 73.666 is amended to read as follows:

§ 73.666 Experimental operation.

See §73.1510 and §73.1520.

41. Section 73.690 is amended to read as follows:

§ 73.690 Frequency measurements.

See §73.1540.

42. the title headnote of subpart H, part 73, is amended to read as follows:

Subpart H—Rules Applicable to all Broadcast Stations

43. Section 73.1001 and headnote are amended to read as follows:

§ 73.1001 Scope.

(a) The rules in this subpart are common to all AM, FM, and TV broadcast services, commercial and noncommercial.

(b) Rules in part 73 applying exclusively to a particular broadcast service are contained in the following: AM, subpart A; FM, subpart B; Noncommercial Educational FM, subpart C; and TV, subpart E.

(c) Certain provisions in this subpart apply to International Broadcast Stations (subpart F, part 73) and Television Broadcast Translator Stations (subpart G, part 73) where the rules for those services so provide.

(d) The provisions of this part applying to licensees also apply to holders of construction permits (permittees).

44. New §73.73.1010 is added to subpart H, part 73, as follows:

§ 73.1010 Cross reference to rules in other Parts.

Certain rules applicable to broadcast services, some of which are also applicable to other services, are set forth in the following Volumes and Parts of the Commission's Rules and Regulations:


(1) Subpart A, “General Rules of Practice and Procedure” (§§ 1.1 to 1.120).


(6) Subpart H, “Ex Parte Presentations” (§§ 1.1121 to 1.1251).


(c) Part 13 (volume I), "Commercial Radio Operations."

(d) Part 17 (volume I), "Construction, Marking, and Lighting of Antenna Structures."


45. New § 73.1020 is added to subpart H, part 73, as follows:

§ 73.1020 Station license period.

(a) Initial licenses for broadcast stations will ordinarily be issued for a period running until the date specified in this section for the State or Territory in which the station is located. If issued after such date, it will run to the next renewal date determined in accordance with this section; and, when renewed, will normally be renewed for 3 years. If the FCC finds that the public interest, convenience, and necessity will be served thereby, it may issue either an initial license or a renewal thereof for a lesser term. The time of expiration of normally issued initial and renewal licenses will be 3 a.m., local time, on the following dates and at 3-year intervals thereafter for stations located in:

(2) Maryland, District of Columbia, Virginia and West Virginia, October 1, 1978.
(3) North Carolina and South Carolina, December 1, 1978.
(5) Alabama and Georgia, April 1, 1979.
(6) Arkansas, Louisiana and Mississippi, June 1, 1979.
(7) Tennessee, Kentucky and Indiana, August 1, 1979.

(8) Ohio and Michigan, October 1, 1979.
(9) Illinois and Wisconsin, December 1, 1979.
(10) Iowa and Missouri, February 1, 1980.
(11) Minnesota, North Dakota, South Dakota, Montana and Colorado, April 1, 1980.
(12) Kansas, Oklahoma and Nebraska, June 1, 1980.
(13) Texas, August 1, 1980.
(15) California, December 1, 1980.
(17) Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island and Vermont, April 1, 1981.
(18) New Jersey and New York, June 1, 1981.

NOTE—For the cutoff date for the filing of applications mutually exclusive with, and petitions to deny, renewal applications, see § 1.616(e) of this chapter.

46. New § 73.1030 is added to subpart H, part 73, as follows:

§ 73.1030 Notifications concerning interference to radio astronomy, research and receiving installations.

(a) Radio astronomy and radio research installations. In order to minimize harmful interference at the National Radio Astronomy Observatory site located at Green Bank, Pocahontas County, W. Va., and at the Naval Radio Research Observatory at Sugar Grove, Pendleton County, W. Va., an applicant for authority to construct a new broadcast station or for authority to make changes in the frequency, power, antenna height, or antenna directivity of an existing station within the area bounded by 39°15' N on the north, 80°30' W on the west, 39°15' N on the south, and 80°30' W on the west shall, at the time of filing such application with the FCC simultaneously notify the following:

Director, National Radio Astronomy Observatory, P.O. Box No. 2, Green Bank, W. Va. 24911.

The notification shall be in writing and set forth the particulars of the proposed station, including the geographical coordinates of the antenna, antenna height, antenna directivity if any, proposed frequency, type of equipment, and power. In addition, the applicant shall indicate in his application to the FCC the date notification was made to the observatory. After receipt of such applications, the FCC will allow a period of 20 days for comments or objections in response to the notifications indicated. If an objection to the proposed operation is received during the 20-day period from the National Radio Astronomy Observatory for itself or on behalf of the Naval Radio Research Observatory, the FCC will consider all aspects of the problem and take whatever action is deemed appropriate.

(b) Radio receiving installations. Protection for Table Mountain Radio Receiving Zone, Boulder County, Colo.: Applicants for a station authorization to operate in the vicinity of Boulder County, Colo., under this part are advised to give due consideration, prior to filing applications, to the need to protect the Table Mountain Radio Receiving Zone from harmful interference. These are the Research Laboratories of the Department of Commerce, Boulder County, Colo. To prevent degradation of the present ambient radio signal level at the site, the Department of Commerce seeks to ensure that field strengths at 40°07'50" N latitude, 105°14'40" W longitude, resulting from new assignments (other than mobile stations) or from the modification or relocation of existing facilities do not exceed the following values:

<table>
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<tr>
<th>Frequency range</th>
<th>Field strength</th>
<th>Power flux density*</th>
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<tr>
<td>Below $540$ kHz</td>
<td>$10^{-6}$ (\text{mW/\text{m}^2})</td>
<td>$10^{-6}$ (\text{W/m}^2)</td>
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<tr>
<td>$540$ to $1600$ kHz</td>
<td>$20^{-6}$ (\text{mW/\text{m}^2})</td>
<td>$20^{-6}$ (\text{W/m}^2)</td>
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<td>$1.9$ to $470$ MHz</td>
<td>$10^{-6}$ (\text{mW/\text{m}^2})</td>
<td>$10^{-6}$ (\text{W/m}^2)</td>
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<td>$470$ to $515$ MHz</td>
<td>$30^{-6}$ (\text{mW/\text{m}^2})</td>
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<tr>
<td>Above $800$ MHz</td>
<td>$1^{-6}$ (\text{mW/\text{m}^2})</td>
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*\(\text{mW/\text{m}^2}\) in authorized bandwidth of service.

§ 73.1020 Station license period.

§ 73.1030 Notifications concerning interference to radio astronomy, research and receiving installations.

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"(2) In advance of filing their applications with the FCC, applicants concerned are urged to communicate with the following:

Radio Frequency Management Coordinator,
Department of Commerce, Research Support Services NOAA/RSX3, Boulder Laboratories, Boulder, Colorado 80302, telephone, 303-499-1000, extensions 6548 or 6549.

(3) The FCC will not screen applications to determine whether advance consultation has taken place. However, applicants are advised that such consultation can avoid objections from the Department of Commerce of proceedings to modify any authorization which may be granted which, in fact, delivers a signal at the reference point in excess of the field strength specified herein.

§73.1510 is added to Subpart H, Part 73, as follows:

§73.1510 Experimental authorizations.

(a) Licensees of broadcast stations may obtain experimental authorizations to conduct technical experimentation directed toward improvement of the technical phases of operation and service, and for such purposes may use a signal other than the normal broadcast program signal.

(b) Experimental authorizations may be requested by filing an informal application with the FCC in Washington, D.C., as are advised that such application for the experimental to be conducted, the nature of the experimental signal to be transmitted, and the proposed schedule of hours and duration of the experimentation. Experimental authorizations shall be posted with the station license.

(c) Experimental operations are subject to the following conditions:

(1) The authorized power of the station may not be exceeded, except as specifically authorized for the experimental operations.

(2) Emissions outside the authorized bandwidth must be attenuated to the degree required for the particular type of station.

(3) The experimental operations may be conducted at any time the station is authorized to operate, but the minimum required schedule of programming for the class and type of station must be met. AM stations also may conduct experimental operations during the experimental period (12 midnight local time to local sunrise) and at additional hours if permitted by the experimental authorization provided no interference is caused to other stations maintaining a regular operating schedule within such periods.

(4) If an experimental authorization permits the use of additional facilities or hours of operation for experimental purposes, no sponsored programs or commercial announcements may be transmitted during such experimentation.

(5) The licensee may transmit regularly scheduled programming concurrently with the experimental transmission if there is no significant impairment on the authorized service.

(6) No changes may be made, either directly or indirectly, for the experimentation; however, normal changes may be made for regularly scheduled programming transmitted concurrently with the experimental transmission.

(d) The FCC may request a report of the research, experimentation and results at the conclusion of the experimental operation.

48. New §73.1520 is added to Subpart H, Part 73, as follows:

§73.1520 Operation for tests and maintenance.

(a) Broadcast stations may be operated for tests and maintenance of their transmitting systems on their assigned frequencies using their licensed operating power and antennas during their authorized hours of operation without specific authorization from the FCC.

(b) Licensees of AM stations may operate for tests and maintenance during the hours from 12 midnight local time to local sunrise, if no interference is caused to other stations maintaining a regular operating schedule within such period. No AM station licensed for "daytime" or "specified hours" of operation may broadcast any regular or scheduled programs during this period of test and maintenance operation.

(c) Licensees of AM stations must obtain a special antenna equipment test authorization using the procedure described in §73.546(a) in order to operate with authorized nighttime power and directional antenna system during nighttime hours when necessary to conduct monitor point field strength measurements and antenna proof of performance measurements.

49. New §73.1530 is added to Subpart H, Part 73, as follows:

§73.1530 Portable test stations. [Definition]

A portable test station is one that is moved from place to place for making field strength and ground conductivity measurements, for selecting station transmitter sites, and conducting other specialized propagation tests. Portable test stations are not normally used while in motion, and may not be used for the transmission of programs intended to be received by the public.

50. New §73.1540 is added to Subpart H, Part 73, as follows:

§73.1540 Carrier frequency measurements.

(a) The carrier frequency of each AM and FM station and the visual carrier frequency and difference between the visual carrier and the aural carrier or center frequency of each TV station shall be measured as often as necessary to insure that they are maintained within the prescribed tolerances. In any event, each station with an authorized operating power greater than 10 watts shall make at least one measurement or determination each calendar month with intervals not exceeding 40 days between successive measurements for each main transmitter in use.

(b) In measuring the carrier frequency, the licensee may use any method or procedure that has sufficient precision to establish that the carrier frequency is within the prescribed departure limits.

(c) The primary standard of frequency for radio frequency measurements is the standard frequency maintained by the National Bureau of Standards or the standard signals of Stations WWV, WWVH, and WWVB of the National Bureau of Standards.

51. New §73.1610 is added to Subpart H, Part 73, as follows:

§73.1610 Equipment tests.

(a) During the process of construction of a broadcast station, the permittee, after notifying the FCC in Washington, D.C. and engineer in charge of the radio district in which the station is located may, without further authority of the FCC, conduct equipment tests for the purpose of such adjustments and measurements as may be necessary to assure compliance with the terms of the construction permit, the technical provisions of the application therefor, the rules and regulations and the applicable engineering standards. For AM stations, tests must be conducted during the experimental period, 12 midnight local time to local sunrise. The FCC may authorize equipment tests other than during the experimental period for AM stations, if such operation is shown to be desirable to the proper completion of construction and adjustment of the transmitting equipment and antenna system. An informal application for such authority, giving full details regarding the need for such tests, shall be filed with the FCC in Washington, D.C. at least 2 days (not including Saturdays, Sundays, and legal holidays when the offices of the FCC are not open) prior to the date on which it is desired to begin such operation.

(b) The FCC may notify the permittee not to conduct tests or may cancel, suspend, or change the date for the beginning of equipment tests if and when such action may appear to be in
(e) The granting of program test authority shall not be construed as approval by the FCC of the application for station license.

(f) The granting of program test authority for a UHF TV station which is not in operation on, but assigned to, the same allocated channel which a 1000 watt UHF translator station is authorized to use (see §1.516(c)). Specifications of facilities, shall notify the licensee of the translator station, in writing, at least 10 days prior to commencing or resuming operation. The TV station licensee shall also certify to the FCC in Washington, D.C. that such advance notice has been given to the translator station licensees.

§ 73.146 Program tests.

(a) Upon completion of construction of an AM, FM, or TV station in accordance with the terms of the construction permit, the technical provisions of the application, the rules and regulations and the applicable engineering standards, and when an application for station license has been filed showing the station to be in satisfactory operating condition, the petitioner may request authority to conduct program tests. Such request shall be filled with the FCC in Washington, D.C. at least 10 days prior to the date on which it is desired to begin such operation. All data necessary to show compliance with the terms and conditions of the construction permit must be filled with the license application.

(b) Program tests shall not commence until specific FCC authority is received. The FCC reserves the right to change the date of the beginning of such tests or to suspend or revoke the authority for program tests.

(c) Unless sooner suspended or revoked, the program test authority continues valid during FCC consideration of the application for license, and during this period further extension of the construction permit is not required. Program test authority shall be automatically terminated by final determination upon the application for station license.

(d) All operation under program test authority shall be in strict compliance with the rules governing broadcast stations and in strict accordance with representations made in the application for license pursuant to which the tests were authorized.

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FEDERAL REGISTER, VOL 43, NO. 146—FRIDAY, JULY 28, 1978
PART 75—RADIO BROADCAST SERVICES

Subpart D—Emergency Broadcast System (EBS)—Continued

Summary: The FCC is amending its rules on political broadcasting and cablecasting to clarify them and resolve uncertainties in their application. Also, to make certain paragraphs fully interpretable of applicable sections of the Communications Act as amended by Congress in 1972, 1974, and 1976. We believe our action will make it much easier for broadcast licensees, cable television system operators, and political candidates to understand the law in this area.

Effective Date: August 23, 1978.

For Further Information:

William B. Ray, Broadcast Bureau, Room 202-B, 202-632-5414, interest in the toll-free telephone number.

In the matter of amendments of Parts 73 and 76 of the Commission's rules relating to broadcasting and cablecasts by legally qualified candidates for public office, 47 FCC 75-509; Report and Order (33 F.C.C. 2nd 12023).

Adopted: July 12, 1978.


1. The Commission has before it for consideration the Notice of Proposed Rule Making adopted March 16, 1978, and released March 24, 1978 (FCC 78-205) and comments filed in response thereto on proposed amendments to the rules relating to broadcasting and cablecasts by legally qualified candidates for public office. Additionally, the Commission considers herein certain other amendments to the political broadcasting and cablecasting rules to make them fully interpretable of Section 315 of the Communications Act of 1934, as amended.

2. Timely comments on the Notice of Proposed Rule Making were filed by eight parties: American Broadcasting Co., Inc. (ABC); Belo Broadcasting Corp. (Belo); CBS, Inc; the firm of Jorgensen, Johnson & Northrop on behalf of eight licensees (Jorgensen); National Association of Broadcasters (NAB); National Broadcasting Co., Inc. (NBC); National Radio Broadcasters Association (NRBA); and Public Broadcasting Service (PBS). After the announced closing date for comments, the National Cable Television Association (NCTA) and the National Black Media Coalition (NBMC) each filed comments on a single but different aspect of the proposed rulemaking. Despite the late filing, both comments have been considered. No reply comments were filed.

Present Definitions of Candidates

3. The particular parts of the political broadcasting and cablecasting rules to which our notice was directed are those defining a "legally qualified candidate for public office" for the purposes of the Communications Act. The definitions in the present broadcast rules, which are almost identical to those in the cable television rules, are as follows:

(a) Definitions.—A "legally qualified candidate" means anyone who has publicly announced that he is a candidate for nomination by a convention of a political party for nomination or for election in a primary, special, or general election in a county, State, or national, and who meets the qualifications prescribed by the applicable laws to hold the office for which he is a candidate, so that he may be voted for by the electorate or by a political party or other method, as follows:

(i) Has qualified for a place on the ballot, or

(ii) Has publicly committed himself to seeking election by the write-in method, and

is eligible under the applicable law to be voted for by the electorate or by another method, and makes a substantial showing that he is a bona fide candidate for nomination or election.

We were concerned about three aspects of these rules: (1) They permit write-in candidates to become legally qualified for purposes of Sections 312 and 315 of the Act earlier than candidates who seek to qualify for places on the ballot; (2) write-in candidates seeking nomination by convention, caucus, or similar means other than a primary election, they specify no requirement for becoming "legally qualified" candidates for nomination.
except public announcement of candidacy and eligibility to hold the office that is sought; (3) with respect to candidates seeking nomination to the officers of President or Vice President of the United States, the rules not only suffer from the deficiency set forth in (2) above but leave unanswered the question of the number of States in which one must qualify for nomination to be considered a candidate nationwide.

PROPOSED NEW DEFINITIONS

4. In order to eliminate these problems, we propose to adopt the following revised definition of a legally qualified candidate:

(a) Legally qualified candidate. (1) A legally qualified candidate for public office is any person who:

(i) Has publicly announced his or her intention to run for nomination or office; and,

(ii) Is qualified under the applicable local, State, or Federal law, to qualify for a place on the ballot for which he or she is a candidate; and,

(iii) Has met the qualifications set forth in either subparagraphs (2), (3), or (4), below.

(2) A person who seeks nomination by any public office, or nomination for any public office, except that of President or Vice President of the United States, shall be considered a legally qualified candidate if, in addition to meeting the criteria set forth in subparagraph (1), above, that person:

(i) Has qualified for a place on the ballot;

(ii) Publicly announces his or her intention to be a write-in candidate and makes a substantial showing that he or she is a bona fide candidate for nomination or office; and

(iii) Has publicly announced his or her intention to be a write-in candidate and makes a substantial showing that he or she is a bona fide candidate for nomination or office.

propositions, that person:

(3) A person seeking nomination to any public office, except that of President or Vice President, by means of a convention, caucus, or similar procedure, shall be considered a legally qualified candidate if, in addition to the criteria set forth in subparagraph (1), above, that person makes a substantial showing that he or she is a bona fide candidate for such nomination.

A person seeking nomination for the officers of President or Vice President of the United States shall be considered a legally qualified candidate in all States and territories of the United States if, in addition to meeting the criteria set forth in subparagraph (1), above,

(i) He or she has not publicly announced his or her intention to run for nomination or office; and,

(ii) He or she has made a substantial showing that he or she is a bona fide candidate for such nomination.

PROPOSED CHANGES

5. The significant changes thus proposed in the new definitions may be summarized as follows:

(a) Subparagraph (2)(ii) seeks to equalize the time prior to an election in which write-in and ballot candidates may be considered legally qualified for purposes of the Communications Act.

(b) Subparagraph (3) adds the requirement that candidates seeking nomination by convention, or means other than the primary election, make a "substantial showing" of bona fide candidacy, which would eliminate from the "legally qualified candidate" category those who lack opportunities and other statutory benefits by merely stating that they are candidates. We also requested comments on whether there should be a limit to the period in which those seeking nomination by means of a convention or similar proceeding to any office except that of President or Vice President might be considered legally qualified candidates for purposes of the Act. For example, under subparagraph (3) should anyone be considered a legally qualified candidate for nomination more than a certain number of days prior to the election or other event which will name the nominees?

(c) In subparagraph (4) we proposed to incorporate into our rules the holding in the Pet Pulitzer case 1 that a candidate who has been endorsed as a candidate for a political party's nomination for President or Vice President in one State must be considered such a candidate nationwide. We also proposed to provide an alternative method of achieving nationwide candidacy status—making "a substantial showing that he or she is a bona fide candidate for such nomination."

COMMENTS ON WRITE-IN CANDIDATE RULES

6. The proposal to equalize the time during which write-in and ballot candidates may be considered legally qualified for purposes of the Communications Act was supported, either in detail or in principle, by seven of the nine parties filing comments on it. ABC, NABC, and Jorgensen supported it without reservation. Belo also endorsed it but suggested slight language changes in the proposed rule. CBS favored the concept of a time limit but stated that the laws of some States set no date before which one cannot qualify for a place on the ballot and suggested that we establish a date, perhaps 90 days before the State's final date for ballot qualification, before which no candidate can be considered legally qualified. The NAB, and Jorgensen, supported the Commission's proposal but suggested that for the sake of uniformity we set our own date before which a candidate will not be considered legally qualified, rather than relying on each State to set its date. PBS and NBMC were the only ones to oppose the time limitation. PBS asserted that this is not a substantial problem, since stations have the right to determine when to make their facilities available to candidates and if a problem does exist with respect to Federal candidates under the "reasonable access" provisions of section 312(a)(7), the Commission can deal with it by setting a date on which "reasonable access" rights vest. PBS also argued that the proposed limit is unnecessary because under the present rules, if a write-in candidate "uses" broadcast facilities prior to the time a candidate is qualified, the intended ballot candidate "can secure equal opportunity rights by declaring that he or she will pursue the office as a write-in candidate, if they fail to obtain ballot status. " Finally, PBS stated that the proposal does not defer to State laws as the commission's policies generally do in this area. PBS thinks that if State law allows a write-in candidate to qualify as a legally qualified candidate before a ballot opportunity, the Commission should do likewise.

7. NBMC's opposition was based on broader grounds. It stated that write-in candidates already are at a disadvantage because they are not as well known as major party candidates, and that even if under the present rules they are able to qualify as candidates and obtain some broadcast coverage, it "will not only lessen the disparity between write-ins and ballot candidates. " NBMC asserted that under the 1959 amendments to section 315 creating four categories of exempt "nonuses," licensees cover the major party candidates in exempt programs during an election but the write-in candidate "is not only not entitled to equal time, but may not even be able to rely on the fairness doctrine," citing Benjamin Spock v. F.C.C. 315 F.2d 42 (1963). NBMC also quoted from the U.S. Supreme Court decision in Williams v. Rhodes, 393 U.S. 23 (1960):

Write-ins are no substitute for a place on the ballot; * * * to force a candidate to rely on write-ins is to burden him with a disability. It makes it more difficult for him to get elected and for the voters to elect him.

NBMC stated that if the rationale for the proposed rule change "is to put all candidates on an equal footing as to
when they are legally qualified, then the major party primary dates are also
unfair. Often, third-party candidates qualify after the major parties can.
Third, therefore, if candidates are willing to be considered
for nomination, and the determination of the 'meaning
of the term in specific cases to licensees, and
sufficiency as to the extent 'to which 'the
extent of their showing that they are bona fide con-
ditions for nomination. The parties dif-
framed to restricting write-in candidates' access
right under where State law puts no such
3. After carefully considering all of the
of this aspect of the proposed
may exercise their reasonable, good
be amended to the rules rather
with respect to local and State candidates,
their campaign committee, delivering
-define the "reasonable access"
and the exercise of licensee discretion regarding all others
appear sufficient to cope with future problems in this area. If
become major, we shall deal with
the standards setting for the
is set forth in the notice and to add
the following time limitation clause:
Except, that no person shall be consid-
ed a candidate for nomination
by the means set forth in this subparagraph
although the time limitation does not apply
in this subparagraph.
We believe the "substantial showing"
requirement should be applied here for
the same reason that we long ago
eliminated the requirement for persons
claiming to be write-in candidates;
that is, to deny to those who do
no more than state that they are candidates
the benefits which Congress
intended to accord serious candidates
for public office. The absence of laws
in many States setting standards for
eligibility of write-in candidates and of
such laws in most if not all States with
respect to eligibility to seek nomination
to local or State office by convention
or caucus, leads us to the conclu-
sion that we must establish some cri-
tria for distinguishing between serious
candidates and those who may be
merely publicity seekers trying to take
advantage of Federal laws which were
enacted to assure equal opportunities
to those genuinely contending for elec-
tion to public office. As for the time
limitation of 90 days before opening of
the convention or caucus, we believe it
reasonable period for all except

However, the lowest unit charge require-
ments of section 315 apply only to primary,
special, and general election, not to can-
moneys or caucuses.

Jorgensen stated that candidates compet-
ing for nomination by convention
for caucus normally need less widespread publicity for their candidates
"since they will be chosen not by
the public at large but by a smaller
number of known delegates. The
convention or caucus candidate will
succeed or fail more as a result of his
direct contacts with the delegates
than as a result of broadcast public-
ity." For this reason, Jorgensen recom-
ended a time limit of no more than 1
month for such candidates. FES
made no suggestions for a pre-convena-
tion time limitation.
tional conventions (which are not covered in subparagraph (3)) and that adoption of a limitation representing a period twice that specified in section 315 of the act for lower unit charges preceding a primary election will give certain local states and political parties an advantage in financing the activities of candidates, broadcast licensees, and cable system operators alike. We are adopting NRBA's suggestion that at least an outline of the meaning of "substantial showing" be included in the rules by adding subparagraph (5) to the "definitions" paragraph. It states the general meaning of the term and gives some examples of activities normally involved in such a showing, while stating that there may be other activities which would contribute to such a showing.

CANDIDATES FOR PRESIDENT AND VICE PRESIDENT

12. All parties commenting on the subject opposed the proposal in subparagraph (4) to codify the ruling in *Pat Paulsen* that a person who has legally qualified as a candidate for his party's nomination for President or Vice President in one state was considered such a candidate nationwide. Because of the complexity of the issue and the fact that the next Presidential election is 2 years away, NRBA suggested allowing more time for considering this question and suggested adding to it from the current rulemaking. PBS also urged that this question be considered in a separate future proceeding and that the Commission at that time also consider the definition of a Presidential candidate for purposes of the general election. It believed that the two definitions are closely related and the definition for purposes of the general election is a most important one. PBS and NBC likewise raised the question of an individual's Presidential candidacy for purposes of the general election.

13. With respect to the general election question, proposed subparagraph (2) already defines a legally qualified candidate in all general elections. To make this fact more clear, we have inserted language to the effect that the provisions of subparagraph (2) apply to general elections to the Presidency and Vice Presidency, although not to nomination for these two offices. There remains, however, the question of whether a person who is a legally qualified candidate in one, two, three, or any number of States and territories less than all of them, is to be accorded nationwide status as a Presidential candidate in the general election for purposes of equal opportunities, freedom from censorship, reasonable access, etc. This question has rarely if ever been raised concerning a general election for President and Vice President. We agree, however, that it should be settled and we shall consider it along with the *Pat Paulsen* issue. In fact, we see no reason why the requirements for gaining nationwide status as a legally qualified candidate for election to the Presidency should be different from those for gaining similar status as a legally qualified candidate for nomination for that office.

14. Although all commenting parties agreed that the 1-State candidacy illustrated in the *Paulsen* ruling was insufficient to gain nationwide status as a candidate, their recommendations ranged all the way from "more than 1" State to as many as 20 States in which the candidate would be required to become legally qualified or make a substantial showing before being considered legally qualified nationwide. NAB pointed out that some States have minimal requirements for voter signatures in order to get on a primary ballot, for example, and that the definition of "candidacy" by PBS and NBC, among others, would have been considered national candidates on the basis of their ballot candidacies and 4 more who were on the ballot in 6 or more States might well have qualified under the "substantial showing" standard.

17. Although NAB stated that some States "have very minimal requirements for voter signatures, so that qualifying as a candidate is a relatively easy task." none of the parties further elaborated in information on this subject. Inquiry by our staff into the requirements of a sampling of States indicates that it is easy to attain ballot status in Presidential primaries in some States, although others make the task much more difficult. In many States, the Secretary of State or a board of State officials selects ballot candidates on the basis of their being "generally advocated and nationally recognized." Some States have qualified for Federal campaign funds if a candidate has national support.* * *

*PBS favors a requirement that he or she is on the ballot in at least 10 States to be eligible for matching Federal funds. 26 U.S.C. § 9901. PBS says "Congress established that standard as a reasonable measure of whether a candidate has national support ."* * *

PBS states that under its proposed 10-States standard, 6 of the candidates in 1976 for Presidential nomination "did not have been considered national candidates on the basis of their ballot candidacies and 4 more who were on the ballot in 6 or more States might well have qualified under the 'substantial showing' standard."

The minimum number of signatures required on petitions ranges from an apparent low of 200 to a percentage of the total State vote for Governor or President in the last general election.

18. After considering the comments and our own experience and research we have decided to overturn one part of the *Paulsen* ruling and to require that a candidate for either nomination or election to the Presidency gain ballot status or make a substantial showing of bona fide candidacy in 10 States in order to qualify for Federal campaign funds. In our staff into the requirements of a sampling of States indicates that it is easy to attain ballot status in Presidential primaries in some States, although others make the task much more difficult. In many States, the Secretary of State or a board of State officials selects ballot candidates on the basis of their being "generally advocated and nationally recognized." Some States have qualified for Federal campaign funds if a candidate has national support.* * *

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fewer than 10 States still will be ac-
corded all of their section 312(a) and 
318 rights in 1976. All rules are con-
sidered consistent with the 1972 
agreement to PBE. It would have permitted between 8 and 14 per-
sons to achieve nationwide candidate 
status in the 1976 Democratic nomi-
nation campaign. According to NBC, 
10 candidates were on the ballot in 
10 or more States in the 1976 gener-
al election and 3 more who were 
on the ballot in from 6 to 9 States 
might also have qualified under the 
"substantial showing" requirement.

19. It should be noted that the 
ruling in Paulsen that he should 
be considered a legally qualified can-
didate for Presidential nomination in 
all States because he had qualified as 
such in New Hampshire was only one 
part of a rule previously enacted 
concerned with the definition of a 
"use" by a candidate, and that neither 
the petition for Commission review of 
the staff ruling nor the appeal to the 
courts was part of the decision we are 
overruling here. Thus, neither the Commission nor any Fed-
eral appellate court has ruled specifi-
cally on the point at issue in subpara-
graph (4). The requirement that a 
candidate gain ballot status or make a 
substantial showing in 10 States in 
order to gain candidate status in all 
States does not mean that a candidate 
failing to reach the 10-State minimum 
is automatically denied broadcast time 
in States where he has not qualified. 
Broadcasters in these States may give 
or sell time to such a candidate if they 
do desire. Our new requirement does 
mean that stations are not required to 
grant equal opportunities or reason-
able access to candidates outside the 
areas in which they have qualified 
unless they have met the 10-State test. 
In some cases, such as Paulsen, it may 
even be to the advantage of the "one-
State" Presidential candidate not to be 
considered a legally qualified candi-
date nationwide. Regardless of that 
consideration, we believe it unreason-
able and contrary to the intent of Con-
gress to hold, for example, that be-
cause a person has obtained a ballot 
position in one State merely filing an 
annunciation of candidacy or obtain-
ing 200 signatures on a petition, he is 
etitiled to all of the rights of a can-
didate for Presidential nomination in 
all other States.

OTHER RULE AMENDMENTS

20. In addition to the foregoing 
amendments, additional ones are nec-
essary to bring our political rules 
into conformity with amendments to the 
Communications Act adopted by 
Congress in recent years. Since the 
amendments are interpretative of stat-
ute or, in one other instance, merely 
supplementary to the requirements already 
herent in the rule, notice of pro-
posed rulemaking need not be pub-
lished nor comments solicited. 5 U.S.C. 
§ 553(b)(A) and (B).

21. In 1973 Congress adopted the 
Federal Election Campaign Act of 
1971 (FECA), amending section 315 of 
the Communications Act in order, 
among other things, to limit the 
charges made for use of broadcast sta-
tions and cable systems by political 
candidates during certain periods. The 
Federal Election Campaign Act was 
amended in 1974 and again in 1976 but 
the above provision relating to charges 
made to candidates was not affected.

22. The Commission issued a public 
otice on March 16, 1972, 37 FR 5796, 
34 FCC 2d 510, interpreting FECA as 
it amended the Communications Act 
and another public notice on June 10, 
1972, 37 FR 15704, interpreting FECA 
as it amended the Communications Act 
in order, among other things, to limit 
the charges made for use of broadcast sta-
tions and cable systems by political 
candidates during certain periods. The 
Federal Election Campaign Act was 
amended in 1974 and again in 1976 but 
the above provision relating to charges 
made to candidates was not affected.

23. For the reasons set forth above, 
we are amending our rules on political 
broadcasting as set forth in appendix 
A. In line with our present policy of 
consolidating the rules governing op-
eration of the different broadcast ser-
ices as they apply to the same sub-
ject, we are substituting for present 
sections 73.120, 73.290, 73.580, and 
73.657 a consolidated section to be 
designated section 73.1940.

24. The specific changes in the 
broadcast rules are as follows: Par. (a) 
"Definitions" is amended as explained 
above and set forth fully in appendix 
A. Par. (b) "General requirements" is 
deleted, since it merely paraphrases 
section 315(a) of the Act as read 
before the 1972 and 1974 amendments. 
Former par. (c)(1) "Rates and prac-
tices" becomes new par. (c) and the 
heading "Charges for use to stations." 
Par. (b) will consolidate references to 
short charges to candidates including 
the provisions of former par. (c)(1) 
and the "lowest unit charge" and 
"comparable charge" provisions of sec-
tion 315(b) of the act as amended. 
Par. (d) becomes new par. (e) and is 
titled "Discrimination between can-
didates." Par. (d) "Records, 
inspection" is being revised to clarify 
its meaning. The present language of 
the first sentence of the rule refers to 
"requests" for broadcast time made 
by or on behalf of candidates for public 
office. It also refers to "the charges 
made, if any, if the request is grant-
ed." [Emphasis added.] Thus, the 
sentence indicates that the rule refers to 
both paid and free time. We believe 
that additional language should be 
added to make clear the fact that gifts 
of political time, whether or not "re-
quested" by candidates, must be en-
tered in the political file and that all 
requests and time provided by the 
licensee without charge should be en-
tered as soon as possible during the 
entire campaign. We believe such 
clarification is consistent with the 
inherent requirements of the rule and 
the purposes for which it was adopted 
and later amended. This is particu-
larly evident in light of the relationship 
of this paragraph to par. (e) the "7-
day rule" since a candidate may be 
unable to make his request for equal 
opportunities within the specified 7-
day period unless he can file his 
request, or inspection of station political 
files what time has been either sold or 
provided free to opposing candidates, 
regardless of whether they make "requests" for 
it. It is equally evident that such gifts 
or sales of time are entered in 
the political file as soon as possible 
throughout the campaign, opposing 
candidates may not be able to file 
their requests for equal opportunity 
within the required period. Accord-
ingly, we are revising the language of par. 
(d) to clarify its requirements and re-
solve any uncertainties as to its mean-
ing that may have existed previously. 
Since the revisions are only of this 
nature, publication of a notice of pro-
posed rulemaking is unnecessary. See 
5 U.S.C. 553(b)(B). In order to elimi-
nate any uncertainty as to the possible 
scope of the rule we also should ex-
plain that it refers to time used by 
supporters of candidates, as well as 
that used by candidates themselves. 
Paras. (e) and (f) of the present rules 
remain unchanged.

ORIGINATION CABLECAST RULES

25. The National Cable Television 
Association's comments did not ad-
dress the specific rule changes pro-
posed in our notice, and we believe 
that this is not the appropriate pro-
cedure in which to rule on the ques-
tions raised therein regarding the 
Commission's authority to adopt rules 
relating to cablecasts by political can-
didates.
26. For the same reasons set forth above for amending our rules on broadcasts by candidates for public office, we are making similar amendments to our rules on origination cabinetcasts by candidates for public office, as set forth in appendix B hereto.

27. Authority for the adoption of the amendments herein is contained in section 4(i) of the Communications Act of 1934, as amended (47 U.S.C. 154(i)).

28. Accordingly, it is ordered, That, effective August 28, 1978, §§73.120, 73.390, 73.590, and 73.657 are amended as set forth below, and new §73.1940 as set forth below is adopted. Further, it is ordered, That, effective August 28, 1978, §§76.5(y) and 76.205 are amended as set forth below.

29. It is further ordered, That, this proceeding is terminated.

FEDERAL COMMUNICATIONS COMMISSION, WILLIAM J. TRICARICO, Secretary.

Part 73 of Chapter 1, Title 47, Code of Federal Regulations, is amended as follows:

1. Section 73.120 is amended to read as follows:

§73.120. Broadcasts by candidates for public office.

See §73.1940.

2. Section 73.290 is amended to read as follows:

§73.290. Broadcasts by candidates for public office.

See §73.1940.

3. Section 73.590 is amended to read as follows:

§73.590. Broadcasts by candidates for public office.

See §73.1940.

4. Section 73.657 is amended to read as follows:

§73.657. Broadcasts by candidates for public office.

See §73.1940.

5. New section 73.1940 is added as follows:

§73.1940. Broadcasts by candidates for public office.

(a) Definitions. (1) A legally qualified candidate for public office is any person who

(i) Has publicly announced his or her intention to run for nomination or office;

(ii) Is qualified under the applicable local, State or Federal law to hold the office for which he or she is a candidate; and

(iii) Has met the qualifications set forth in either subparagraphs (2), (3), or (4), below.

(2) A person seeking election to any public office including that of President or Vice President of the United States, or seeking nomination for any public office except that of President or Vice President, by means of a primary, general or special election, shall be considered a legally qualified candidate if, in addition to meeting the criteria set forth in subparagraph (1) above, that person:

(i) Has qualified for a place on the ballot, or

(ii) Has publicly committed himself or herself to seeking election by the write-in method and is eligible under applicable law to be voted for by sticker, by writing in his or her name on the ballot or by other method, and makes a substantial showing that he or she is a bona fide candidate for nomination or office.

Persons seeking election to the office of President or Vice President of the United States shall, for the purposes of the Communications Act and the rules thereunder, be considered legally qualified candidates only in the District of Columbia. Any person who has met the requirements set forth in paragraph (a) (1) (and 2) of this rule, though the headquarters in some instances might be the residence of the candidate or his campaign manager. Not all of the listed activities are necessarily required in each case to demonstrate a substantial showing, and there may be activities not listed herein which would contribute to such a showing.

(b) Charges for use of stations. The charges, if any, made for the use of any broadcasting station by any person who is a legally qualified candidate for any public office in connection with his campaign for nomination for election, or election, to such office shall not exceed:

(1) During the 45 days preceding the date of a primary or primary runoff election and during the 60 days preceding the date of a general or special election in which such person is a candidate, the lowest unit charge of the station for the same class and amount of time for the same period, and

(2) At any other time the charges made for comparable use of such station by other users thereof. The rates charged to all such candidates for the same office shall be uniform and shall not be rebated by any means directly or indirectly. A candidate shall be charged no more than the rate the station would charge if the candidate were a commercial advertiser whose advertising was directed to promoting its business within the same area as that encompassed by the particular office for which such person is a candidate. All discount privileges otherwise offered by a station to commercial advertisers shall be available upon equal terms to all candidates for public office.

(3) This paragraph shall not apply to any station which is not licensed for commercial operation.

FEDERAL REGISTER, VOL. 43, NO. 146—FRIDAY, JULY 28, 1978
(c) Discrimination between candidates. In making time available to candidates for public office, no licensee shall make any discrimination between candidates in practices, regulations, facilities, or services for or in connection with the service rendered pursuant to this part, or make or give any preference to any candidate for public office or subject any such candidate to any prejudice or disadvantage; nor shall any licensee make any contract or other agreement which shall have the effect of permitting any legally qualified candidate for any public office to broadcast to the exclusion of other legally qualified candidates for the same public office.

(d) Records, inspection. Every licensee shall keep and permit public inspection of a complete record (political file) of all requests for broadcast time made by or on behalf of candidates for public office, together with an appropriate notation showing the disposition made by the licensee of each such request, and the charges made, if any, if the request is granted. When free time is provided for use by or on behalf of such candidates, a record of the free time provided shall be placed in the political file. All records required by this paragraph shall be placed in the political file as soon as possible and shall be retained for a period of 2 years. See sections 1.526-27 of this chapter.

(e) Time of request. A request for equal opportunities must be submitted to the licensee within 1 week of the day on which the first prior use, giving rise to the right of equal opportunities, occurred:

Provided, however, That where the person was not a candidate at the time of such first prior use, he shall submit his request within 1 week of the first subsequent use after he has become a legally qualified candidate for the office in question.

(i) Burden of proof. A candidate requesting equal opportunities of the licensee, or complaining of noncompliance of the Commission shall have the burden of proving that he and his opponent are legally qualified candidates for the same public office.

Part 76 of Chapter I, Title 47, Code of Federal Regulations, is amended as follows:

Section 76.5(y) is amended to read as follows:

§ 76.5 Definitions

• • • •

(y) Legally qualified candidate. (1) Any person who:

(I) Has publicly announced his or her intention to run for nomination or office;

(II) Is qualified under the applicable local, State or Federal law to hold the office for which he or she is a candidate; and,

(III) Has met the qualifications set forth in either subparagraphs (2), (3), or (4), below.

(2) A person seeking election to any public office to fill an office having a candidate for nomination in the United States, or nomination for any public office except that of President or Vice President, by means of a primary, general or special election, shall be considered a legally qualified candidate if, in addition to meeting the criteria set forth in subparagraph (1) above, that person:

(I) Has qualified for a place on the ballot, or

(II) Has publicly committed himself or herself to seeking election by the write-in method and is eligible under applicable law to be voted for by sticker, by writing in his or her name on the ballot tournament, by name otherwise printed, and makes a substantial showing that he or she is a bona fide candidate for nomination or office.

Persons seeking election to the office of President or Vice President of the United States, or for the purposes of the Communications Act and the rules thereunder, be considered legally qualified candidates only in those States or territories (or the District of Columbia) in which they have met the requirements set forth in paragraphs (y)(1) and (2) of this rule; Except, That any such person who has met the requirements set forth in paragraph (y)(1) and (2) in at least 10 States (or nine and the District of Columbia) shall be considered a legally qualified candidate for election in all States, territories and the District of Columbia for purposes of this Act.

(3) A person seeking nomination to any public office to use the system's origination channel(s) and facilities therefor, the system operator shall afford equal opportunities to all other such candidates for that office: Provided, however, That such cable television system operator shall have no power of censorship over the material cablecast by any such candidate: And provided further, That an appearance by a legally qualified candidate on any:

(I) Bona fide news cast,

(II) Bona fide news interview,

(III) Bona fide news documentary (if the appearance of the candidate is incidental to the presentation of the subject or subjects covered by the news documentary), or

(IV) On-the-spot coverage of bona fide news events (including but not limited to political conventions and activities incidental thereto) shall be deemed to be use of the facilities of the system within the meaning of this paragraph.
(b) Charges for use of cable systems. The charges, if any, made for the use of any cable television system by any component are legally qualified candidates for public office, or on behalf of such candidates, a record of the free time provided shall be placed in the political file. All records required by this paragraph shall be placed in the political file as soon as possible and shall be retained for a period of 2 years.

(e) Time of request. A request for equal opportunities for use of the origination channel(s) must be submitted to the cable television system operator within one (1) week of the time on which the first prior use, giving rise to the right of equal opportunities occurred. Provided, however, That where a person was not a candidate at the time of such first prior use, he shall submit his request within one (1) week of the first subsequent use after he has become a legally qualified candidate for the office in question.

(f) Burden of proof. A candidate requesting such equal opportunities of the cable television system operator, or complaining of noncompliance to the Commission, shall have the burden of proving that he and his opponent are legally qualified candidates for the same public office.

[FED Doc. 78-20854 Filed 7-27-78; 8:45 am]

(6712-01)

[00Docket No. 21255; FCC 78-4831]

PART 83—STATIONS ON SHIPBOARD IN THE MARITIME SERVICES

Permitting Aircraft To Use Maritime Mobile VHF Frequencies Under Certain Conditions

AGENCY: Federal Communications Commission.

ACTION: Report and order amending the rules.

SUMMARY: The Commission's rules are being amended to permit aircraft stations to use certain VHF maritime mobile frequencies. These changes are a result of changes made in the International radio regulations at the 1974 World Maritime Administrative Radio
Conference. This action will make the Commission's rules consistent with the international radio regulations.


FOR FURTHER INFORMATION CONTACT:
Kemp J. Beaty, Safety and Special Radio Services Bureau, 202-632-7197.

SUPPLEMENTARY INFORMATION:
In the matter of amendment of the rules to permit aircraft to use maritime mobile VHF frequencies under certain conditions, docket No. 21255, FCC 78-488; report and order (proceeding terminated) (42 FR 28164).

Adopted: July 12, 1978.

Released: July 26, 1978.

By the Commission.

1. A notice of proposed rulemaking in the above-captioned matter was released May 27, 1977, and published in the Federal Register on June 2, 1977 at 42 FR. 28164. The specified time for filing comments and reply comments has passed.

2. The proposed rule amendment was designed to incorporate into the Commission's rules certain changes to the international radio regulations which were adopted at the 1974 Maritime World Administrative Radio Conference (WARC). Those changes would permit aircraft stations to use maritime frequencies in the VHF band 156-158 MHz under certain limited circumstances.

3. Comments were filed by the Lorain Electronics Corp. (Lorain), the Helicopter Association of America (HAA), the U.S. Coast Guard (USCG), the North Pacific Marine Radio Council (NPMRC), the Pacific Towboat & Salvage Co. (PT&S), Northwest Instrument (Northwest), the Lake Carriers Association (LCA), the County of Los Angeles Department of Communications (Los Angeles), the Central Committee on Telecommunications of the American Petroleum Institute (API), the American Institute of Merchant Shipping (AIMS), the St. Philip Towing & Transportation Co. (St. Philip), the Southern California Marine Radio Council itself and its San Diego and Point Conception Divisions separately (SCMRC). There were no reply comments, HAA, Northwest, Los Angeles and St. Philip generally favored the proposal. Lorain, USCG, NPMRC, PT&S, LCA, API, AIMS, and SCMRC were opposed to certain of the changes proposed.

4. Lorain and LCA were concerned about interference to marine VHF public correspondence channels if aircraft were permitted access to these frequencies, especially in an automated system as exists on the Great Lakes. Possible interference to United States Coast Guard VTS communications on channels 11, 12 and 14 were cited by the USCG and API. USCG suggested a further condition of prohibiting use by aircraft within 60 miles of a VTS area. API felt that aircraft should not be authorized the use of VTS frequencies. NPMRC, Northwest, API and AIMS all commented about the difficulty of enforcing the 1,000-foot altitude limitation. NPMRC, PT&S and API also pointed out that an aircraft at 1,000 feet with a 5-watt transmitter would have a substantially greater coverage area than a vessel with a 25-watt transmitter. SCMRC and PT&S felt aircraft should be prohibited from using the "already overcrowded" port operations frequencies. Both commentors point out that a "loss of communications when moving and docking a supertanker in a crowded port area could result in serious collision causing severe damage to property and the environment along with the attendant possible loss of life. NPMRC, Northwest, API and SCMRC all said if aircraft were permitted the use of marine VHF frequencies they should be limited to a few specific intership frequencies. NPMRC and SCMRC were of the opinion that aircraft should not be licensed "automatically" on these frequencies but should have to submit a detailed "showing of need". In addition SCMRC felt aircraft should be required to monitor channel 16 just as a vessel is required to do so.

5. St. Philip in their comments supporting the proposal requests that the altitude restriction be raised to 2,500 feet and transmitter power increased to 25 watts. Los Angeles favors the proposal because of their large area of coastline but they also request that aircraft be permitted the use of the U.S. Coast Guard liaison frequency 157.1 MHz to allow communications between private aircraft and the U.S.
Coast Guard for search and rescue purposes. Northwest supports the proposal but, as indicated in paragraph 4, feels that a few specific frequencies should be assigned for this use. HAA submitted their comments indicating that the Commission's proposal is too broad. The concerns of many of the commentors regarding the interference potential of aircraft operating on these frequencies are valid. However, only a small number of aircraft will be authorized the use of these frequencies and particular types of aircraft, mainly seaplanes, have a legitimate need for communications on marine VHF frequencies. Furthermore, aircraft communications are restricted to those in support of maritime activities in which maritime stations are primarily involved.

1. St. Philip's request that the altitude restrictions be raised and the maximum power be increased cannot be accommodated. To do so would intolerably increase interference to maritime communications as well as violate the international radio regulations which limits aircraft use to 5 watts power and 1,000 feet of altitude. Los Angeles provides no information to support their request to include 157.1 MHz as one of the frequencies aircraft may use. Further, this is a U.S. Coast Guard frequency and its use by non-Government entities, other than vessels, has been authorized only after careful examination and coordination with the Coast Guard. Since the Coast Guard has made no request to have this frequency included for use by non-Government aircraft we do not feel it is appropriate to permit this usage. SCMRC's suggestion that aircraft be required to monitor 156.8 MHz (channel 16) does not contain any information that such a requirement would contribute to the safety system's operation. Accordingly, we are not adopting any of the requested changes discussed in this paragraph.

2. Our original proposal, if adopted, would permit aircraft to use all maritime mobile VHF frequencies except for four specific frequencies. For the reasons raised in the comments and discussed herein, we are modifying our proposal as follows:
   a. The use of channel 6 (156.3 MHz), the internship safety frequency, will be limited to use by aircraft for safety communications only.

   b. Aircraft will not be authorized the use of VHF public correspondence or port operations frequencies as these frequencies are less tolerable to interference, already overcrowded with maritime usage, and public correspondence frequencies normally would not be frequencies used in direct support of maritime activities. In addition, interference by an aircraft using a port operations frequency could disrupt communications at a critical time during the movement or docking of a vessel. This could create a situation which could lead to widespread damage, pollution and the possible loss of life.

c. Aircraft will be permitted the use of channel 87 (156.375 MHz), 8 (156.4 MHz), 68 (156.425 MHz), 9 (156.45 MHz), 70 (156.525 MHz), 72 (156.625 MHz), and 18 (156.9 MHz) as working frequencies.

Under this modification it is anticipated that aircraft and vessels will be equipped and operational procedures established so that most contacts will be on the appropriate working frequencies. In those cases where an aircraft cannot raise the vessel on the working frequency; channel 16 (156.8 MHz) which will be monitored by the vessel may be used to establish initial contact and a selection of a working frequency.

3. Accordingly, it is ordered, That, pursuant to the authority contained in sections 4(1) and 303 (c), (h) and (r) of the Communications Act of 1934, as amended, the Commission's rules are amended, as set forth below, effective August 28, 1978.

4. It is further ordered, That this proceeding is terminated.

Federal Communications Commission,
William J. Tricario, Secretary.

Part 83 of chapter I of title 47 of the Code of Federal Regulations is amended as follows:

Part 83—Stations on Shipboard in the Maritime Services

1. In section 83.351, paragraph (a) is amended by adding numeral "76" to the table, and paragraph (b) is amended by adding a new footnote, numbered 76, to read as follows:

§ 83.351 Frequencies available.

(a) * * *
CHAPTER I—U.S. FISH AND WILDLIFE SERVICE, DEPARTMENT OF THE INTERIOR

CHAPTER II—NATIONAL MARINE FISHERIES SERVICE, NATIONAL OCEANIC AND ATMOSPHERIC ADMINISTRATION, DEPARTMENT OF COMMERCE

Listing and Protecting Loggerhead Sea Turtles as "Threatened Species" and Populations of Green and Olive Ridley Sea Turtles as Threatened Species or "Endangered Species"


ACTION: Final rule.

SUMMARY: The National Marine Fisheries Service (NMFS) and the U.S. Fish and Wildlife Service (FWS), Department of the Interior, determine the loggerhead sea turtle (Caretta caretta) to be a threatened species under the Endangered Species Act of 1973 (the Act). In addition, the green sea turtle (Chelonia mydas, which includes the subspecies C. mydas agassizi, and C. mydas caretta) and the olive (Pacific) ridley sea turtle (Lepidochelys olivacea) (hereinafter referred to as the Pacific ridley) are determined to be threatened species under the Act except that the Florida and Mexican Pacific coast breeding populations of green sea turtles and the Mexican Pacific coast breeding population of Pacific ridley sea turtles are determined to be endangered species. This rulemaking also contains protective regulations for threatened species of sea turtles. The primary differences as a result of listing these populations as endangered instead of threatened are that incidental catch by commercial fishermen is prohibited and there are no exceptions for zoological exhibition or educational purposes, taking of injured, dead, or stranded specimens, taking of species under State-Federal Cooperative Agreements for research or conservation, or subsistence taking of green turtles in the water by residents of certain U.S. territories in the Pacific.

DATES: This rule becomes effective 30 days after publication in the Federal Register by Environmental Protection Agency of availability of the final Environmental Impact Statement.

Federal Register, Vol. 43, No. 145—Friday, July 23, 1978

[4310-55]

Title 50—Wildlife and Fisheries

CHAPTER I—U.S. FISH AND WILDLIFE SERVICE, DEPARTMENT OF THE INTERIOR

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

Listing and Protecting Loggerhead Sea Turtles as "Threatened Species" and Populations of Green and Olive Ridley Sea Turtles as Threatened Species or "Endangered Species"

Cross Reference: For a regulation on the above entitled matter, issued jointly by the Department of Commerce/National Oceanic and Atmospheric Administration/National Marine Fisheries Service and the Department of the Interior/Fish and Wildlife Service, see FR Doc. 78-21047 in the rules and regulations section of this issue of the Federal Register.

[4310-22]
status review of these three species, published in the Federal Register on August 28, 1973, NMFS and FWS sent a telegram to all diplomatic and consular posts soliciting comments on the proposed action and information on sea turtles found in their jurisdiction. On May 20, 1974, Robert Nordstrom, Director of the Fisheries Divisions, National Marine Fisheries Service, requested that NMFS hold a public hearing on the proposed regulations regarding sea turtles. On August 20, 1975, notice was published in the Federal Register of the NMFS decision to prepare an environmental impact statement (43 FR 36401). On November 14, 1975, notice was published in the Federal Register postponing the NMFS public hearing from December 3, 1975, to February 25, 1976 (40 FR 53051). The National Marine Fisheries Service submitted its DEIS on January 30, 1976, to the Council on Environmental Quality (CEQ). On February 6, 1976, CEQ announced in the Federal Register the availability of the DEIS and opening of the 45 day comment period on the DEIS (41 FR 5429). Also on February 6, 1976, notice by NMFS was published in the Federal Register extending the comment period on the proposed regulations treating these three species as threatened, but recommended limited harvesting of green sea turtles be allowed. Governor Grasso and Tripp supported listing the loggerhead and Pacific ridley as threatened. Governors Mandel and Wallace supported listing the green sea turtle as an endangered species under the Endangered Species Act of 1973 (16 U.S.C. 1531 et seq.) was enacted into law and superseded the Endangered Species Conservation Act of 1969. The 1973 act provides legal authority for this action. On April 23, 1974, F. Wayne King, Director of Conservation and Environmental Education for the New York Zoological Society, submitted a formal petition under the new law to list the green sea turtle as an endangered species and the loggerhead and Pacific ridley sea turtles as threatened species. Following a NMFS preliminary status review of these three species, NMFS and FWS sent letters on August 8, 1974, to the Governors of the States, Territories, Possessions, and the Commonwealth of Puerto Rico, where green, loggerhead, and Pacific ridley sea turtles are resident, announcing a NMFS/FWS status review of these species and requesting views and data relevant to the status of these species. On August 9, 1974, Wayne King met with the Secretary of Interior to have the green sea turtle listed under the "similarity of appearance" provision of the act. Mariculture, Ltd. (now known as Cayman Turtle Farm, Ltd. and hereinafter referred to as Cayman Farm), Grand Cayman Island, British West Indies, a business involved in the raising and marketing of captive green sea turtles, submitted a formal petition on August 15, 1974, to list the green sea turtle as a threatened species, but to exempt turtles bred or raised in captivity from this classification. A formal review by NMFS/FWS of the status of green, loggerhead, and Pacific ridley sea turtles was announced on August 18, 1974, in the Federal Register (39 FR 25605; 39 FR 25607). On May 20, 1975, the NMFS/FWS determination to propose listing green, loggerhead, and Pacific ridley sea turtles as threatened species was published in the Federal Register (40 FR 21982, 40 FR 21974). That proposal summarized the factors thought to be contributing to the threatened state of these sea turtles could become endangered within the foreseeable future, specified the regulations which would be applicable to conserve these species if such a determination were made, and solicited comments, suggestions, objections, and factual information from any interested person. In July 1975, NMFS and FWS sent a telegram to all diplomatic and consular posts soliciting comments on the proposed regulations treating these three species of sea turtles as threatened under the "similarity of appearance" provisions. On October 15, 1976, denial of the hearing requested by Cayman Farm was published by the Department of the Interior in the Federal Register (41 FR 45573). On July 15, 1977, a Memorandum of Understanding (MOU) concerning the jurisdiction of sea turtles between NMFS and FWS was signed. This MOU established sole agency jurisdiction with NMFS while the turtles are in the water and with FWS while they are on land. The Environmental Defense Fund submitted a request on February 28, 1978, to reopen the public comment period in light of the long time that had elapsed since publication of proposed regulations and to hold a public hearing on the proposal to list green, loggerhead, and Pacific ridley sea turtles as threatened species, and the draft environmental impact statement (DEIS) (40 FR 36401). On November 14, 1975, notice was published in the Federal Register extending the comment period on the proposed regulations and to submit newly acquired evidence and related data. On March 27, 1978, NMFS and FWS announced in the Federal Register that the public comment period was reopened until April 17, 1978 (45 FR 15300). On October 5, 1978, CEQ announced in the Federal Register the availability of the DEIS and opening of the 45 day comment period on the DEIS (41 FR 5429). Also on February 6, 1976, notice by NMFS was published in the Federal Register extending the comment period on the proposed listing of the DEIS and public hearing from March 8, 1976 to March 22, 1976 (41 FR 5413). On February 25-26, 1976, an informal, fact-finding public hearing was held in Washington, D.C. on the proposed listing of the three species of sea turtles and the DEIS. Scientists, conservationists, businessmen, shrimpers, and representatives from State and foreign governments participated in this hearing. On March 19, 1976, CEQ published notice in the Federal Register extending the public comment period on the DEIS until April 5, 1976 (42 FR 11602). On June 16, 1976, NMFS/FWS proposed regulations listing the loggerhead, and Pacific ridley sea turtles as threatened species under the "similarity of appearance" provisions were published in the Federal Register (41 FR 27944). The informal final listing regulations (on the proposal of May 29, 1975) are effective, the proposed "similarity of appearance" regulations will be withdrawn as indicated in the June 16, 1976 proposal. Cayman Farm requested on July 22, 1976, that a public hearing be held on the proposed regulations treating these three species of sea turtles as threatened under the "similarity of appearance" provisions. On October 15, 1976, denial of the hearing requested by Cayman Farm was published by the Department of the Interior in the Federal Register (41 FR 45573).
RULES AND REGULATIONS

Summary of Comments and Recommendations

Section 4(b)(1)(C) of the act requires that a summary of comments and recommendations relating to a proposed listing be published in the Federal Register prior to adding the species to the endangered or threatened list. A press release on the proposal was issued by the Department of Commerce on May 30, 1975. Public comment periods were open from May 20, 1975 to July 18, 1975; from February 6, 1976 to April 5, 1976; and from March 27, 1976 to April 17, 1978. Due to the great number of comments received during these periods, only those offering substantive comments have been summarized and enumerated here. However, all public comments were considered in the preparation of final regulations.

All comments are available for review between 9 a.m. and 5 p.m. at the Marine Mammal and Endangered Species Division, National Marine Fisheries Service, 3500 Whitehaven Street NW., Washington, D.C.

The majority of comments concerned the following issues, and are summarized below by category: (1) whether or not to list these three species of sea turtles or populations thereof, as threatened or endangered; (2) whether or not to allow an exception for the incidental catch of sea turtles by commercial fishermen; and (3) whether or not to allow the subsistence taking of threatened sea turtles.

(1) The majority of comments received concerned the appropriate listing category for these species. All three species were proposed to be listed as threatened. Hundreds of cards and letters were received supporting the listing of the sea turtles, most of which favored an endangered classification. However, many supported a threatened listing and many others favored listing, but made no recommendations as to the appropriate category. As indicated above, those comments which offered no rationale or other information have not been enumerated. Substantive comments were received from 73 parties: 24 supported a threatened listing for all three species; 12 favored an endangered listing for all species; 17 supported a population approach to the listing; and various comments were received from 20 others (4 to list the green as endangered and the loggerhead and Pacific ridley as threatened; 4 to list the green and loggerhead as threatened; 1 to list the green and loggerhead as endangered; 1 to list the loggerhead as threatened; 2 to list the green as endangered; 4 to list the green as threatened; 2 not to list the green; and 2 not to list the loggerhead).

Of those 24 comments supporting a threatened classification for the 3 sea turtles under consideration, 10 were received from the States and Territories (New Jersey, California, Texas, Connecticut, South- Carolina, New York, Delaware, Guam, and Puerto Rico), 5 from researchers/biologists, 2 from the environmental community, 2 from industry, 2 from the Federal Government (regional offices of the Army Corps of Engineers), and 3 from other interested parties. These parties expressed a belief there was a serious decline in sea turtle stocks, but the stocks were not in present danger of extinction. Commentors felt that protective regulations would be adequate for the conservation of these species. Some believed an endangered classification would be unduly restrictive. One biologist believed the existing data to be too fragmentary to warrant an endangered listing. State commentors expressed views that the proposed regulations would strengthen existing State regulations protecting sea turtles.

Those 12 who supported an endangered classification for these species included 8 from the environmental community, 1 researcher/biologist, and 3 other interested parties. They expressed the belief that current data indicated that all three species of sea turtles are in danger of extinction throughout all or a significant portion of their ranges, and further that they are extinct in parts of their former ranges. Commentors provided additional data to support this viewpoint. In addition, an environmental group argued that political and geographic populations are endangered and since they are indistinguishable from other populations, the species as a whole must be listed as endangered to insure adequate protection.

Those 17 favoring a population approach to listing (i.e., evaluating each population and, based on the best available information, determining whether they are endangered or threatened or neither) included 7 from the environmental community, 3 from researchers/biologists, 3 from industries, 1 from the Federal Government (CEQ), 1 from Nicaragua, 1 from the Trust Territory of the Pacific, and 1 other interested individual. The act defines "species" to include "any subspecies of fish or wildlife or plants and any other group of fish or wildlife of the same species or smaller taxa (in combination) that interbreed when mature." Some commentors pointed out that sea turtles aggregate into intraspecific populations which are spatially and functionally independent of other populations within the same species. Therefore, they argued that based on existing evidence, certain populations are endangered and should be so listed. These commentors also indicated that data for the remaining populations are insufficient to support an endangered listing and therefore these populations should be listed as threatened.

Recommendations for listing populations of green sea turtles as endangered were received in four states: Thailand, Sri Lanka, Indonesia, Philippines, certain of the Western Indian Ocean, Sarawak, Caroline Islands, Hawaii, Costa Rica, Mexico, Bermuda, Florida, and Caribbean populations. The following populations of Pacific ridleys were recommended as endangered: The Gulf of Thailand, Sri Lanka, Mexico, certain of the Western Indian Ocean, and Surinam populations. The Mexican population of loggerhead turtles was also recommended for endangered listing.

Response

In determining how to list these sea turtles, NMFS and FWS scientists analyzed the status of individual populations. This task was complicated by two factors. First: Although our listing was based on the best available scientific and commercial data and there are overall declines in many significant declines in the population of these species, the data base for many populations is poor. Statistically valid data are available only for a few populations and much of the available information for all three species is qualitative rather than quantitative.

The status of sea turtle populations is poorly known though generally thought to be declining worldwide with some local populations of sea turtles spend only a small fraction of their life on the land, little information has been obtained on their populations. Most population estimates are based on beach counts of nesting females (the males do not generally return to land after entering the sea as hatchlings) from which extrapolations are made of total population size based on sex ratios of 1:1. Population declines are suggested by repetitive, decreasing counts of nesting females on known accessible beaches.

Sea turtles inhabit much of the tropical and subtropical seas of the world. The species addressed in this rulemaking have circumglobal distributions. Nesting sites for each of these species are numerous, scattered, and have not been counted accurately. Generally, wherever suitable nesting beaches occur there has been evidence of sea turtle utilization. Although studies have been made on some geo-
and site fixation of the Caribbean green turtles is identified by scientists for nests during a nesting season. Further, loggerhead sea turtles seem to have a less developed sense of nest site fixation.

Green turtles are herbivorous, gregarious, herding animals which are highly migratory and susceptible to overexploitation. Consequently, the number of turtles within a population is of greater significance in evaluating the status of green turtles than in other species. For example, the loggerhead is a solitary, carnivorous species with localized distribution. The species tends to live in proximity to the nesting grounds.

Whether a species over its entire range or individual populations should be listed as endangered or threatened under the terms of the act was difficult to determine. The point at which any species becomes in danger of extinction is not clear from the act. Since the designation of "threatened" refers to the foreseeable future and of "endangered" refers to the present, it is apparent that an endangered species is one that is in more immediate danger of extinction than a threatened species. The National Marine Fisheries Service and U.S. Fish and Wildlife Service determined that the data base for any of the three species or individual populations was not sufficient to determine any identifiable populations are in imminent danger of extinction with the exception of the Florida and Pacific Mexican breeding populations of green turtles and the Pacific Mexican breeding population of Pacific ridleys.

Although evidence on individual populations is fragmentary, we know that these three species of sea turtles have suffered drastic reductions in abundance from historical levels throughout most of their ranges. The major reasons for these declines are overexploitation, loss of habitat, and predation. In certain areas population decreases are not due to the loss of turtles but to overexploitation in commercial fishing operations. It is highly probable that, if the factors causing declines in some species of sea turtles remain unchanged, these sea turtles will be facing extinction throughout significant portions of their ranges in the foreseeable future.

After a thorough review and consideration of all the scientific and commercial data available, NMFS and FWS have determined that the green, loggerhead, and Pacific ridley sea turtles are at least threatened throughout all or a significant portion of their ranges, as herein specified, due to one or more of the five factors described in detail: overexploitation; pollution; habitat degradation; introduction of exotic species; and overexploitation in commercial fishing operations.

(a) Factor: The present or threatened destruction, modification, or curtailment of habitat or range of the species. Human population expansion has been instrumental in reducing available nesting habitat. The loss of suitable nesting habitat is caused by human activities such as land and loggerhead sea turtles, land reclamation, road and seawall construction, beach development, and recreational utilization, have seriously affected sea turtle habitat. In many areas, the encroachment has been from both sides of the turtle's normal habitat. That in turn has caused the turtle to move to areas such as ornamental gardens or more remote locations.

(b) Factor: Overexploitation for commercial, sporting, scientific, or educational purposes. Sea turtles (eggs and adults) are utilized worldwide as a food item and are particularly desired in some nations as a source of protein. Harvesting for subsistence and commercial seafood trade is widespread because of the desirability and high value of sea turtles and their products. The green turtle is prized as a food item (stew, soups, snacks, and other meals in several products), and commercial fisheries harvesting for sea turtles occur in Costa Rica, Mexico, Nicaragua, and other Central American countries. The Pacific ridley is utilized primarily for shell and to a lesser extent for food. The loggerhead is used for food in some areas such as the Indian Ocean. These turtles are also taken for shell products and curios.

Little sport fishing seems to occur for sea turtles though there is evidence some turtles have been taken or harassed by fishermen in Florida waters and elsewhere. However, the use of turtle nets by sport fishermen has also been reported.

(c) Factor: Disease or predation. The incidence of parasites and disease in wild sea turtles is unknown. No data are available to support such agents as being a major contributing factor to the decline in sea turtle abundance.

Predation is a major cause of mortality at all stages in the life cycle of sea turtles. Both human and wild carnivores (carnivore, coyotes, weasels, etc.) prey heavily on turtle nests. Hatchlings are consumed on the beach by birds and in the water by fish. Subadults and adults are taken by man and marine mammals. In the United States and other countries, the available habitat for many turtle predators has become constrained due to human habitation. Because many turtle nesting beaches lie inside these constraints, the incidence of animal predation has increased.

(d) Factor: The inadequacy of existing regulatory mechanisms. Most mainland coastal States within the United States where sea turtles occur have legislation protecting sea turtles from commercial exploitation. While nesting females, eggs, and young are often protected, there is a lack of uniformity in State and local controls.

Hawaii allows the capture of green sea turtles for home consumption if the carapace length equals or exceeds 36 inches. The U.S. Pacific Trust Territory controls the take of sea turtles as does American Samoa. In the United States and other countries, the available habitat for many turtle predators has become constrained due to human habitation. Because many turtle nesting beaches lie inside these constraints, the incidence of animal predation has increased.

(e) Factor: Other natural or manmade factors affecting the continued existence of the species. Sea turtles are taken incidentally in many commercial fisheries such as the shrimp and industrial fish trawl, purse seine, and gill net fisheries in various parts of the
world. In the United States, this problem is most serious in the trawl fisheries of the South Atlantic and Gulf of Mexico regions. Incidental capture occurs in shrimp trawl fisheries off Mexico, Central America, and the northeastern coast of South America, but this is undocumented. In some areas and at certain times of the year the incidental take may be a significant contribution to subadult and adult sea turtle mortality. There is evidence that sea turtles are taken occasionally in the Pacific tuna purse seine fishery.

The Florida breeding population of green sea turtles is recognized as a discrete breeding group. In the 19th century, this population was abundant and reportedly nested in large numbers on Florida beaches. Due to commercial exploitation and loss of habitat, the population was decimated. No nests were known in the twentieth century until recently when a small amount of nesting activity was discovered along the southeast coast of Florida.

Scientists believe that this population currently contains less than 100 mature adults. Because of the size of this stock, the status of the population is fragile and any adverse activity such as commercial or uncontrolled scientific exploitation, incidental take or loss of habitat could result in the immediate extinction of this stock. Therefore, the Florida green turtle population is listed as endangered.

Evidence submitted during the last comment period documents the loss of green sea turtle nesting populations along the Pacific coast of Mexico and the overharvest of green sea turtles in the Baja California area which led to the conclusion that this population would be in danger of extinction within 3 years. For these reasons, NMFS and FWS determined that population should be presently listed as endangered.

Evidence was also supplied on the Pacific ridley on the Pacific coast of Mexico indicating that the annual take of this species since the early 1950's to the present is estimated to be 500,000 to 1,000,000 turtles. Specifically, in Oaxaca State in 1977, 70,000 female Pacific ridleys were reportedly taken from a nesting population estimated to number 150,000. This Pacific ridley stock is beginning to show the same signs of stress that existed with the Atlantic ridley, an endangered species, in the 1950's. Scientists have estimated that this stock may be beyond recovery in 3 years.

While the available data clearly indicated drastic reductions in certain populations of green, loggerhead, and Pacific ridley sea turtles, there were no data available to show that these species are "bred in captivity" or endangered throughout a significant portion of their ranges. Estimates of populations indicate that statutes of the species as a whole are not so fragile in contrast to the Florida green sea turtle that a reasonable expectation of the loss of habitat, and/or commercial exploitation or incidental take will result in extinction of the species throughout a significant portion of their ranges. Moreover, the species as a whole are not believed to be subject to the type of pressure being exerted on the Mexican breeding populations of green and Pacific ridley sea turtles. Thus, the evidence does not indicate that these species as a whole should be listed as endangered nor that additional populations should be presently listed as endangered.

(2) Another issue for which considerable comments were received was the proposed exception for commercial mariculture operations. The proposed regulations provided an exception for importation, exportation, taking, and transporting of sea turtles (and their parts and products) derived from mariculture. The provision stated that after 2 years the exception would apply only to turtles derived from captive-bred parents. Comments were received from 44 parties concerning this issue.

Approximately 24 of these were opposed to this exception. These included 12 from the environmental community, 6 from researchers/biologists, 2 from State agencies of New York, 3 from industries, and 1 from another interested party. Opponents argued that little progress has been made in achieving "self-sufficiency," and questioned the possibility of ever achieving a completely closed-cycle operation. It was argued that mariculture is accompanied by ecological and pathological problems due to holding turtles in tanks on land. Also argued was that mariculture is heavily dependent on wild stocks. A mariculture operation anticipates a final release to the wild to avoid the vulnerable period of hatching mortality. In addition, they argued that mariculture can help to conserve wild stocks by providing superior but cheaper turtle products from captive animals and thus reduce pressure on wild populations. Further, they asserted that mariculture can provide a dependable source of protein for human consumption. They claimed that cultured turtles could be used to restore depleted wild stocks. A mariculture operation purports to buy green turtle eggs from Surinam, which are considered "doomed" because the eggs are taken from eroding beaches and, if left in the nest, would be destroyed. In addition, this operation anticipates a final taking of eggs in 1979, and indicated it would be a "doomed" stock by 1980. It also provided evidence of increasing success of eggs being laid by turtles which mated in captivity.

RESPONSE

After much consideration, NMFS and FWS decided not to provide an exception for mariculture. The primary reasons for this decision were that little or no scientific benefit would be received, that the mariculture operations would not be monitored adequately, and that increased worldwide demand for sea turtles and sea turtle products would be encouraged. This condition could lead to increased take of wild sea turtles and possibly result in the stimulation of poaching, which would be inconsistent with our mandate under the Act to adopt regulatory measures to bring threatened species to the point where they no longer need to be listed under the Act.
No evidence has been received that Cayman Farm, or any other mariculture operation, has made significant research contributions in the 3 years since the proposed regulations were published (May 1975). Cayman Farm is the only known mariculture operation of significant size in the world. Evidence provided for the 1976 NMFS hearing by Cayman Farm, indicated three turtles which were born in captivity had successfully nested in captivity. No information has been received since the hearing that additional captive-bred nesting success has been achieved. Many scientists knowledgeable in sea turtles, take the view that this operation will not provide much useful information for conserving sea turtles.

Monitoring Cayman Farm would require observers to be stationed at the facility a regular basis. Our review of the proposed regulations contained an exception for non-trawl fisheries within State waters. The Assistant Administrator shall consult, as he deems proper, with affected fishing industries with respect to these designations. The Assistant Administrator shall consult, as he deems appropriate, with the Governor(s) and the Marine Conservation Department(s) of the affected State(s). The Assistant Administrator shall also consult with the appropriate Regional Fishery Management Councils and with affected fishing industries with regard to these designations. The National Marine Fisheries Service agreed with commentators who believed that “areas of substantial breeding or feeding” was too broad a phrase would put many shrimpers out of business. Hence, many comments were received objecting to the language “areas of substantial breeding or feeding” in the proposed regulations. Some felt the phrase was too general and could not be enforced. Others feared that a strict interpretation could put many shrimpers out of business. Many were opposed to the immediate return of captive-bred sea turtles to the water without attempting to revive them prior to release. Others, although not opposed to an exception, believed that incidental catch should be controlled and substantially reduced. Suggestions made included developing a net to exclude turtles, designating critical habitat, eliminating fishing in breeding areas, setting limits on incidental captures, and having a permit system for incidental catch.

RESPONSE

The act prohibits taking of any endangered species incidental to commercial fishing. Therefore, the incidental catch of the Florida and Mexican Pacific coast green sea turtle populations and the Mexican Pacific coast Pacific Ridley population will be prohibited because of this endangered status. Conservation measures for threatened species, however, may be promulgated which will allow an incidental catch. Most incidentally taken sea turtles are caught inadvertently by shrimp trawls. Presently, there is no way to avoid incidental capture of turtles in shrimp trawls, however, NMFS has been developing an “excluder panel” which is designed to exclude the mouth of standard shrimp trawls that would prevent, or substantially reduce, the incidental capture of sea turtles. Although preliminary designs have been tested, these need to be comparatively tested with conventional trawls under commercial shrinking conditions. The National Marine Fisheries Service has accelerated its 1978 gear program and is testing the excluder panels on shrimp grounds this year with the aid of the shrimp industry. The objective of this program is, in part, to obtain as much experimental gear, research, and habitat data as possible so that acceptable new design can be achieved by the end of the 1978 season. Our goal is to promulgate regulations requiring the use of the panel to prevent, or substantially reduce, incidental catch of sea turtles without significantly reducing shrimp production. Sea turtles are occasionally caught inadvertently in other fisheries (e.g., pet food fishery, menhaden fishery, tuna fishery). The incidental catch and mortality of sea turtles in these fisheries is not nearly as significant as the incidental capture in the shrimp fishery. The exclusion panel under development is not adaptable to non-trawl fisheries.

The National Marine Fisheries Service and the U.S. Fish and Wildlife Service are considering candidate areas where turtles are concentrated for designation as Restricted Fishing Areas and/or Critical Habitat. A Restricted Fishing Area is an area where the incidental catch is prohibited or otherwise controlled. Controls may include proper gear usage, fishing methods or procedures, or other regulatory controls to reduce or eliminate incidental catch of sea turtles. Prior to the designation, an area which is prohibited or otherwise controlled elsewhere will be proposed as a Restricted Fishing Area at a later date.

The proposed regulations would have prohibited incidental catch in areas of substantial breeding or feeding. The National Marine Fisheries Service agreed with commentators who believed that “areas of substantial breeding or feeding” was too vague, unenforceable, and under strict interpretation, could unnecessarily put shrimp out of business. Hence, those comments were deleted and a provision was added for designating Restricted Fishing Areas. Our accelerated gear program and anticipated designation of Restricted Fishing Areas will enable the NMFS to assess the incidental capture of sea turtles and, at the same time, not close fisheries. The recommendation...
for a prohibition of all incidental catch was rejected because the data to indicate shrimping was detrimental to sea turtles throughout the geographical range of the fishery were not available.

Setting limits on incidental captures and establishing a permit system for incidental catch were rejected as difficult to enforce and administer. Catch limits may be imposed in selected areas designated as Restricted Fishing Areas.

We agreed with commentators who were opposed to the immediate return of comatose turtles to the water. The regulations provide that resuscitation be attempted before a comatose turtle is returned to the water.

(4) A limited number of comments were received on whether or not to allow subsistence taking of threatened sea turtles. The proposed regulations did not provide an exception for subsistence. Comment from 10 parties were received addressing this issue.

Of these, nine were in support of allowing subsistence taking, the majority of these being from State and Territorial governors or State agencies where subsistence fishing occurs. These included Hawaii, Guam, American Samoa, and the Trust Territory of the Pacific. Their comments were mainly restricted to the green sea turtle and stressed the need to consider social and economic factors. They related the importance of the green sea turtle as a source of food for many of the island’s inhabitants. Evidence was provided indicating the importance of turtles in the cultural way of life in some areas. It was also argued that enforcement would be nearly impossible. Hawaii expressed the opinion that existing State regulations provided adequate protection and that Federal regulations should not be more restrictive. Comment was received in support of subsistence taking provided it is adequately researched and enforced, only allowed where stocks are plentiful, and not allowed on nesting beaches. Two individuals believed it should be allowed by natives in the Pacific Trust Territory for local consumption. One biologist supported subsistence fishing in the Trust Territory if it were carefully monitored, and in Hawaii only after comprehensive investigations indicate that subsistence taking would not be detrimental to that population.

One comment was received from the environmental community, and was endorsed by others, specifically addressing support of a prohibition on subsistence taking on the basis that alternative sources of food are available. It should also be noted that comments were received in general support of the proposed regulations which contained no exception for subsistence.

RESPONSE

Subsistence fisheries for sea turtles exist within U.S. territorial waters. Most are opportunistic in nature, though there are directed fisheries for eggs and adults in the Trust Territory. Some turtles, primarily green, are taken in Puerto Rican and U.S. Virgin Island waters by local fishermen. Hawaii permits the take of green turtles in excess of 36 inches for home use. A limited opportunistic take of turtles (probably green turtles) occurs near Guam. In the Trust Territory, turtle eggs and meat are a traditional food source.

Although the record provides no evidence of subsistence turtle fishing in the Caribbean, NMFS believes increased “subsistence” taking of green turtles has substantially contributed to the decline in Western Caribbean nesting groups. The absence of indigenous natives in Puerto Rico and the Virgin Islands precludes the establishment of a long “cultural” ties to the taking of sea turtles for subsistence purposes such as is found in the Pacific Islands. Localized “subsistence” fishing for sea turtles does occur but the motivating factor is esthetic rather than nutritional. The green turtle does not contribute significantly to the food needs of Puerto Rican or Virgin Islands residents and prohibiting taking would not have a major nutritional impact. Lastly, because of the close proximity of other breeding groups and the high volume of Caribbean inter-island commerce, it would be impossible to control the flow of turtle products through the Puerto Rican and Virgin Islands nesting area. It would be difficult to effectively stop the illegal trade of sea turtles consumed in Puerto Rico or the Virgin Islands as “subsistence taken.” Because of the increase in human impact on Caribbean sea turtles and the absence of a documented subsistence food need for turtle meat, it is necessary. FWS decided that no subsistence taking for green turtles or other species of sea turtles should be allowed in Puerto Rico or the Virgin Islands.

Hawaii referenced State regulations that permit the taking of green turtles only in excess of 36-inch carapace length for home consumption. In the State’s opinion, such protection was adequately protecting the population. However, NMFS and FWS have concerns over increased takings and sale of turtle shell and other products to tourists in Hawaii. For these reasons and because there are alternative food sources available in Hawaii, no exception is provided for taking green sea turtles in that area.

Sea turtles reportedly provide a major food source for many Pacific Island inhabitants, and in areas such as the Yap Islands, play a major role in traditional culture.

The available information on the Western Pacific green turtle population is, at best, incomplete. Reports indicate increased harvesting of eggs and adults has occurred in some areas due to improved native transportation to remote Islands. These activities may be instrumental in causing the population declines reported in some areas. However, information submitted showed certain nesting colonies were healthy. There was no strong evidence to support a seriously declining green turtle population which could not support historical harvest levels conducted in a traditional manner.

Because of the condition of the western Pacific population (other than Hawaii), allowing a subsistence take at historical levels is believed consistent with our obligation to conserve threatened species. Thereafter, NMFS and FWS decided to allow a traditional subsistence taking of green turtles by residents of the Trust Territory. No subsistence taking will be allowed in other areas. Turtles may be taken only in the water and must be returned to the sea. For the sustenance of the individual or immediate family of the individual taking the turtle.

The National Marine Fisheries Service and the U.S. Fish and Wildlife Service will work to obtain data on the extent of subsistence fishing and the status of the populations affected by that activity. Further decisions on regulating subsistence fishing will be based on those data.

SUMMARY OF FINAL REGULATIONS

Generally, the proposed regulations would have prohibited (with some exceptions) take, importation, exportation, and interstate and foreign commerce of green, loggerhead, and Pacific ridley turtles. These activities are essentially the same as prohibited activities for endangered species, except interstate commerce prohibition does not take effect for 1 year and the proposed regulations included more exceptions than allowed for endangered species. These final regulations contain the same prohibitions, as were in the proposed regulations. There are however, changes in the exceptions. Other than allowing more exceptions, these regulations governing threatened species are the same as those allowed for endangered species. An exception for scientific, propagation, or survival purposes was authorized under permit in the proposed regulations. The final regulations provide this exception but include a more detailed description of the procedures for the submission and approval of applications for permits. A transition period (in which to obtain permits) for
ongoing sea turtle activities falling in this category is also provided.

The proposed regulations did not except public display, zoological exhibition, or educational purposes from taking prohibitions. The final rulemaking authorizes exception under permit for certain federal and state agency employees. This exception is repeated in the final regulations. An exception for research or conservation program takings under Cooperative Agreement was contained in the proposed regulations. This exception is also repeated in the final regulations.

The proposed regulations contained an exception for incidental catch provided that: (a) The specimen was caught by fishing gear not directed toward these sea turtles; (b) the person responsible was not fishing in an area of substantial breeding or feeding of these sea turtles; and (c) any captured sea turtle is immediately returned to the water, whether dead or alive, and with due care to minimize injuries to live turtles. The final regulations provide an exception for incidental taking, subject to any future controls on gear and Restricted Fishing Areas, provided that: (a) The taking was by fishing gear during fishing or research activities conducted at sea and not directed toward sea turtles; (b) any sea turtle so taken must be handled with due care to prevent injury to live sea turtles and must be returned to the water immediately whether it is dead or alive; if it is alive and unconscious, before returning it to the water, that turtle shall be attempted to be revived by turning the turtle on its back and pumping its plastron by hand or foot; and (c) any sea turtle so taken must not be consumed, landed, offloaded, transshipped, or kept below deck.

The proposed regulations contained a 2-year exception for mariculture operations dependent on taking from the wild. Thereafter, the exception was limited to mariculture operations independent of taking from the wild. The exception was to be under permit conditioned on, among other things, a marking or other identification system for mariculture products, Government certification, by the mariculturist, that collection of wild eggs would not be detrimental to survival of the species in the wild, and during the first 2 years demonstrating progress toward becoming self-sufficient. No exception for any mariculture is provided by the final regulations.

The proposed regulations contained an exception (grandfather clause) for turtles held in captivity or in a controlled environment on the date of publication of final regulations and not held in the course of a commercial activity on such date. This exception has been deleted from the final regulations because the long period during which the proposal was pending should have been sufficient notice to the public that controls on sea turtles, and their parts and products were forthcoming. Also, the grandfather clause in the act is available to cover items such as jewelry or antiques which were held for non-commercial purposes on December 28, 1973 (the effective date of the act).

The proposed regulations did not contain an exception for subsistence taking. The final regulations provide an exception to take turtles in the water for home consumption only by residents of the Trust Territory of the Pacific Islands. Taking of nesting females and eggs is prohibited.

The proposed regulations contained a 1-year exemption to minimize undue economic hardship tied to a prior contract commitment. No exception for economic hardship is provided in the final regulations since more than 1 year has transpired since the turtles were formally proposed for listing.

Lastly, the final regulations provide procedures for processing permit applications based on the MOU between NMFS and FWS on sea turtle jurisdiction.

**EFFECT OF THE RULEMAKING**

Section 7 of the act provides:

The Secretary shall review other programs administered by him and utilize such programs in furtherance of the purposes of this act. All other Federal departments and agencies shall, in consultation with and with the assistance of the Secretary, utilize their authorities in furtherance of the purposes of this act by carrying out programs for the conservation of endangered species and threatened species listed pursuant to section 4 of this act and by taking such action necessary to insure that actions authorized, funded, or carried out by them do jeopardize the continued existence of such endangered species and threatened species or result in the destruction or modification of habitat of such species which is determined by the Secretary, after consultation as appropriate with the affected States, to be critical.

The National Marine Fisheries Service and the U.S. Fish and Wildlife Service prepared, in consultation with an ad hoc interagency committee, guidelines for Federal agencies for the application of section 7 of the act. These guidelines were superseded by final regulations governing Interagency Cooperation published by NMFS and FWS and January 4, 1978, in the Federal Register (43 FR 870) to assist Federal agencies in complying with section 7.

The National Marine Fisheries Service will propose, in August 1978, the Cape Canaveral ship channel as Critical Habitat for loggerhead and Atlantic ridley sea turtles. Other areas may be considered as a result of the gear research program currently in progress.

Sections 9 and 10 of the act and endangered species regulations already published in title 50 of the Code of Federal Regulations set forth a series of general prohibitions and exceptions which apply to all endangered species. The regulations which pertain to the threatened sea turtles are now contained in parts 220 and 227 of title 50 and are set forth below.

**INTERNATIONAL EFFECTS**

All three species of sea turtles are listed on Appendix I of the Convention with the exception of the Australian population of green sea turtles. The Convention prohibits international trade in Appendix I species (with limited exceptions) conducted primarily for commercial purposes. Appendix I species taken on the high seas cannot be landed commercially under the provisions of the Convention. However, the Convention does not apply to the taking of sea turtles within any nation’s jurisdiction. Many countries (e.g., Mexico, Japan, and a number of European countries where markets exist) have not ratified the Convention. Mexico has protective legislation of green turtles but adequate enforcement is questionable. Further, because Mexico has signed but not ratified the Convention it can engage in unregulated trade in sea turtles or sea turtle products with other countries not formally implementing the Convention (nonmember or nonratifying members). United States-Mexican trade primarily in these sea turtles for commercial purposes is prohibited.

The National Marine Fisheries Service and the U.S. Fish and Wildlife Service will continue to encourage international cooperation in the conservation of these species.

**NATIONAL ENVIRONMENT POLICY ACT**

Both a draft and a final EIS have been prepared by NMFS and are on file in the offices of the Division of Marine Mammal and Endangered Species, NMFS, Washington, D.C.

Because this final rulemaking lists green, loggerhead, and Pacific ridley sea turtles in their own right, the similarity of appearance proposal of June 16, 1976, by NMFS and FWS (41 FR 24378) is withdrawn.

The primary author of this rule is Robert B. Gorrell, Acting Endangered Species Program Manager, Division of Marine Mammal and Endangered Species, NMFS, 202-634-7471.

**REGULATION PROMULGATION**

Accordingly, 50 CFR § 17.11, 17.42(b) and 50 CFR Chapter II are amended as follows:

FEDERAL REGISTER, VOL. 43, NO. 146—FRIDAY, JULY 28, 1978
1. The list of Endangered and Threatened Wildlife in 50 CFR § 17.11 is amended by adding the green, loggerhead and olive (Pacific) ridley sea turtles to the list, alphabetically, under "Reptiles" as indicated below:

<table>
<thead>
<tr>
<th>Common Name</th>
<th>Scientific Name</th>
<th>Population</th>
<th>Known Distribution</th>
<th>Portion of range where threatened or endangered</th>
<th>Status</th>
<th>When Listed</th>
<th>Special Rules</th>
</tr>
</thead>
<tbody>
<tr>
<td>Turtle, Leatherback Sea ***</td>
<td><em>Chelonia mydas</em></td>
<td>Wherever found except in those areas where it is listed as endangered as set forth below</td>
<td>Circumglobal in tropical and temperate seas and oceans</td>
<td>Entire</td>
<td>T</td>
<td>50 CFR § 17.42(b) and Parts 220 and 227</td>
<td></td>
</tr>
<tr>
<td>Turtle, Green Sea</td>
<td><em>Chelonia mydas</em></td>
<td>Breeding colony populations in Florida and on the Pacific coast of Mexico</td>
<td>All State waters of Florida including Hutchinson and Jupiter Islands; and Pacific coast of Mexico including the Gulf of California</td>
<td>Entire</td>
<td>F</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Turtle, Loggerhead Sea</td>
<td><em>Caretta caretta</em></td>
<td>N/A</td>
<td>Circumglobal in tropical and temperate seas and oceans</td>
<td>Entire</td>
<td>T</td>
<td>50 CFR § 17.42(b) and Part 220 and 227</td>
<td></td>
</tr>
<tr>
<td>Turtle, Olive (Pacific) Ridley Sea</td>
<td><em>Lepidochelys olivacea</em></td>
<td>Wherever found except in those areas where it is listed as endangered as set forth below</td>
<td>Circumglobal in tropical and temperate seas and oceans</td>
<td>Entire</td>
<td>T</td>
<td>50 CFR § 17.42(b) and Part 220 and 227</td>
<td></td>
</tr>
<tr>
<td>Turtle, Olive (Pacific) Ridley Sea</td>
<td><em>Lepidochelys olivacea</em></td>
<td>Breeding colony population in Pacific Coast of Mexico</td>
<td>Pacific coast of Mexico including the Gulf of California</td>
<td>Entire</td>
<td>E</td>
<td>50 CFR § 17.42(b) and Part 220 and 227</td>
<td></td>
</tr>
</tbody>
</table>

FEDERAL REGISTER, Vol. 43, No. 146—Friday, July 28, 1978
2. A new special rule §12.23(b) is added to 50 CFR as follows:

§12.23 Special rules—permits.

... (b) Green sea turtle (Chelonia mydas), loggerhead sea turtle (Caretta caretta), olive ridley sea turtle (Lepidochelys olivacea) (these do not include the populations listed as endangered in §17.11).

1. Prohibitions. Subject to the permits allowed under the following paragraph (b)(2) of this section, all of the provisions set forth in §17.31 (which incorporate portions of §17.21) shall apply to this wildlife with the following exceptions:

(b) Section 17.21(b)(2) (self-defense) is not applicable.

(c) In §17.21(c)(3)(i), the word "orphaned" is replaced by the word "stranded."

(ii) Defect §17.21(c)(3)(iv) (wildlife threatening human safety).

(ii) Section 17.21(c)(e) and (f) do not apply to any delivery, receipt, carriage, transportation, shipment, sale or offer for sale in interstate commerce which takes place within 1 year after the effective date of this regulation and which involves specimens taken prior to such effective date.

(x) The prohibition against taking shall not apply to incidental catches, as specified in 50 CFR 227.32(e).

(v) The prohibition against taking within the United States or the territorial sea of the United States shall not apply to subsistence taking, as specified in 50 CFR 227.32(d).

(b) Permits. (1) For those activities which come under the jurisdiction of the Service, only permits for scientific purposes, enhancement of propagation or survival, zoological exhibition or educational purposes, are available under §17.32. Procedures for issuance of permits are found in §17.32 and, for those activities which come under the jurisdiction of the National Marine Fisheries Service, Subpart E of Part 220. All the provisions of §17.32 apply to permits issued by the Service.

(2) Activities which are ongoing on the effective date of this regulation and which are for scientific purposes or for enhancement of propagation or survival may continue without permit for up to 90 days as specified in 50 CFR 227.73(a).

3. 50 CFR Part 220 is amended by adding the following new Subpart E:

Subpart E—Permits Involving Endangered or Threatened Sea Turtles


Subpart E—Permits Involving Endangered or Threatened Sea Turtles

§229.50 Purpose.

This subpart establishes procedures for issuance of permits for scientific purposes or to enhance the propagation or survival of "endangered" or "threatened" sea turtles and zoological exhibition or educational purposes for "threatened" sea turtles.

§229.51 Permit applications.

Applications for permits to take, import, export or engage in any other prohibited activity involving any species of sea turtle listed in 50 CFR §17.11 shall be submitted to the Wildlife Permit Office (WPS) of the United States Fish and Wildlife Service in accordance with either 50 CFR 222.23(a) (Endangered Species) or 50 CFR §17.32(a) (Threatened Species) as appropriate. Applications involving activities under the jurisdiction of the National Marine Fisheries Service (NMFS) as defined in 50 CFR §222.23(a) and 50 CFR §227.4 shall be forwarded by the WPO to NMFS.

§229.52 Issuance of permits.

(a) Applications under the jurisdiction of the WPO shall be reviewed and acted upon in accordance with 50 CFR §17.22 or 50 CFR §17.23 as appropriate.

(b) NMFS shall make a complete review of applications forwarded to it by the WPO in accordance with §229.51 and determine the appropriate action to be taken in accordance with 50 CFR §222.23(b) and §222.23(c). In instances where the application involves activities under both NMFS jurisdiction, NMFS shall issue permits or letters of denial and provide WPO with copies of its actions.

(c) Where a permit application involves activities under both NMFS jurisdiction, each agency will process the application for activities under its jurisdiction, WPO will issue either a permit or a letter of denial.

(d) Where a permit application for activities under NMFS jurisdiction also requires a permit under the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) (50 CFR part 223), NMFS will process the application for activities under its jurisdiction. WPO will issue the final document by means of a combination ESA/CITES permit or a letter of denial.

§229.53 Other requirements.

Permits issued by NMFS under this Subpart shall be administered and comply with the provisions of 50 CFR §17–§227 as appropriate.

4. 50 CFR §222.23(a) is amended by deleting the period after the words, "Atlantic ridley sea turtle (Lepidochelys kempii)" and inserting the following: Green sea turtle (Chelonia mydas) breeding colony populations in Florida and on the Pacific coast of Mexico, and the olive ridley sea turtle (Lepidochelys olivacea) breeding colony populations on the Pacific coast of Mexico.

5. Sections 222.23(a), 222.23(b), and 222.23(c)(13) of 50 CFR Chapter II are amended by deleting the following language set off by quotation marks—

(a) "Of these, the National Marine Fisheries Service and the U.S. Fish and Wildlife Service presently share endangered species jurisdictional responsibility for sea turtles."

(b) "A copy of each application for a permit involving sea turtle(s) will be forwarded by the National Marine Fisheries Service to the U.S. Fish and Wildlife Service."

(c) "13) If the permit application involves a sea turtle(s), both the National Marine Fisheries Service and the U.S. Fish and Wildlife Service must concur prior to issuance since these two agencies presently share jurisdiction on sea turtles."

Substitute the following language for that deleted above in section 222.23(a) and amend paragraph (b) by adding the material set forth below to the end of the first full sentence:

§222.23 Permits for scientific purposes or to enhance the propagation or survival of the affected endangered species.

(a) Of these, the National Marine Fisheries Service has sole agency jurisdiction for sea turtles while the turtles are in the water and the U.S. Fish and Wildlife Service has jurisdiction for sea turtles while the turtles are on land.

(b) Except for permits involving sea turtles in which case the applicant shall follow the procedures set out in 50 CFR Part 220 Subpart E.

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RULES AND REGULATIONS

Subpart B—Threatened Marine Mammals

§ 227.11-227.30 [Reserved]

Subpart C—Threatened Marine Fish

227.31-227.70 [Reserved]

Subpart D—Threatened Marine Reptiles

227.71 Prohibitions.

227.72 Exceptions to prohibitions.


Subpart A—General Provisions

§ 227.1 Purpose.

The regulations contained in this part apply only to the threatened species enumerated in § 227.4.

(a) The provision of this part are in common spatial arrangement that interbreed when mature, under the jurisdiction of the Secretary of Commerce which have been determined to be threatened species under the Endangered Species Act of 1973 and provide for the conservation of such species by establishing rules and procedures to govern activities involving the species.

(b) The term "Act" means the Endangered Species Act of 1973, as amended, 16 U.S.C. § 1531-1547; the regulations contained in this part apply only to the threatened species enumerated in § 227.4; and the term "threatened species" means those species as defined in the Act, and in Parts 217-222 and Part 225 of this Chapter II which prescribe additional restrictions or conditions governing threatened species.

(c) Certain of the threatened fish or wildlife listed in 50 CFR 17.11 and enumerated in 50 CFR 227.4 are included in Appendix I or II to the Convention on International Trade in Endangered Species of Wild Fauna and Flora. The importation, exportation, and reexportation of such species are subject to additional regulations provided in Part 23, Chapter I (Title 50).

§ 227.2 Scope.

(a) The regulations contained in this part applies only to the threatened species enumerated in § 227.4.

(b) The provision of this part are in common spatial arrangement that interbreed when mature, under the jurisdiction of the Secretary of Commerce which have been determined to be threatened species under the Endangered Species Act of 1973 and provide for the conservation of such species by establishing rules and procedures to govern activities involving the species.

(c) Certain of the threatened fish or wildlife listed in 50 CFR 17.11 and enumerated in 50 CFR 227.4 are included in Appendix I or II to the Convention on International Trade in Endangered Species of Wild Fauna and Flora. The importation, exportation, and reexportation of such species are subject to additional regulations provided in Part 23, Chapter I (Title 50).

§ 227.3 Definitions.

In addition to the definitions contained in the Act, and in Parts 217 and 225 of this Chapter, and unless the context otherwise requires, in this Part 227:

(a) "Act" means the Endangered Species Act of 1973, as amended, 16 U.S.C. § 1531-1547;

(b) "Assistant Administrator" means the Assistant Administrator for Fisheries, National Oceanic and Atmospheric Administration, Department of Commerce, or his authorized delegate. The Assistant Administrator for Fisheries is in charge of the National Marine Fisheries Service;

(c) "Ongoing project(s)" means an activity for scientific purposes or to enhance the propagation or survival of such species which are not conducted in the course of a commercial activity initiated before the listing of the affected species;

(d) "Plastron" means the ventral part of the shell of a sea turtle consisting of nine symmetrically placed bones overlaid by horny plates; and

(e) "Sea Turtle(s)" means those sea turtle species enumerated in § 227.4 and any part(s), product(s), egg(s) or offspring thereof, or the dead body or part(s) thereof.

§ 227.4 Enumeration of Threatened Species.

The species listed as threatened under the act which are under the jurisdiction of the Secretary of Commerce are:

(a) Green sea turtle (Chelonia mydas) except for those populations listed under 50 CFR § 222.23(a).

(b) Loggerhead sea turtle (Caretta caretta).

(c) Pacific ridley sea turtle (Lepidochelys olivacea) except for those populations listed under 50 CFR 222.23(a).

§§ 227.5-227.10 [Reserved]

Subpart B—Threatened Marine Mammals

§§ 227.11-227.30 [Reserved]

Subpart C—Threatened Marine Fish

§§ 227.31-227.70 [Reserved]

Subpart D—Threatened Marine Reptiles

§ 227.71 Prohibitions.

Except as provided in § 227.72 it is unlawful for any person subject to the jurisdiction of the United States to commit, to attempt to commit, to solicit, to procure, to deliver, to receive, to carry, to transport, or ship by any means whatsoever, any such species taken prior to the effective date of the listing of the species for 1 year after such listing;

(b) sell, or offer for sale, in interstate commerce any such species;

(d) sell, or offer for sale, in foreign commerce any such species;

(g) deliver, receive, carry, transport, or ship in interstate commerce, by any means whatsoever, and in the course of commercial activity; provided that this paragraph (g) shall not apply to any such species taken prior to the effective date of the listing of the species for 1 year after such listing.

§ 227.72 Exceptions to prohibitions.

(a) Scientific, propagation, or survival permits. (1) The Assistant Administrator may issue permits authorizing activities which would otherwise be prohibited under § 227.71 for scientific purposes or to enhance the propagation or survival of such species. Applications for these permits are subject to the provisions of Part 220 of this Chapter II.

(2) Ongoing scientific, propagation, or survival projects, which otherwise be prohibited by § 227.71 may continue without a permit until an application for a permit has been denied or 90 days from the effective date of the listing of the affected species, whichever comes first. If a permit has not been denied, ongoing projects may continue beyond this 90-day period provided that the individual responsible for such project(s) has applied for a permit and receives a letter from the Assistant Administrator stating that the application is complete and sufficient for processing within the 90-day period. Projects not receiving a permit or letter indicating sufficiency by the 90th day must cease. Within 30 days of receipt of the application, the Assistant Administrator will determine the completeness and sufficiency of the application for processing. If an application is deemed complete and sufficient for processing, a permit will be issued or denied within the next 30 days beginning with the date of the letter informing the applicant that the application is sufficient. Approved projects shall continue in accordance with the conditions of the permit.

(b) Permits for Zoological Exhibitions or Educational Purposes. The Assistant Administrator may issue permits authorizing activities which would otherwise be prohibited under § 227.71 for zoological exhibition or educational purposes. Applications for these permits are subject to the provisions of Part 220 of this Chapter II.

(c) Exceptions for injured, dead, or stranded specimens. If any member of any threatened species listed in § 227.4 is found injured, dead, or stranded,
any agent or employee of the National Marine Fisheries Service, the U.S. Coast Guard, or any other Federal land or water management agency, or any agent or employee of a State agency responsible for fish and wildlife who is designated by his or her agency for such purposes, may, when acting in the course of his or her official duties, take such specimens without a permit if such taking is necessary to aid a sick, injured, or stranded specimen or salvage a dead specimen which may be useful for scientific study. Wherever possible, live specimens shall be returned to their aquatic environment as soon as possible. Every action shall be reported in writing to the Assistant Administrator within 30 days, and reports of further occurrence shall be made as deemed appropriate by the Assistant Administrator until the specimen is either returned to its environment or disposed of. Reports shall be mailed by registered or certified mail, return receipt requested, to the Assistant Administrator for Fisheries, National Marine Fisheries Service, Washington, D.C. 20363, and shall contain the following information:

(i) Name and position of the official or employee involved;
(ii) Description of the specimen(s) involved;
(iii) Date and location of disposal;
(iv) Circumstances surrounding the action;
(v) Method of disposal;
(vi) Disposition of the specimen(s), including, where the specimen(s) has been retained in captivity, a description of the place and means of confinement, and the measures taken for its maintenance and care; and
(vii) Such other information as the Assistant Administrator may require.

(d) Exception for research or conservation. Any employee or agent of the National Marine Fisheries Service, the Fish and Wildlife Service, or a State fish and wildlife agency operating a conservation program pursuant to the terms of a Cooperative Agreement with the National Marine Fisheries Service or the Fish and Wildlife Service in accordance with Section 6(c) of the Act, designated by his or her agency for such purposes, may, when acting in the course of his or her official duties, take any threatened species to carry out scientific research or conservation programs. All such takings shall be reported within 30 days of the taking to the Assistant Administrator who may request additional reports of the taking and research at his discretion.

(e) Exception for incidental taking—

(1) General. Except as provided in paragraphs (e)(2) and (e)(3) of this section, the incidental taking of any member of any species listed in §227.3 during fishing or scientific research activities not directed toward such members of such species is allowed under the following conditions:

(i) Any specimen so taken must be handled with due care to prevent injury to live specimens, and must be returned to the water immediately whether it is dead or alive unless it is a sea turtle which is alive and unconscious, in which case before returning it to the water, resuscitation must be attempted by turning the turtle on its back and pumping its plastron by hand or foot; and

(ii) Any specimen so taken must not be consumed, sold, landed, offloaded, transshipped, or kept below deck.

(2) Restricted Fishing Areas. [Reserved]

(3) Gear. [Reserved]

(4) Subsistence. The prohibition in §227.31(b) shall not apply with respect to the taking of any member of the species of green sea turtle (Chelonia mydas) in waters seaward of mean low tide for personal consumption by residents of the Trust Territory of the Pacific Islands if such taking is customary, traditional and necessary for the sustenance of such resident and his immediate family. Sea turtles so taken cannot be transferred to non-residents or sold.

Note—The National Marine Fisheries Service and the U.S. Fish and Wildlife Service have determined that this document does not contain a major action requiring preparation of an environmental impact statement under Executive Order 11993 and OMB Circular A-167.


Terry L. Leavitt,
Assistant Administrator for Fisheries.


Lyman A. Greenwell,
Director, U.S. Fish and Wildlife Service.

[FEDERAL REGISTER, VOL. 43, NO. 145—FRIDAY, JULY 28, 1978]
proposed rules

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

[1620-01]  
COST ACCOUNTING STANDARDS BOARD  
[4 CFR Parts 403, 410, 422]  
ACCOUNTING FOR INDEPENDENT RESEARCH AND DEVELOPMENT AND BID AND PROPOSAL COSTS  
AGENCY: Cost Accounting Standards Board.  
ACTION: Proposed rule.  
SUMMARY: The Cost Accounting Standards Board is proposing a standard which, if adopted, would be one of a series of cost accounting standards which the Board is promulgating to achieve increased uniformity and consistency in the cost accounting principles followed by defense contractors and subcontractors under Federal contracts. This proposed rule would provide criteria for the accumulation of costs of independent research and development (I.R. & D.) and bid and proposal (B. & P.) projects and the allocation of such costs to cost objectives, based on the beneficial or causal relationship between such costs and cost objectives. The application of these criteria should increase the probability that I.R. & D. and B. & P. costs are allocated to final cost objectives in a uniform and consistent manner.  
DATE: Written comments must be received on or before October 2, 1978.  
ADDRESS: Written comments should be sent to the Cost Accounting Standards Board, 441 G Street NW., Room 4836, Washington, D.C. 20548.  
FOR FURTHER INFORMATION CONTACT: Clark G. Adams, Project Director, Cost Accounting Standards Board, 441 G Street NW., Room 4836, Washington, D.C. 20548.  
SUPPLEMENTARY INFORMATION: In addition to the proposed standard, related amendments to standards 4 CFR Part 403 and 4 CFR 410 are being proposed. The Board solicits comments on the proposed cost accounting standard and related amendments. During the course of research, comments were received stating objections to the prohibition of allocating deferred I.R. & D. costs. Those voicing objections, however, did not provide sufficient criteria to determine when an I.R. & D. project's costs should be deferred and when they should not. The Board, therefore, requests that anyone objecting to the prohibition in this standard provide to the Board objective criteria for making this determination. Also, in addition to your comments and suggestions relative to the proposed standard, we would appreciate your providing us with the following information: (1) To what extent would the provisions of the proposed standard affect the dollar amount of I.R. & D. and B. & P. costs allocable to Government contracts for 1 year as compared to present practices and regulations? To the extent practical, please relate any such differences in allocable costs to the specific section of the standard. (2) Would the implementation of the proposed standard result in increased or decreased administrative costs? If so please provide details as to the nature of such costs and show how much of any increased or decreased costs would be one-time and how much would be continuing. By increased or decreased costs, we mean incremental costs. (3) What function(s), if any, would be added or deleted from the contractor's activities as a result of this standard? (4) Any costs which do not satisfy the definition of G. & A. expense in this standard, but which have been classified by a business unit as G. & A. expenses, can remain in the G. & A. expense pool unless they can be allocated to a business unit cost objectives on a beneficial or causal relationship which is best measured by a base other than a cost input base.  

It is proposed to amend 4 CFR Part 410, Allocation of business unit general and administrative expenses to final cost objectives, by deleting paragraph (d) of § 410.40 in its entirety and inserting the following in lieu thereof.  
§ 410.40 Fundamental requirement.  
| (d) Any costs which do not satisfy the definition of G. & A. expense in this standard, but which have been classified by a business unit as G. & A. expenses, can remain in the G. & A. expense pool unless they can be allocated to a business unit cost objectives on a beneficial or causal relationship which is best measured by a base other than a cost input base. |

It is proposed to amend 4 CFR chapter III by adding a new Part 422 to read as follows:  
PART 422—COST ACCOUNTING STANDARD ACCOUNTING FOR INDEPENDENT RESEARCH AND DEVELOPMENT AND BID AND PROPOSAL COSTS  
Sec. 422.10 General applicability.  
422.20 Purpose.  
422.30 Definitions.  
422.40 Fundamental requirement.  
422.50 Techniques for application.  
422.60 Illustrations.  
422.70 Exemption.  
422.80 Effective date.  


It is proposed to amend 4 CFR Part 403, Allocation of home office expense to segments, by deleting paragraph (b)(5) of § 403.40 and inserting the following in lieu thereof.  
§ 403.40 Fundamental requirement.  
| (b) * * * * * |

(5) Independent research and development and bid and proposal costs. The costs of independent research and development and bid and proposal efforts allocated by a home office shall be allocated in accordance with the provisions of 4 CFR Part 422.  

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development and bid and proposal costs are for the allocation of such costs to cost objectives based on the beneficial or causal relationship between such costs and cost objectives. Consistent application of these criteria will improve cost allocation.

§ 422.39 Definitions.
(a) The following are definitions of terms prominent in this standard.
   (1) Allocate. To assign an item of cost, or a group of items of cost, to one or more cost objectives. This term includes both direct assignment of cost and the reallocation of a share from an indirect cost pool.
   (2) Bid and proposal (B. & P.) costs. The costs incurred in the effort of preparing, submitting, and supporting bids and proposals (whether or not solicited) on potential contracts which effort is neither sponsored by a grant, nor required in performance of a contract and which falls within the following:
      (i) Administrative costs including the cost of the nontechnical effort for the physical preparation of the technical proposal documents and also the cost of the technical and nontechnical effort for the preparation and publication of the cost data and other administrative data necessary to support the contractor's bids and proposals, and
      (ii) Technical costs incurred to specifically support the contractor's bid or proposal, including the costs of system and concept formulation studies and the development of engineering and production engineering data.
   (3) Business unit. Any segment of an entire business organization which is not divided into segments.
   (4) Cost input. The cost, except G. & A. expenses, which for contract costing purposes is allocable to the production of goods and services during a cost accounting period.
   (5) General and administrative (G. & A.) expenses. Any management, financial, and other expense which is incurred by or allocated to a business unit and which is for the general management and administration of the business unit as a whole. G. & A. expense does not include those management expenses whose beneficial or causal relationship to cost objectives can be more directly measured by a base than a cost input base representing the total activity of a business unit during a cost accounting period.
   (6) Home office. An office responsible for directing or managing two or more, but not necessarily all, segments of an organization. It typically establishes policy for, and provides guidance to, the segments in their operations. It usually performs management, supervisory, or administrative functions, and may also perform service functions in support of the operations of the various segments. An organization which has intermediate levels, such as groups, may have several home offices which report to a common home office. An intermediate organization may be both a segment and a home office.
   (7) Independent research and development (I.R. & D.) costs. The costs of effort which is neither sponsored by a grant, nor required in performance of a contract of the organization, and which falls within any of the following three areas: (i) Basic and applied research, (ii) Product or service development, and (iii) Systems and other concept formulation studies.
   (8) Indirect cost. Any cost not directly identified with a single final cost objective, but identified with two or more final cost objectives or with at least one intermediate cost objective.
   (9) Segment. One of two or more divisions, sections, branches, or other subdivisions of an organization reporting directly to a home office, usually identified with responsibility for profit and/or producing a product or service. The term includes Government-owned contractor-operated (GOCO) facilities, and Joint ventures and subsidiaries (domestic and foreign) in which the organization has a majority ownership. The term also includes those Joint ventures and subsidiaries (domestic and foreign) in which the organization has less than a majority of ownership, but over which it exercises control.

§ 422.40 Fundamental requirement.
(a) I.R. & D./B. & P. projects shall be treated as if they were final cost objectives, except that business unit general and administrative expenses are not allocated to such projects.
(b) Each IR&D/B&P project shall be allocated for separately, and the costs of all such projects shall in turn be accumulated in a separate pool(s) apart from other costs.
(c) (1) Costs incurred clearly and exclusively for a particular IR&D/B&P project shall be allocated only to that project and shall be accounted for as a direct cost of that project,
   (2) The IR&D/B&P cost pool(s) at the home office shall be allocated to segments by means of a base representing the total activity of all segments reporting to that home office,
   (3) The IR&D/B&P cost pool(s) of a segment shall be allocated to final cost objectives of that segment by means of a base representing the total activity of that segment. The base selected shall be that best represents the total activity of a typical cost accounting period.

§ 422.50 Techniques for application.
(a) IR&D/B&P cost pool(s) of a home office or segment shall include any IR&D/B&P costs incurred in that home office or segment less any such costs that are directly allocated from a home office or segment.
(b) Only those types of cost which would be treated as direct costs of a final cost objective shall be treated as direct costs of IR&D/B&P projects.
(c) The costs of IR&D/B&P projects performed at a segment at the request of another segment or a home office shall be directly allocated to the requesting organization.
(d) The IR&D/B&P costs accumulated in a home office pool(s) shall be allocated to all segments under the home office by means of a cost input base representative of the total activity of such segments except where paragraph (e) below applies.
(e) Where a particular segment receives significantly more or less benefit from IR&D/B&P costs than would be reflected by the allocation of such costs to the segment on a cost input base, the Government and the contractor may agree to a special allocation of IR&D/B&P costs to such segment commensurate with the benefits received. The amount of a special allocation to any segment made pursuant to such an agreement shall be excluded from the pool(s) of IR&D/B&P costs to be allocated to the segment and the cost input data of any such segment shall be excluded from the base used to allocate the IR&D/B&P pool(s).
(f) The base used to allocate the IR&D/B&P cost pool(s) of a business unit to cost objectives shall be the same base used by the business unit to allocate its general and administrative expense in accordance with 4 CFR 410.50.
(g) The IR&D/B&P cost pool(s) may be combined with the G&A expense pool for allocation to final cost objectives provided that provision is made to identify the IR&D/B&P cost separately from the G&A expenses in the combined pool.
(h) IR&D/B&P costs incurred in a cost accounting period shall not be allocated to cost objectives of any other cost accounting period.

§ 422.60 Illustrations.
(a) Segment A receives a request to provide support for an IR&D project of Segment B. Segment A performs
the requested project but does not directly allocate the costs for such project to Segment B. As a result, the costs are included in the IR&D pool of Segment A and allocated to final cost objectives of Segment A. This accounting practice is not in compliance with the requirements of §422.50(a).

(b) Segment C, in accordance with its established accounting practice, charges administrative effort including typing to an indirect cost pool. The costs of typing are included as an indirect cost of the department assigned to prepare the proposal. In submitting a major proposal, Segment C assigns several typists to the proposal project on a full-time basis and charges the typists' time directly to the proposal project, rather than to the departmental overhead pool. Because the segment charges the cost of the typing effort incurred for this one proposal on a different basis from that used to charge typing effort in the department, the accounting practice is not in compliance with the requirements of §422.50(b).

(c) Segment D requests that Segment E provide support for an IR&D project. Segment E allocates to the project requested by Segment D all the incurred direct and related indirect costs, including an allocation of the performing segments' G&A expense. Segment E then directly allocates the cost of the project to Segment D. Since Segment D requested Segment E's support and Segment E directly allocated the direct and related indirect costs (including G&A) to Segment D, Segment E's accounting practice is in compliance with the requirements of §422.50(c) and 4 CFR Part 410.

(d) (1) Contractor F has six operating segments and a research laboratory, which is not part of the home office but is a separate segment. The research laboratory performs effort under R&D contracts, performs IR&D projects for the benefit of the contractor as a whole, and performs IR&D for the advancement of its own technical expertise. It also performs work on IR&D projects as specifically requested by any one of the six segments. The laboratory directly allocates theIR&D costs of the requested project to the requesting segment. The IR&D costs incurred for the advancement of its own technical expertise are allocated to the final cost objectives of the laboratory. The remaining IR&D costs of the laboratory are for the general benefit of the research laboratory and of the six operating segments and are accumulated at the home office and allocated to the segments on a cost input base representing the total activity of all the segments. This accounting practice is in compliance with the requirements of §422.50(d).

(2) Company G has two research laboratories; one established as an integral part of a group home office and a second established as a segment reporting to the group home office. Both laboratories only perform IR&D which is for the general benefit of the other segments of the company. The IR&D costs incurred by the group home office and the segment (laboratory) are pooled at the group home office for allocation purposes to the other segments reporting to that home office. The group home office uses a total cost input base which consists of the total cost input of the other segments to allocate the pooled IR&D costs. This accounting practice is in compliance with the requirements of §422.50(d).

(e) Company H has a research laboratory established at the home office which performs primarily applied research and experimental development for the benefit of the general research laboratories of the company, which performs primarily applied research and experimental development. All indirect costs of the general research laboratories are allocated to the general research laboratories. The accounting practice is not in compliance with the requirements of §422.50(e).

(f) Business Unit I allocates its G&A expense pool by means of a total cost input base in accordance with the provisions of 4 CFR Part 410. The Business Unit, however, establishes a base for allocation of its IR&D/B&P cost pool by removing certain major subcontracts. The base with the subcontracts removed is not the same base used to allocate its G&A expense pool, and therefore is not representative of the total activity of the cost accounting period. The accounting practice is not in compliance with the requirements of §422.50(f).

§422.70 Exemption.

This Standard shall not apply to contractors who are subject to the provisions of Federal Management Circumstances (Principles for Determining Cost Applicable to Grants and Contracts with State and Local Governments).

§422.80 Effective date.

(a) The effective date of this Cost Accounting Standard is [reserved].

(b) This Cost Accounting Standard shall be followed by each contractor on or after the start of his next fiscal year beginning after the receipt of a contract to which this Cost Accounting Standard is applicable.

[FR Doc. 78-20999 Filed 7-27-78; 8:45 am]
settlements are found to be in the general interest of the public. Consideration of settlements to which the parties have not unanimously agreed but which are supported by substantial evidence on the record and meet the standards of the Federal Power Act or Natural Gas Act also permits a more expeditious resolution of an ongoing proceeding. Mobil Oil Corporation v. F.P.C., 417 U.S. 283 (1974).

Nevertheless, the need for more fully developed records, or records on which a reasoned decision can be made, has become apparent in recent cases in which offers of settlement with certain contested issues were submitted to the Commission before the parties had the opportunity, or having been presented the opportunity chose not to exercise it, to submit testimony or to cross-examine those witnesses who submitted testimony. In an effort to alleviate this problem, and, more importantly, to expedite the final decisions and to provide the assurance that participants are afforded due process of law in presenting and litigating their views before this Commission, the Commission is proposing new procedures for certifying settlement agreements to the Commission once a hearing has been ordered. Before that time, the parties may submit an offer of settlement to the Commission. The Commission invites interested persons to comment on this proposed rulemaking.

B. SUMMARY OF THE COMMISSION'S PROPOSED REGULATIONS

The proposed procedures are intended to assure that offers of settlement certified to the Commission are either unanimously supported or, if contested by any participants to the proceeding, that the presiding administrative law judge has determined that all parties had an opportunity to present evidence or have waived their right to do so, as to issues which they contest. The Commission may thereby render a decision on contested issues, on the basis of substantial record evidence, consistent with the requirements of due process.

In cases where a hearing has been ordered by the Commission, the Commission proposes to review offers of settlement only upon certification of the offer of settlement and all pertinent documents, testimony, and exhibits by the presiding administrative law judge. If the offer of settlement is contested, the judge shall certify the offer of settlement together with his finding that the contested issues are severable and either his decision on the merits of contested issues, or, if a waiver of the initial decision is requested, his determination that the record contains substantial evidence to enable the Commission to reach a decision on the merits of contested issues. The participants shall outline the scope of the offer of settlement, including applicable contracts, schedules, or documents filed with the Commission in current and, if applicable, prior proceedings.

Comments. The Commission currently receives comments from the parties on offers of settlement with the Commission. The Commission proposes that, where a hearing has been ordered by the Commission, the settlement shall be filed with the presiding officer. The Secretary shall certify to the offer of settlement and provide for the filing of initial comments (and reply comments, if deemed appropriate) by the presiding officer with the settlement offer. The Bureau of filing comments by the presiding officer is to allow him to determine prior to certification whether an offer of settlement is unanimously supported and ripe for Commission review as a settlement, or, if portions of it are contested, to determine if the participants wish to present further evidence on the record, and to render a decision on the contested portions of the offer of settlement in the absence of a request for a hearing. In consideration of the foregoing, it is proposed to amend Part I, Subchapter A, Chapter 7 of Title 18, Code of Federal Regulations, as set forth below.

Any interested person may submit to the Federal Energy Regulatory Commission, 825 North Capitol Street NE, Washington, D.C. 20426, to be received no later than August 31, 1978, views, comments, and suggestions in writing concerning all or part of the amendments proposed herein. Written submittals will be placed in the Commission's public files and will be available for public inspection at the Commission's Office of Public Information, Room 100, 825 North Capitol Street NE, Washington, D.C. 20426, during regular business hours. The Commission will consider all such written submittals before acting on the matters herein proposed. An original and 14 copies of each such written submittal should be filed with the Secretary of the Commission. Submitted to the Commission should indicate the name, title, mailing address,
and telephone number of the person to whom communications concerning the proposal should be addressed.

Comments on all aspects of the proposal are solicited.


By order of the Commission.

KENNETH F. PLUNKETT,
Secretary.

1. Code of Federal Regulations, chapter I of title 18, part 1, subchapter A, § 1.1(c), is amended by adding new subparagraph (23) reading as follows:

§1.1 The Commission.

(23) Offer of settlement. For the purpose of this paragraph and §§1.18, 1.36, and 1.40(d)(2)(v), an offer of settlement shall include all documents, testimony, and exhibits which provide support for the offer of settlement, a list of all schedules, contracts, documents, or data within the scope of the settlement, and a proposed notice suitable for publication in the Federal Register.

2. Code of Federal Regulations, chapter I of title 18, part 1, subchapter A, § 1.18(e), is revised to read as follows:

§1.18 Conferences; offers of settlement.

(3) Unopposed offer of settlement. If the offer of settlement is unopposed, the presiding officer shall certify to the Commission that the offer of settlement, his statement that the offer of settlement is unopposed, and the evidentiary record, which shall include support for the offer of settlement.

(4) Concluded offers of settlement. If the offer of settlement is opposed in whole or in part, the presiding officer shall either: (i) Defer his certification of the offer of settlement until he has reached a decision supported by substantial record evidence on the remaining contested issues; or (ii) upon a determination that the disposition of the remaining contested issue or issues will not affect the settlement, certify to the Commission the uncontested portion of the offer of settlement, as provided in subparagraph (3) of this paragraph, specifying issues which are contested and are severable from the offer of settlement, and proceed with hearing procedures on the remaining contested issues.

3. Code of Federal Regulations, chapter I of Title 18, Part 1, Subchapter A, § 1.30(c)(3) and § 1.30(c)(4) are amended to read as follows:

§1.30 Decisions.

(3) Except as provided in §1.18(e)(4)(Ili), requests for waiver and omission of the intermediate decision procedure shall be by motion filed with the Commission at any time during, but not later than five days next following, the conclusion or adjournment sine die of the hearing; shall be in writing under oath, subscribed and verified; and shall in all other respects conform to the requirements of §§1.12 and 1.15 to 1.17, inclusive: Provided, however, That during sessions of hearings in proceedings, motions for such waiver and omission may be made orally on the record before the presiding officer, who shall forthwith report the same to the Commission.

§2.1 [Amended]


[F.R. Doc. 78-20868 Filed 7-31-78; 8:45 a.m.]
DEPARTMENT OF THE TREASURY
Customs Service
19 CFR Part 123
CUSTOMS RELATIONS WITH CANADA AND MEXICO

Proposed Rulemaking—Amending the Customs Regulations Relating to Violations in Manifests for Vehicles and Certain Vessels Arriving From Canada or Mexico

AGENCY: U.S. Customs Service, Department of the Treasury.

ACTION: Proposed rule.

SUMMARY: This proposed rule would establish uniform procedures for handling discrepancies in the manifests of vehicles and certain vessels arriving from Canada or Mexico. The proposed rule is intended to provide instructions for the public and Customs officers to ensure uniform treatment of all cases involving a discrepancy in a manifest.

DATES. Comments must be received on or before: August 30, 1978.

ADDRESSES: Written comments should be addressed to the Commissioner of Customs, Attention: Regulations and Legal Publications Division, 1301 Constitution Avenue NW., Washington, D.C. 20229.

Comments submitted will be available for public inspection in accordance with §103.8(b) of the Customs regulations (19 CFR 103.8(b)) during regular business hours at the Regulations and Legal Publications Division, Headquarters, U.S. Customs Service, 1301 Constitution Avenue NW., Washington, D.C. 20229.

FOR FURTHER INFORMATION CONTACT:

SUPPLEMENTARY INFORMATION: The U.S. Customs Service proposes to amend §123.9 of the Customs regulations (19 CFR 123.9). The present regulations do not satisfactorily state the applicable statutory provisions or outline the procedures to be followed in situations involving incorrect manifests. The proposed amendment is designed to promote uniform treatment in cases involving discrepancies in manifests for vessels of less than 5 net tons arriving otherwise than by sea from Canada or Mexico and all vehicles arriving from Canada or Mexico. For the purposes of the Customs regulations, vessels which arrive in the United States “otherwise than by sea” generally are those which arrive via the Great Lakes or via rivers or other inland waters. However, no precise definition of the term “otherwise than by sea” governs every case. The Customs Service has ruled that a vessel arriving from Mexico via the Falcon Reservoir arrives “otherwise than by sea.” On the other hand, in “Border Line Transportation Co. v. Haas,” 123 F. 2d 199 (ninth circuit 1942), cert. den. 318 U.S. 763, the court held that a vessel arriving from British Columbia via the Strait of Juan de Fuca arrived “by sea.”

Section 440 of the Tariff Act of 1930, as amended (19 U.S.C. 1460) is applicable to vessels of less than 5 net tons arriving otherwise than by sea from Canada or Mexico and to vehicles arriving from Canada or Mexico. For violations involving those vehicles and vessels, section 460 rather than section 584 is the proper authority for violations that are covered by both statutes because section 460 is more specific in scope. Paragraph (a) of proposed §123.9 details the specific situations covered by sections 460 and 584.

Penalties should be assessed under section 460 if a manifest is not filed or if it fails to include all of the merchandise imported or brought in on those vessels or vehicles. On the other hand, a penalty would be assessed under section 584 if a manifest listed merchandise that is not found on board a vehicle or a vessel of less than 5 net tons arriving otherwise than by sea from Canada or Mexico.

REPORT OF DISCREPANCY

Paragraph (b) of §123.9 of the Customs regulations (19 CFR 123.9(b)) establishes a procedure for reporting discrepancies in a manifest to the Customs Service. The present procedure is limited to the situation where a private individual discovers the discrepancy. Proposed §123.9(b) is divided into two parts. The first part concerns the situation where a private individual discovers the discrepancy. The proposal states the 60-day time period from the date of arrival for a private individual to report the discrepancy to the district director of Customs who received the original manifest. Paragraph (a) of proposed §123.9 refers to the time limits set in §4.12 of the Customs regulations (19 CFR 4.12). Stating the time limit in the proposed section will eliminate the need to refer to another section. The second part of proposed §123.9(b) concerns the situation where a Customs officer discovers the discrepancy before it is reported to the Customs Service. In this part of the proposed section there is a requirement for the district director concerned to notify the private individual of the discrepancy. The proposal also requires the private individual to explain the discrepancy within 30 days of the district director's notification or within 60 days after arrival, whichever is later.

Section 440 concerns the filing of a post entry to correct manifest discrepancies, which is a foreign port required to make entry. That section does not apply to vessels of less than 5 net tons arriving otherwise than by sea from Canada or Mexico or to vehicles arriving from Canada or Mexico. Accordingly, the reference to section 440 is deleted from proposed §123.9.

Section 460 of the Tariff Act of 1930, as amended (19 U.S.C. 1460) is applicable to vessels of less than 5 net tons arriving otherwise than by sea from Canada or Mexico and to vehicles arriving from Canada or Mexico. For violations involving those vehicles and vessels, section 460 rather than section 584 is the proper authority for violations that are covered by both statutes because section 460 is more specific in scope. Paragraph (a) of proposed §123.9 details the specific situations covered by sections 460 and 584.

Penalties should be assessed under section 460 if a manifest is not filed or if it fails to include all of the merchandise imported or brought in on those vessels or vehicles. On the other hand, a penalty would be assessed under section 584 if a manifest listed merchandise that is not found on board a vehicle or a vessel of less than 5 net tons arriving otherwise than by sea from Canada or Mexico.
The proposed amendment provides a definition of the term "clerical error or other mistake". That term is already defined in §§4.12(a)(5) and 6.7(h)(5) of the Customs regulations (19 CFR 4.12(a)(5), 6.7(h)(5)). However, although the definition of clerical error or other mistake is important with respect to handling cases involving discrepancies in manifests, the term has not been defined in §123.9 of the Customs regulations (19 CFR 123.9). The proposed amendment would add a new paragraph (g) to §123.9 that would contain the definition of "clerical error or other mistake" used in §§4.12(a)(5) and 6.7(h)(5).

Accordingly, the U.S. Customs Service proposes to amend §123.9 of the Customs regulations (19 CFR 123.9) and the heading of that section to read as follows:

§123.9 Explanation of a discrepancy in a manifest.

(a) Provisions applicable—(1) Failure to file a manifest; overages. If there is a failure to file a manifest in accordance with §123.5 or merchandise is found that is not listed on the manifest filed in accordance with §123.5 (an overage), the merchandise and the vessel or vehicle in which it was brought or imported into the United States are subject to forfeiture and the master of the vessel or the person in charge of the vehicle is liable, in addition to any other penalty equal to the value of the merchandise under section 460, Tariff Act of 1930, as amended (19 U.S.C. 1460).

(2) Shortages. If merchandise is manifested but not found on board (a shortage), the master of the vessel or other person in charge or the owner of that vessel or vehicle shall be subject to a penalty of $500 under section 584, Tariff Act of 1930, as amended (19 U.S.C. 1584).

(b) Report of discrepancies.—(1) Discrepancies discovered by master or person in charge. The master, person in charge, or agent of the vessel or vehicle shall report all discrepancies to the district director within 60 days after the date of arrival by completing a report for an overage or a declaration for a shortage. The overage report or shortage declaration may be made, on the appropriate manifest form, as listed in §123.4, or on Customs form 5931, discrepancy report and declaration. If no manifest had been filed, an original copy of the appropriate form, as listed in §123.4 should be used. In each case where a manifest form is used, it shall be marked or stamped "Discrepancy Reported" or "Shortage Declaration," as appropriate. The form used shall list the merchandise involved and state the reasons for the discrepancy.

(2) Discrepancies discovered by Customs. The district director shall immediately advise the master, person in charge, owner, or agent of any discrepancies discovered by Customs officers which have not been reported by the master, person in charge, owner, or agent. Thereafter, such master, person in charge, owner, or agent shall file an explanation of the discrepancy as required by paragraph (b)(1) of this section within 30 days of that notification or within 60 days after arrival of the vessel or vehicle, whichever is later. The district director may notify the master, person in charge, owner, or agent of a discrepancy by furnishing a copy of Customs form 5931 to that person, or by any other appropriate means.

(c) Statement on report of discrepancy required. The overage report or shortage declaration shall bear the following statement signed by the master of the vessel, the person in charge of the vehicle, the owner of the vessel or vehicle or an authorized agent:

I declare to the best of my knowledge and belief that the discrepancy described herein occurred for the reasons stated. I certify that evidence to support a claim of non-importation or proper disposition of merchandise will be retained in the carrier's files for a period of at least 1 year from the date of this report of discrepancy and will be made available to Customs upon demand.

(d) Action on the discrepancy report. Any penalty or liability to forfeiture incurred under 19 U.S.C. 1460 shall be remitted under section 816, Tariff Act of 1930, as amended (19 U.S.C. 1818), and in accordance with the proviso of 19 U.S.C. 1584, no penalty or liability to forfeiture shall be incurred under 19 U.S.C. 1584, if:

(1) There is a timely filing of the manifest discrepancy report;

(2) There has been no loss of revenue;

(3) The district director is satisfied that the discrepancy resulted from clerical error or other mistake; and

(4) In the case of a discrepancy not initially reported by the master, person in charge, owner, or agent, the district director is satisfied that there was a valid reason for the failure to so report.

Otherwise, applicable penalties under 19 U.S.C. 1460 and 1584 shall be assessed and the vessel or vehicle shall be liable to forfeiture (see §162.31 of this chapter).

(e) Penalty assessment. For the purpose of assessing penalties under 19 U.S.C. 1460 or 1584, the value of the merchandise shall be determined as prescribed in §162.43 of this chapter.

(1) Lack of knowledge does not relieve liability. The fact that the master of the vessel, the person in charge of the vehicle, or the owner of the vessel or vehicle had no knowledge of a discrepancy shall not relieve the master, the person in charge, or the owner from a penalty, or the vessel or vehicle from liability to forfeiture, incurred under 19 U.S.C. 1460 and 1584.

(g) Clerical error or other mistake defined. For the purpose of this section, the term "clerical error or other mistake" is defined as a non-negligent, inadvertent, or typographical mistake in the preparation or transmission of manifests. However, repeated similar manifest discrepancies by the same individuals may be considered the result of negligence and not clerical error or other mistake.

This amendment is proposed under the authority of R.S. 251, as amended
PROPOSED RULES

Footwear classifiable under schedule 7, part 1A, Tariff Schedules of the United States—

(1) The manufacturer's style number.

(2) The importer's style number.

(3) Component materials of upper with percentage (value) of each component (if fiber, and if fiber plus rubber and/or plastic is less than 50 percent, state the percentage by weight and value of each fiber used).

(4) Component materials of entire article with percentage (value) of each component. If the materials in (3) and (4) are primarily leather, answer only (10) and (11). Otherwise answer all questions.

(5) Component materials of sole with percentage (value) of each component.

(6) Percentage of weight of entire article.

(a) Fiber.

(b) Rubber and/or plastic.

(c) Other (specify material).

(7) Percentage of exterior surface area of upper:

(a) Leather.

(b) Rubber and/or plastic.

(c) Other (specify material).

(8) Whether there is a foxing-like band around bottom of upper.

(9) Whether the upper extends over the ankle.

(10) Type of construction:

(a) Cement.

(b) Molded or vulcanized.

(c) Turned.

(d) Unsoled moccasin.

(e) Welt.

(1) Other.

(11) If the component material of chief value of the entire article is leather, state if made on a male or female last. Customs Form 5523 may be used for furnishing the additional information.

Approved: July 17, 1978.

G. R. DICKERSON,
Acting Commissioner of Customs.

Richard J. Davis,
Assistant Secretary
of the Treasury.

DEPARTMENT OF HEALTH,
EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Parts 172 and 182]

(Docket No. 78N-01531)

GUM GUAJAC

Removal as a Food Ingredient and Regulation

Food Additive for Direct Human Use in Foods

AGENCY: Food and Drug Administration.

FOOD AND DRUG ADMINISTRATION

PROPOSED RULES

Footwear classifiable under schedule 7, part 1A, Tariff Schedules of the United States—

(1) The manufacturer's style number.

(2) The importer's style number.

(3) Component materials of upper with percentage (value) of each component (if fiber, and if fiber plus rubber and/or plastic is less than 50 percent, state the percentage by weight and value of each fiber used).

(4) Component materials of entire article with percentage (value) of each component. If the materials in (3) and (4) are primarily leather, answer only (10) and (11). Otherwise answer all questions.

(5) Component materials of sole with percentage (value) of each component.

(6) Percentage of weight of entire article.

(a) Fiber.

(b) Rubber and/or plastic.

(c) Other (specify material).

(7) Percentage of exterior surface area of upper:

(a) Leather.

(b) Rubber and/or plastic.

(c) Other (specify material).

(8) Whether there is a foxing-like band around bottom of upper.

(9) Whether the upper extends over the ankle.

(10) Type of construction:

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DEPARTMENT OF HEALTH,
EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Parts 172 and 182]

(Docket No. 78N-01531)

GUM GUAJAC

Removal as a Food Ingredient and Regulation

Food Additive for Direct Human Use in Foods

AGENCY: Food and Drug Administration.
ACTION: Proposed rule.

SUMMARY: This proposal would remove gum guaiac from the list of direct human food ingredients that are generally recognized as safe (GRAS) and from the list of approved food additives. The safety of this substance has been evaluated as part of the comprehensive review of all GRAS ingredients currently being conducted by FDA. There is no evidence to indicate that gum guaiac is used in foods at this time, and it is therefore impossible to evaluate fully potential food uses.

DATE: Comments by September 26, 1978.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:


SUPPLEMENTARY INFORMATION:

A comprehensive safety review of human food ingredients classified as generally recognized as safe (GRAS) or subject to a prior sanction is being conducted by the Food and Drug Administration. The Commissioner of Food and Drugs has issued several notices and proposals initiating this review (see the FEDERAL REGISTER of July 26, 1973 (38 FR 20440)). The safety of gum guaiac has been evaluated as part of this review. In accordance with the provisions of § 170.35 (21 CFR 170.35), the Commissioner proposes to remove this ingredient from the GRAS list and from food additive regulations permitting direct food uses of the ingredient.

Gum guaiac is obtained from *Guaiacum officinale* L. (lignum vitae) and *Santalum L. bastard lignum vitae* or *holywood*. The gum is found as an exudate on the trunks of the trees which are native to tropical America. Gum guaiac was used extensively in the 1930's and 1940's as an antioxidant in lard and fat products. However, it was reported in the 1951 edition of Bailey's *Industrial Oil and Fat Products* that use of gum guaiac as an antioxidant in lard had been discontinued.

Gum guaiac is listed in § 182.3336 (21 CFR 182.3336) as GRAS for use in edible fats and oils as a chemical preservative under a regulation published in the FEDERAL REGISTER of November 20, 1959 (24 FR 9368). It is also listed in § 172.510 (21 CFR 172.510) as a natural flavoring substance.

The indirect uses of gum guaiac are listed in § 181.24 (21 CFR 181.24) as a prior-sanctioned substance used as an antioxidant in the manufacture of food-packaging material, and in § 175.300 (21 CFR 175.300) as an antioxidant in the production of resins and polymeric coatings.

A representative cross section of food manufacturers was surveyed by the National Academy of Sciences/National Research Council (NAS/NRC) to determine the specific food in which gum guaiac was used and the amounts in the specific food. There was no indication that gum guaiac was used in food products in 1970.

Gum guaiac has been the subject of a search of the scientific literature from 1920 to the present. The criteria used in the search were chosen to discover any articles that considered (1) chemical toxicity, (2) occupational hazards, (3) metabolism, (4) reaction products, (5) degradation products, (6) any reported carcinogenicity, teratogenicity, or mutagenicity, (7) dose response, (8) reproductive effects, (9) histology, (10) embryology, (11) behavioral effects, (12) detection and (13) processing. A total of 49 abstracts on gum guaiac were reviewed, and 7 particularly pertinent reports from the literature review have been summarized in a scientific literature review.

The scientific literature review shows the following information as known about gum guaiac.

**General Information:**

- Gum guaiac is listed in § 181.24 (21 CFR 181.24) as a prior-sanctioned substance used as an antioxidant in the manufacture of food-packaging material, and in § 175.300 (21 CFR 175.300) as an antioxidant in the production of resins and polymeric coatings.
- A representative cross section of food manufacturers was surveyed by the National Academy of Sciences/National Research Council (NAS/NRC) to determine the specific food in which gum guaiac was used and the amounts in the specific food. There was no indication that gum guaiac was used in food products in 1970.
- Gum guaiac has been the subject of a search of the scientific literature from 1920 to the present. The criteria used in the search were chosen to discover any articles that considered (1) chemical toxicity, (2) occupational hazards, (3) metabolism, (4) reaction products, (5) degradation products, (6) any reported carcinogenicity, teratogenicity, or mutagenicity, (7) dose response, (8) reproductive effects, (9) histology, (10) embryology, (11) behavioral effects, (12) detection and (13) processing. A total of 49 abstracts on gum guaiac were reviewed, and 7 particularly pertinent reports from the literature review have been summarized in a scientific literature review.
- The scientific literature review shows the following information as known about gum guaiac.

**Animal Route**

<table>
<thead>
<tr>
<th>Animal</th>
<th>Route</th>
<th>LD₅₀ (mg/kg body weight)</th>
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<tr>
<td>Guinea pigs</td>
<td>Oral</td>
<td>1120</td>
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</table>

Six human subjects were given a total of 10 doses of 2 or 3 grams of gum guaiac at a food level of 0.05 to 0.1 g of gum guaiac daily, in addition to a standard diet. Three dogs received 1 g daily (about 100 mg per kg body weight), and three dogs served as controls. At the end of the test, all but one dog had gained weight, and in the exception, the loss was apparently not significant. Histological examination of intestines, lungs, kidneys, livers, and spleens revealed no untoward effects.

A similar experiment was conducted with eight adult cats for 34 to 117 weeks. Three groups of cats received 0.5 to 1.0 g of gum guaiac daily, in addition to a standard diet. Three dogs received 1 g daily (about 600 mg per kg body weight). Only one cat, receiving 1 g of gum guaiac daily, failed to gain weight. Gross and histological examination of the lungs, kidneys, livers, and spleens revealed no untoward effects. The intestinal mucosa was not inflamed.

Four women and seven men ingested 0.05 to 0.1 g of gum guaiac (about 1 to 2 mg per kg of body weight) mixed in chocolate pellets daily for periods of 16 to 104 weeks. Five subjects continued for another 90 weeks. Red and white blood cell counts, hemoglobin determinations, and Fishberg's (1930) modification of Volhard's urine-concentration test for kidney function were performed each month. Stool consistency and body weight were noted. No abnormalities in these parameters were detected and all subjects remained healthy.

Lehman at al cited an unpublished 2-year study of R.N. Bieter in which one group of 10 rats was fed a diet containing 0.5 percent gum guaiac (about 600 mg per kg of body weight), and another group of 10 rats received no gum guaiac. There was no discernable difference between the two groups as determined by mortality and pathological examination.

In a lifetime study, four groups of 10 rats each were fed a basal diet containing 0.05, 0.05, 0.5 percent (estimated to be in range of 0.5 to 500 mg per kg body weight) of gum guaiac. The second and third generation descendents (80 in number) of the original rats were maintained throughout their lives on the same diet as their parents. No differences were observed between the experimental groups and the controls in regard to body weight, growth rate, life span, reproductive, or pathological examination. In all three generations, there were no discernable differences between the treated and control groups with respect to number of pregnancies, number of young born, and number of young weaned.

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PROPOSED RULES

No reports on the teratogenicity, mutagenicity, carcinogenicity, or allergic reactions of gum guaiac have come to the attention of the Select Committee.

All the available safety information on gum guaiac has been carefully evaluated by qualified scientists of the Select Committee. It is the opinion of the Select Committee that:

The literature on the biological activity of gum guaiac shows that it is not possible to evaluate fully the safety of present or potential food uses of this ingredient.

The Select Committee has considered the evidence for and against the use of gum guaiac in food. It concludes that the entire group of GRAS substances included in the proposal elicit a large enough response to be considered for GRAS affirmation on the basis of a petition submitted in accordance with §170.3 (21 CFR 170.35).


The proposal constitutes a waiver of the specific regulated indirect use of the substance (21 CFR 175.300) that is not affected by this proposal. This proposal also does not affect the present use of gum guaiac in pet food or animal feed.

Copies of the scientific literature review of gum guaiac and the report of the Select Committee are available for review at the office of the Hearing Clerk (HFA-305), Food and Drug Administration, room 4-65, 5600 Fisher Lane, Rockville, Md. 20857, and may be purchased from the National Technical Information Service, 5285 Port Royal Road, Springfield, Va. 22151, as follows:

Title Order No. Price
--- --- ---
Gum guaiac (literature review) A02 $4.00
Gum guaiac (select PB-274-474/AS Committee report) A02 $4.00

The proposal is not subject to change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(g), 409, 701(a), 82 Stat. 1055, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348, 371(a)) and under authority delegated to the Commissioner (21 CFR 5.1), it is proposed that parts 172 and 182 be amended as follows:

§172.510 [Amended]
1. In part 172 by deleting the entry for "guaiac" from the table in paragraph (b) of §172.510 Natural flavoring substances and natural substances used in conjunction with flavors.

§182.3336 [Deleted]
2. In part 182 by deleting §182.3336 Gum guaiac.

The Commissioner hereby gives notice that he is unaware of any prior sanction for the use of this ingredient in food under conditions different from those stated in part 181 (21 CFR part 181). Any person who intends to assert or rely on such a sanction shall submit proof of its existence in response to this proposal. The proposed regulation will constitute a determination that excluded uses would result in adulteration of the food in violation of section 402 of the Federal Food, Drug, and Cosmetic Act.

Withdrawal and Reissuance of Proposal to Discontinue Certification of all 80-Unit Insulin Products

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: This agency is withdrawing its original proposal and is reposing to discontinue the certification of all 80-unit (U-80) insulin products.

In addition, it is requesting comments on (1) the suitability of 100-unit (U-100) insulin as the only standard strength, and (2) the need for the continued certification of a low-potency insulin product for pediatric use. The purpose of this proposal is to reduce the potential for patient errors that results from having insulin available in two high concentrations and syringes calibrated for use with more than one concentration.

DATES: Comments by November 27, 1978. The agency proposes that the final rule based on this proposal become effective 180 days after date of publication in the Federal Register.
PROPOSED RULES

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:
Marc H. Hoffman, Bureau of Drugs (HFD-30), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-5229.

SUPPLEMENTARY INFORMATION:
In the Federal Register of November 15, 1974 (39 FR 40301), the Commissioner of Food and Drugs proposed to discontinue certification of all insulin products containing 80 USP units per milliliter (ml) (U-80 insulin). None of the comments responding to the original proposal objected to its intent. Some of the comments, however, questioned the proposed discontinuance of U-80 insulin at a time when sufficient supplies of U-100 insulin were not available. In addition, some comments questioned whether diabetics using U-80 insulin and their physicians had sufficient knowledge of the proposed action to effect an orderly transition to U-100 usage. Statistics compiled by the Food and Drug Administration's (FDA's) Certification Services Branch, on file in the office of the Hearing Clerk, reveal that in the past few years, there has been a definite trend toward greater acceptance of U-100 insulin and away from use of U-80 insulin. The most current figures available, those for January 1975 through October 1977, show that significantly more batches of U-100 insulin have been and are currently being certified (and consequent vials produced) than is the case with U-80 insulin.

In view of this wide acceptance of U-100 insulin, and with the understanding that sufficient supplies of syringes are available for the administration of U-100 insulin, the Director of the Bureau of Drugs to whom the Commissioner has delegated the authority to amend the insulin regulations believes it appropriate to propose discontinuance of the certification of U-80 insulin products. Because of the length of time since the November 15, 1974 proposal, and because of the changes referred to above, the Director has decided to issue another proposal on this matter. Accordingly, the November 15, 1974 proposal is withdrawn and replaced by this document.

Also in the Federal Register of November 15, 1974 (39 FR 40284), the Commissioner issued a final regulation providing for the certification of modified insulin products in the 100-unit strength (U-100 insulin). This was done with the intention of later phasing out the U-80 insulin concentrations already on the market and possibly phasing out the U-40 concentrations, also at some later date.

Section 506(a) of the Federal Food, Drug, and Cosmetic Act states that a batch of insulin shall be certified if it has such characteristics as identity, strength, quality, and purity as prescribed in the regulations as necessary to adequately insure safety and efficacy of use. Insulin products are presently available over-the-counter in the United States in concentrations of 40, 80, and 100 units of insulin per ml. (This proposal does not affect the status of 500-unit insulin, available only on a prescription basis.) It should be noted that "insulin" is used throughout this document to refer to both regular and modified insulin products available over-the-counter.

There have been reports of adverse reactions as a result of patient errors due to confusion in matching the prescribed concentration to the correct syringe or to the correct calibration. A single concentration of U-100 for general use would be expected to eliminate such patient errors. The advantage of the 100-unit concentration is that its numerical relationship to the decimal system makes the dosage easier to calculate and measure. In addition, with the higher concentration, a smaller volume per injection is needed, which can reduce the discomfort of the injection.

This proposal does not call for revoking the certification of any batches of U-80 insulin certified prior to the effective date of the final rule. Batches certified prior to that date would remain on the market until they become outdated. The agency is proposing that the final rule become effective 180 days after publication in the Federal Register. Such a delay in the effective date is intended to provide a sufficient phase-over and adjustment period for the insulin and syringe manufacturers involved, as well as for the affected public. Because many diabetics and private physicians who may be affected by the final order do not normally have access to the Federal Register, FDA plans to distribute this proposal as widely as possible through an educational program conducted in cooperation with trade and professional groups.

It should be noted that American manufacturers export U-80 insulin for sale abroad. Under the provisions of section 801(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(d)), shipments of uncertified insulin to foreign countries are lawful. Consequently, discontinuance of certification for U-80 used in this country would still permit production of that insulin concentration for sale abroad.

U-100 insulin is now available only in the United States and Canada. The lack of U-100 insulin available outside of North America, however, should pose virtually no problem for Americans traveling abroad as the increased concentration of insulin, combined with its stability at room temperature, make it possible for most travelers to take along an adequate supply. The main concern would be to protect the vials from extremes of heat and cold.

Revoking the provisions for certifying U-80 insulin, as proposed here, could be an action taken on its own or could be the first step toward making insulin available in only one high concentration. Although the Director is not now proposing to stop the certification of U-0 insulin, such a proposal may be published in the future. First, however, the Director would like to receive comments from interested persons, particularly insulin users and their physicians, pertaing to the basic policy of stopping the certification of U-0 and, perhaps, U-10 insulin. In particular, the Director is interested in obtaining comments on the suitability of having one concentration of insulin available as well as the need for the continued certification of a low concentration insulin product for pediatric use. Responses to the following questions will be especially valuable:

1. Should the ultimate goal be to have only one strength of insulin available?
2. If only one strength of insulin is available, should it be insulin containing 100 units per milliliter?
3. Is there a demonstrated need for a low-potency insulin, such as U-10, U-20, or U-40, for pediatric use?

The Director of the Bureau of Drugs has determined that this document does not contain an agency action covered by § 25.1(b) (21 CFR 25.1(b)); therefore, consideration by the agency of the need for preparing an environmental impact statement is not required.

Accordingly, under the Federal Food, Drug, and Cosmetic Act (sec. 506, 55 Stat. 551 (21 U.S.C. 356)) and under authority delegated to the Commissioner (21 CFR 5.1) and redelegated to the Director of the Bureau of Drugs (21 CFR 5.73), the Director proposes to amend parts 369 and 429 by removing all references to 80-unit insulin as follows:

§ 369.21 [Amended]

1. In part 369, § 369.21 Drugs; warning and caution statements required by regulations is amended in the entry for insulin by deleting the number "80" and the commas immediately preceding and following it.
PROPOSED RULES

DEPARTMENT OF THE TREASURY

Internal Revenue Service

[26 CFR Part 1]

(DR-152-76)

INTEREST RELATED TO EXEMPT-INTEREST DIVIDENDS

Proposed Rulemaking

AGENCY: Internal Revenue Service, Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations concerning interest related to exempt-interest dividends. Changes to the applicable law were made by the Tax Reform Act of 1976. The regulations would provide the public with the guidance needed to understand the effects of the Act that may affect certain taxpayers who own shares of stock in certain regulated investment companies.

DATES: Written comments and requests for a public hearing must be received by September 25, 1978. The amendments are proposed to be effective for taxable year beginning after December 31, 1975.

ADDRESS: Send comments and requests for a public hearing to: Commissioner of Internal Revenue, Attention: CL:PR.T (LR-152-76), Washington, D.C. 20224.

FOR FURTHER INFORMATION CONTACT:


SUPPLEMENTARY INFORMATION:

BACKGROUND

This document contains proposed amendments to the Income Tax Regulations (26 CFR Part 1) under section 265 of the Internal Revenue Code of 1954. These amendments are proposed to conform the regulations to section 213(c)(4) of the Tax Reform Act of 1976 (80 Stat. 1952) and to be issued under the authority contained in section 7805 of the Internal Revenue Code of 1954 (68A Stat. 917; 26 U.S.C. 7805).

The Tax Reform Act of 1976 added a new paragraph (4) to section 265. This new paragraph denies a deduction to a taxpayer for interest in indebtedness incurred or continued to purchase or carry shares of stock of a regulated investment company during the taxable year of the holder thereof that distributes exempt-interest dividends.

COMMENTS AND REQUESTS FOR A PUBLIC HEARING

Before adopting these proposed regulations, consideration will be given to any written comments that are submitted (preferably six copies) to the Commissioner of Internal Revenue. All comments will be available for public inspection and copying. A public hearing will be held upon written request to the Commissioner by any person who has submitted written comments. If a public hearing is held, notice of the time and place will be published in the Federal Register.

DRAFTING INFORMATION

The principal author of these regulations was Robert H. Waltuch of the Legislation and Regulations Division of the Office of the Chief Counsel, Internal Revenue Service. However, personnel from other offices of the Internal Revenue Service and Treasury Department participated in developing the regulations, both on matters of substance and style.

PROPOSED AMENDMENTS TO THE REGULATIONS

The proposed amendments to 26 CFR Part 1 are as follows:

Paragraph 1. The following new section is added immediately after §1.265-2:

§1.265-3 Nondeductibility of interest relating to exempt-interest dividends.

(a) In general. No deduction is allowed for the interest on indebtedness that relates to exempt-interest dividends distributed by a regulated investment company.

(b) Illustrating to exempt-interest dividends. (1) If an indebtedness is either incurred or continued to purchase or carry shares of stock in a regulated investment company which during the shareholder's taxable year distributes exempt-interest dividends (as defined in section 852(b)(5) of the Code), then all or a portion of the interest on the indebtedness relates to the exempt-interest dividends. If the regulated investment company distributes only exempt-interest dividends to the shareholder during that shareholder’s taxable year, then all of the interest paid or accrued relates to exempt-interest dividends. If the regulated investment company distributes exempt-interest dividends in addition to taxable dividends (excluding capital gain dividends distributed or capital gains required to be included in the shareholder's computation of long-term capital gains under section 852(b)(5)(D)) to the shareholder during the shareholder's taxable year, then a portion of the interest paid or

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accrued by the shareholder during that shareholder's taxable year relates to exempt-interest dividends.

(2) To determine the portion of the interest that relates to the exempt-interest dividends the total amount of interest paid or accrued on the indebtedness is multiplied by a fraction. The numerator of the fraction is the amount of exempt-interest dividends received. The denominator of the fraction is the sum of the exempt-interest dividends and taxable dividends received (excluding capital gain dividends received or capital gains required to be included in the shareholder's computation of long-term capital gains). See section 652(d)(3)(D).

JEROME KURTZ,
Commissioner of Internal Revenue.

[FR Doc. 78-21050 Filed 7-27-78; 8:45 am]

[6330-01]

[23 CFR Part 1]

[LR-2-78]

REQUIREMENTS RELATING TO CERTAIN EXCISES INVOLVING A FOREIGN CORPORATION

Extension of comment period for hearing request

AGENCY: Internal Revenue Service, Treasury.

ACTION: Extension of time for comments and requests for a public hearing.

SUMMARY: This document provides notice of an extension of time for submitting comments and requests for a public hearing concerning the notice of proposed rulemaking with respect to requirements relating to certain exchanges involving a foreign corporation. The extended deadline for submission of comments and requests for a public hearing is October 2, 1978.

DATES: Written comments and requests for a public hearing must be delivered or mailed by October 2, 1978.

ADDRESS: Send comments and requests for a public hearing to: Commissioner of Internal Revenue, Attention: CCLR-T (LR-2-78), Washington, D.C. 20224.

FOR FURTHER INFORMATION CONTACT:


SUPPLEMENTARY INFORMATION: By a notice of proposed rulemaking published in the Federal Register for Friday, December 30, 1977 (42 FR 65132 and 65204), comments and requests for a public hearing with respect to the proposed rules were to be delivered or mailed to the Commissioner of Internal Revenue, Attention: CCLR-T (LR-2-78), Washington, D.C. 20224, by February 28, 1978. By a notice published in the Federal Register for Tuesday, February 21, 1978 (43 FR 7245), this date was extended to May 1, 1978, and was additionally extended to August 1, 1978, by a notice published in the Federal Register for Monday, May 1, 1978 (43 FR 18570). The date by which such comments and requests must be delivered or mailed is hereby further extended to October 2, 1978.

This document does not meet the criteria for significant regulations set forth in paragraph 8 of the proposed Treasury directive appearing in the Federal Register for Wednesday, May 24, 1978.

ROBERT A. BLEY,
Director, Legislation and Regulations Division.

[FR Doc. 78-21050 Filed 7-27-78; 6:38 am]

[6510-25]

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[29 CFR Part 1926]

CONNECTICUT

Notice of the Connecticut State Plan for Public Employees Only and Its Availability for Public Comment

AGENCY: Occupational Safety and Health Administration, Department of Labor.

ACTION: Proposed rule.

SUMMARY: This document gives notice of the submission by Connecticut of a State plan for the enforcement of occupational safety and health standards applicable to public sector employment only. After an opportunity for public comment, the Assistant Secretary of Labor for Occupational Safety and Health will approve the plan if it meets the criteria set forth in the Occupational Safety and Health Act of 1970 and applicable regulations.

DATES: Interested person(s) are hereby given until August 24, 1978, to submit in writing data, views, and arguments concerning the plan.

ADDRESS: Written comments and requests for a hearing should be submitted to the Director, Federal Compliance Program, Occupational Safety and Health Administration, Department of Labor, room N3101, Third and Constitution Avenue NW., Washington, D.C. 20210.

FOR FURTHER INFORMATION CONTACT:


LOCATION OF PLAN FOR INSPECTION AND COPYING

A copy of the plan may be inspected and copied during normal business hours at the following locations: Office of State Programs, 2100 M Street NW., room 149, Washington, D.C. 20210; Office of the Regional Administrator, Occupational Safety and Health Administration, room 1804, John F. Kennedy Federal Building; Boston, Mass. 02203; Connecticut Department of Labor, 200 Foley Brook Boulevard, Wethersfield, Conn. 06107.

SUPPLEMENTARY INFORMATION:

AUTHORITY

Section 18 of the Occupational Safety and Health Act of 1970 ("the Act," 29 U.S.C. 651) provides that a State which desires to assume responsibility for the development and enforcement of standards relating to any occupational safety and health issue with respect to which a Federal standard has been promulgated may submit a plan to the Assistant Secretary of Labor for Occupational Safety and Health ("Assistant Secretary") describing in detail the proposed program. Regulations promulgated pursuant to the act at 29 CFR part 1956 provide that a State may submit a State plan for the development and enforcement of occupational safety and health standards applicable only to employees of the State and its political subdivisions ("public employees"). Under these regulations the Assistant Secretary will approve a State plan for public employees if, in her judgement, the plan provides for the development and enforcement of standards relating to hazards in employment covered by the plan which are or will be at least as effective in providing safe and healthful employment and places of employment for public employees as standards promulgated and enforced under section 6 of the Federal Act. In making this determination the Assistant Secretary will consider, among other things, the criteria and index of effectiveness set forth in 29 CFR 1956, subpart B.

BACKGROUND

A State plan for the enforcement of occupational safety and health standards in Connecticut was approved by the Assistant Secretary on December 28, 1973 (38 FR 10152; 29 CFR 1952.300 and seq.). This plan included coverage of
private workplaces as well as a program for public employees. By an act of the Connecticut General Assembly, effective July 1, 1978 (P.A. 77-610), the Connecticut Occupational Safety and Health Act was amended to exclude private employers. The Connecticut Department of Labor, Occupational Safety and Health Division, under the direction of the Governor, has adopted the plan as the State plan for public employees only. A letter from Gov. Ella Grasso to the Assistant Secretary, dated September 19, 1977, the State has agreed to withdraw the existing State plan upon approval of the plan for public employees only.

DESCRIPTION OF THE PLAN

The plan designates the Connecticut Department of Labor as the State agency responsible for administering the plan throughout the State. The Connecticut Occupational Safety and Health Act, as amended, is the principal regulatory document for work-related health and safety, and pursuant to P.L. 93-279, the Connecticut Legislature in 1973 and amended as follows: P.A. 74-176, P.A. 75-285, P.A. 77-107, and P.A. 77-610. Under the legislation the Connecticut Department of Labor, Occupational Safety and Health Division, has full authority to enforce and administer all laws and rules protecting the safety and health of employees of the State and its political subdivisions. In addition, the legislation is accompanied by a statement of the Governor's support and a legal opinion that it meets the requirements of the Connecticut Constitution.

The plan establishes procedures for variances and the protection of employees from hazards under a variance; insurance in response to complaints; provides employer and employee representatives an opportunity to accompany inspectors and to call attention to possible violations before, during, and after inspections; notification to employees of their representatives when no compliance action is taken as a result of alleged violations, including informal review; notification of employees of their protection; protection of employees against discharge or discrimination in terms and conditions of employment; adequate safeguards to protect trade secrets; provision for prompt notices to employers and employees of violations of standards and abatement requirements; sanctions against employers for violation of standards and orders; employers' right to appeal citations for violations, abatement periods and proposed penalties; employees' right to appeal abatement periods; and employee participation in review proceedings. Also included are provisions for right of entry for inspection, prohibition of advance notice of inspection, and the requirement for both employers and employees to comply with the applicable rules, standards and orders, and employer obligations to maintain records and provide reports as required. Further, the plan provides assurances of a fully trained adequate staff and sufficient funding.

Any interested person(s) may request an informal hearing concerning the proposed plan or any part thereof. If the Assistant Secretary finds that substantial objections are filed, she may hold a hearing on the subjects and issues involved.

DECISION

The Assistant Secretary will consider all relevant comments, arguments, and requests submitted in accordance with this notice or any hearing afforded pursuant to 29 CFR part 1902.11. She will thereafter issue her decision on the approvability of the plan, which decision will be published in the Federal Register.

Signed at Washington, D.C., this 20th day of July 1978.

EJLA BINGHAM, Assistant Secretary of Labor.

[FR Doc. 78-20645 Filed 7-27-78; 8:45 am]

[1410-01]

COPYRIGHT ROYALTY TRIBUNAL

[37 CFR Part 302]

FILING OF CLAIMS TO CABLE ROYALTY FEES; PROOF OF FIXATION

Proposed Rule With Respect to Proof of Fixation of Copyrighted Works

AGENCY: Copyright Royalty Tribunal.

ACTION: Proposed rule.

SUMMARY: The proposed rule establishes the policy and procedures of the Copyright Royalty Tribunal concerning the submission to the Tribunal during proceedings for the distribution of cable royalty fees of evidence of the fixation of works in a tangible medium as required by section 102(a) of the Copyright Act. Under the proposed rule, the filing of tangible fixations would not be required, and controversies concerning the fixation of works would be resolved on the basis of other appropriate evidence. It is necessary that the proposed rule be adopted so that claimants to cable royalty fees will have timely knowledge of the evidence of fixation that may be required by the Tribunal.

DATES: Comments must be received on or before August 21, 1978.

ADDRESS: Interested persons should submit 10 copies of their comments to Chairman, Copyright Royalty Tribunal, *1111 20th Street NW, Washington, D.C. 20036.

FOR FURTHER INFORMATION CONTACT:

Thomas C. Brennan, Chairman, Copyright Royalty Tribunal, 202-653-5175.

SUPPLEMENTARY INFORMATION:

Section 111(d)(6) of the act for General Revision of the Copyright Law directs the Copyright Royalty Tribunal to provide for the distribution of cable royalty fees, and to resolve controversies concerning the distribution of such fees among copyright owners and claimants. Section 102(a) establishes as one of the conditions of copyright protection that a work be fixed in a tangible medium of expression.

Shortly after the constitution of the Copyright Royalty Tribunal, the agency was requested to establish a policy concerning the evidence that may be required to resolve disputes as to whether a particular work which is the subject of a claim was fixed in a tangible medium. In an advisory letter of January 31, 1978, the Copyright Royalty Tribunal stated that participation in the royalty distribution proceedings does not require copyright owners to preserve and submit to the Copyright Royalty Tribunal simultaneous fixations of live transmissions. Subsequently in the Federal Register of May 5, 1978 (43 FR 19424), in connection with the publication of the proposed rule as to the filing of claims to cable fees, the Copyright Royalty Tribunal invited comments as to “what proof of fixation, other than the visual video tape or film, should be required in a royalty distribution proceeding.” Comments were requested to consider “such form of proof as affidavits from authorized personnel, and the technical feasibility of preserving an identifiable frame or frames from each program.” Seven comments were received by the Copyright Royalty Tribunal.

The majority of the comments expressed the view that any requirement that fixation of live transmissions be established by submission of frames, although technically feasible, would be burdensome, expensive, and of limited value as proof of actual fixation. However, the Motion Picture Association of America believes that “some material evidence should be required as independent affirmative proof of fixation.”

The proposed rule provides that in the event of a controversy as to whether a work was fixed in a tangible medium, the CRT will not require the...
submission of tangible fixations in whole or in part. Any such controversy would be resolved on the basis of affidavits, other documentary evidence, and such oral testimony as may be necessary.

Such proposed rule reads as follows:

Under 17 U.S.C. 116(c)(2), 37 CFR Ch. III is amended by adding a new § 305.4, as follows:

§ 305.4 Justification of claims.
(a) Not later than the first day of November of each year, every person or entity which has filed a claim pursuant to § 305.2 shall file with the Copyright Royalty Tribunal a statement claiming the proportionate share of compulsory license fees for which such person or entity believes is entitled. The statement shall include a detailed justification for the requested entitlement and shall also include such specific information as the Copyright Royalty Tribunal may require by regulation or order.
(b) The entitlement justification statement required by subsection (a) need not be filed with the Copyright Royalty Tribunal if it has been determined by the Tribunal that there is no controversy as to the distribution of royalty fees.

§ 305.5 Forms.

The Copyright Royalty Tribunal does not provide printed forms for the filing of claims.

Thomas C. Brennan, Chairman, Copyright Royalty Tribunal.

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PROPOSED RULES

FOR FURTHER INFORMATION CONTACT:
Thomas C. Brennan, Chairman, Copyright Royalty Tribunal, 202-653-5175.

SUPPLEMENTARY INFORMATION:
Section 116(c)(2) directs the Copyright Royalty Tribunal to adopt regulations whereby persons claiming to be entitled to compulsory license fees for the performance of nondramatic musical works by coin-operated phonorecord players may file claims to such fees. The Tribunal in the Fernald Register of February 14, 1978 (43 FR 6226), published an advance notice of proposed rulemaking. The proposed rule is to be distinguished from the proposed rule published on May 12, 1978 (43 FR 20513), concerning access to establishments in which phonorecord players are located.

Such proposed rule reads as follows:

Under 17 U.S.C. 116(c)(2), 37 CFR Chapter III is amended as follows:

By adding a new Part 305, to read as follows:

PART 305—CLAIMS TO PHONORECORD PLAYER (JUKEBOX) ROYALTY FEES

§ 305.1 General.

§ 305.2 Time of filing.

§ 305.3 Content of claims.

§ 305.4 Justification of claims.

§ 305.5 Forms.


§ 305.1 General.

This regulation prescribes procedures pursuant to 17 U.S.C. 116(c)(2), whereby persons claiming to be entitled to compulsory license fees for public performances of nondramatic musical works by means of coin-operated phonorecord players shall file claims with the Copyright Royalty Tribunal.

§ 305.2 Time of filing.

During the month of January in each year every person claiming to be entitled to phonorecord player fees for performances of nondramatic musical works during the preceding calendar year shall file a claim with the Copyright Royalty Tribunal. Claimants may file jointly or as a single claim. A performing rights society shall not be required to obtain from its affiliates separate authorizations, apart from their standard affiliation agreements, for purposes of this filing and fee distribution.

§ 305.3 Content of claims.

The claims filed shall include the following information:
(a) The full legal name of the person or entity claiming compulsory license fees. Performing rights societies are not required to include lists of affiliates to whom distributions would be made by such societies.
(b) The full address, including a specific number and street name or rural route, of the place of business of the person or entity.
(c) A specific agreement to accept as final the determination of the Copyright Royalty Tribunal in any controversy concerning the distribution of royalty fees, except for the judicial review provided in 17 U.S.C. 810.

§ 305.4 Justification of claims.

(a) Not later than the first day of November of each year, every person or entity which has filed a claim pursuant to § 305.2 shall file with the Copyright Royalty Tribunal a statement claiming the proportionate share of compulsory license fees to which such person or entity believes it is entitled. The statement shall include a detailed justification for the requested entitlement and shall also include such specific information as the Copyright Royalty Tribunal may require by regulation or order.
(b) The entitlement justification statement required by subsection (a) need not be filed with the Copyright Royalty Tribunal if it has been determined by the Tribunal that there is no controversy as to the distribution of royalty fees.

§ 305.5 Forms.

The Copyright Royalty Tribunal does not provide printed forms for the filing of claims.

Thomas C. Brennan, Chairman, Copyright Royalty Tribunal.

[FR Doc. 78-20936 Filed 7-27-78; 8:45 am]

[6560-01]

ENVIRONMENTAL PROTECTION AGENCY

[40 CFR Part 65]

STATE AND FEDERAL ADMINISTRATIVE ORDERS PERMITTING A DELAY IN COMPLIANCE WITH STATE IMPLEMENTATION PLAN REQUIREMENTS

Proposed Approval of an Administrative Order Issued by the State of Idaho Department of Health and Welfare to FMC Corp.

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: EPA proposes to approve an administrative order issued by the State of Idaho Department of Health and Welfare to FMC Corp. The order requires the company to bring air emissions from its elemental phospho-
rus plant in Pocatello, Idaho, into compliance with certain regulations contained in the federally approved Idaho State Implementation Plan (SIP) by July 1, 1979. Because the order has been issued to a major source and permits a delay in compliance with provisions of the SIP, it must be approved by EPA before it becomes effective as a delayed compliance order under the Clean Air Act (the act). If approved by EPA, the order will constitute an addition to the SIP. In addition, a source in compliance with an approved order may not be sued under the Federal enforcement or citizen suit provisions of the act for violations of the SIP regulations covered by the order. The purpose of this notice is to invite public comment on EPA's proposed approval of the order as a delayed compliance order.

DATE: Written comments must be received on or before August 28, 1978.

ADDRESSES: Comments should be submitted to Director, Enforcement Division, EPA, Region X, 1200 Sixth Avenue, Seattle, Wash. 98101. The State order, supporting material, and public comments received in response to this notice may be inspected and copied (for appropriate charges) at this address during normal business hours.


SUPPLEMENTARY INFORMATION: FMC Corp. operates an elemental phosphorus plant at Pocatello, Idaho. The order under consideration addresses emissions from the furnace stack scrubbers, the burden level, and ore crusher at the facility, which are subject to regulations B and P, rules and regulations for the control of air pollution in Idaho. The regulations limit the emissions of particulate matter, visible emissions, and fugitive dust, and is part of the federally approved Idaho State Implementation plan. The order requires final compliance with the regulation by July 1, 1979, through installation of secondary scrubbers on the furnace stacks. A medusa crossover system is to be installed for control of fugitive emissions. The source has consented to the terms of the order and has satisfied all increments due at this time.

Because this order has been issued to a major source of particulate emissions and permits a delay in compliance with the applicable regulation, it must be approved by EPA before it becomes effective as a delayed compliance order under section 113(d) of the Clean Air Act (the act). EPA proposes to approve the order because it satisfies the appropriate requirements of this subsection.

The order is approved by EPA, source compliance with its terms would preclude Federal enforcement action under section 113 of the act against the sources for violations of the regulation covered by the order during the period the order is in effect. Enforcement against the source under the citizen suit provisions of the act (section 304) would be similarly precluded. If approved, the order would also constitute an addition to the Idaho SIP.

All interested persons are invited to submit written comments on the proposed order. Written comments received by the date specified above will be considered in determining whether EPA may approve the order. After the public comment period, the Administrator of EPA will publish in the Federal Register the Agency's final action on the order in 40 CFR Part 65. The provisions of 40 CFR Part 65 will be promulgated by EPA soon, and will contain the procedure for EPA's issuance, approval, and disapproval of orders under section 113(d) of the act. In addition, part 65 will contain sections summarizing orders issued, approved, and disapproved by EPA. A prior notice proposing regulations for part 65, published at 40 FR 14876 (April 2, 1975), will be withdrawn, and replaced by a notice promulgating these new regulations.

(42 U.S.C. 7413, 7601)


DONALD P. DUBois,
Regional Administrator, Region X.

[FR Doc. 78-20359 Filed 7-27-78; 8:45 am]

LEGAL SERVICES CORPORATION

[45 CFR Part 1602]

FREEDOM OF INFORMATION ACT

Amendments to the Regulations

AGENCY: Legal Services Corporation.

ACTION: Proposed amendment.

SUMMARY: The Legal Services Corporation proposes to amend regulations issued in accordance with the Freedom of Information Act. The only substantive change would be in the fees charged for locating and reproducing materials requested under the act. The fees have been adjusted to reflect actual cost to the Corporation. Other changes are technical or stylistic in nature.

DATES: Comments must be received on or before September 11, 1978.


FOR FURTHER INFORMATION CONTACT:

Stephen S. Walters, 202-376-5113.

SUPPLEMENTARY INFORMATION:

Section 1005(g) of the Legal Services Corporation Act, 42 U.S.C. 2996d(g) provides that the Corporation shall be subject to the provisions of the Freedom of Information Act, 5 U.S.C. 552.

A final regulation was published in the Federal Register on November 13, 1975 (40 FR 52947). The only substantive change the proposed amendment is in section 1602.13, Fees. These have been adjusted to reflect the actual charge to the Corporation of locating and reproducing materials requested under the Freedom of Information Act. The provisions of section 1602.13 authorizing waiver of fees under certain conditions remain in effect. Section 1602.5, Regional Records Rooms has been revised to show the addresses of the Corporation's regional offices as of June 15, 1978. The phrases to be deleted from the definitions section are now included in Part 1600, the general Definitions section that was published on May 5, 1976 (41 FR 16811), and applies to all the regulations. The other changes are stylistic.

Accordingly, it is proposed that 45 CFR Part 1602 be revised to read as follows:

PART 1602—PROCEDURES FOR DISCLOSURE
OR PRODUCTION OF INFORMATION UNDER
THE FREEDOM OF INFORMATION ACT

Sec. 1602.1 Purpose.

1602.2 Definitions.

1602.3 Policy.

1602.4 Index of Records.

1602.5 Central Records Room.

1602.6 Regional Records Rooms.

1602.7 Use of Records Rooms.

1602.8 Availability of Records on Request.

1602.9 Invoking Exemption to Withhold a Requested Record.

1602.10 Officials Authorized to Grant or Deny Requests for Records.

1602.11 Denials.

1602.12 Appeals of Denials.

1602.13 Fees.

Authority: Section 1005(g); 42 U.S.C. 2996d(g).

§1602.1 Purpose.

This Part prescribes the procedures by which records of the Legal Services Corporation may be made available pursuant to section 1005(g) of the Legal Services Corporation Act, 42 U.S.C. § 2996d(g), and the Freedom of Information Act, as amended in 1974, 5 U.S.C. 552.

§1602.2 Definitions.

As used in this Part—
(a) "FOIA" means the Freedom of Information Act, as amended in 1974, 5 U.S.C. 552;
(b) "Records" means books, papers, maps, photographs, or other documentary materials, regardless of physical form or characteristics, made or received by the Corporation in connection with the transaction of the Corporation's business and preserved by the Corporation as evidence of the organization, functions, policies, decisions, procedures, operations, or other activities of the Corporation, or because of the informational value of data in them. The term does not include books, magazines, or other materials held for purposes and available through any offici-
ally designated library of the Corporation.

§ 1602.3 Policy
The Corporation will make records concerning its operations, activities, and business available to the public to the maximum extent reasonably possible. Records will be withheld from the public only in accordance with the FOIA and this regulation. Records that may be exempt from disclosure may be made available as a matter of discretion when disclosure is not prohibited by law, and it does not appear adverse to legitimate interests of the Corporation or of any individual.

The Corporation will attempt to provide assistance to requesting parties, including information about how a request may be submitted. The Corporation will act on requests for records in a timely manner.

§ 1602.4 Index of Records.
The Corporation will maintain a current index of records maintained in the central records room, to facilitate access thereto by any member of the public.

(b) Certain records maintained in the central records room described in paragraph (c) of this subsection, there will be available in the central records room the following:
(1) All final opinions, including concurring and dissenting opinions, and orders made in the adjudication of cases;
(2) Statements of policy and interpretations adopted by the Corporation;
(3) Administrative staff manuals and other material to which the public has a right of access;
(4) To the extent feasible, guidelines, forms, published regulations, notices, program descriptions, and other records considered to be of general interest to members of the public in understanding activities of the Corporation or in dealing with the Corporation in connection with those activities.

(c) Certain types of staff manuals or instructions, such as instructions to auditors or inspection staff, or instructions covering certain phases of contract negotiation, that deal with the performance of functions that would automatically be rendered ineffective by general awareness of the Corporation's techniques or procedures, may be exempt from mandatory disclosure even though they affect or may affect the public. These records will not be maintained in the central records room.

(d) Certain records maintained in the central records room, or otherwise made available pursuant to this Part may be "edited" by the deletion of identifying details concerning individuals, to prevent a clearly unwarranted invasion of personal privacy. In such cases, the record shall have attached to it a full explanation of the deletion.

§ 1602.6 Regional Records Rooms.
(a) Each regional office shall have either a specially designated records room similar to the central records room described in § 1602.5 or, if that is not feasible, a designated area within the office, a principal function of which is to serve the public in accordance with the provisions of this Part. The Corporation will endeavor to maintain and have readily available in its regional offices the records described in § 1602.5(b), and will designate a records officer in each regional office to receive and process requests submitted pursuant to this Part.
(b) The regional records rooms as of June 15, 1978, are located at the following addresses:

BOSTON REGIONAL OFFICE, 84 STATE STREET, ROOM 520, BOSTON, MASS. 02101.
NEW YORK REGIONAL OFFICE, 10 EAST 40TH STREET, ROOM 1010, NEW YORK, N.Y. 10016.
PHILADELPHIA REGIONAL OFFICE, 1100 BROAD ST., PHILADELPHIA, PA. 19102.
NORTHERN VIRGINIA REGIONAL OFFICE, 1730 N. LYNDALE STREET, SUITE 900-ROCKVILLE, ARLINGTTON, VA. 22209.
CHICAGO REGIONAL OFFICE, 310 SOUTH MICHIGAN AVENUE, 24TH FLOOR, CHICAGO, ILL. 60604.
ATLANTA REGIONAL OFFICE, 515 PEACHTREE STREET, N.E., NINTH FLOOR, ATLANTA, GA. 30308.
SAN FRANCISCO REGIONAL OFFICE, 177 POST STREET, SUITE 890, SAN FRANCISCO, CALIF. 94104.
DENVER REGIONAL OFFICE, 1280 CHAMPA STREET, SUITE 500, DENVER, COLO. 80202.
SEATTLE REGIONAL OFFICE, 506 SECOND AVENUE, ROOM 1621, SEATTLE, WASH. 98101.

§ 1602.7 Use of records rooms.
(a) Any member of the public who wishes to inspect or copy records regularly maintained in the central or a regional records room may secure access to these records by presenting himself or herself at the records room during business hours. No advance notice or appointment is required, although persons wishing to make extended use of regional office facilities should take account of the possible limitations in these facilities.
(b) Each records room will also be available to any member of the public to inspect and copy records which are not regularly maintained in such room. To obtain such records a person should present his or her request identifying the records to the records officer. Because it will sometimes be impossible to produce these records or copies of them on short notice, a person who wishes to use records room facilities to inspect or copy such records is advised to arrange a time in advance, by telephone or letter requesting made to the records officer of the facility which he or she desires to use. Persons submitting requests by telephone will be advised by the records officer or another designated employing whether a written request would be advisable to aid in the identification and expeditious processing of the records sought. Persons submitting written requests should identify the records sought in the manner provided in § 1602.8(b) and should indicate whether they wish to use the records room facilities on a specific date. The records officer will endeavor to advise the requesting party as promptly as possible if, for any reason, it may not be possible to make the records sought available on the date requested.

§ 1602.8 Availability of records on request.
(a) In addition to the records made available through the records rooms, the Corporation will make such records available to any person in record-
annce with paragraphs (b) and (c) of this section unless it is determined that such records should be withheld and are exempt from mandatory disclosure under the FOIA and §1602.9 of these regulations.

(b) Requests.

(1) A request will be acceptable if it identifies a record with sufficient particularity to enable officials of the Corporation to locate the record with a reasonable amount of effort. Requests seeking records within a reasonably specific category will be deemed to conform to the statutory requirement of a request which “reasonably describes” such records if professional employees of the Corporation who are familiar with the subject matter area of the request would be, with a reasonable amount of effort, to determine which particular records are encompassed within the scope of the request, and to search for, locate, and collect the records with the least burdening or materially interfering with operations because of the staff time consumed or the resulting disruption of files. If it is determined that a request does not reasonably describe the records sought as specified in this paragraph, the response denying the request on that ground shall specify the reasons why the request failed to meet the requirements of this paragraph and shall extend to the requesting party an opportunity to confer with Corporation personnel in order to attempt to reformulate the request in a manner that will meet the needs of the requesting party and the requirements of this paragraph.

(2) To facilitate the location of records by the Corporation, a requesting party should try to provide the following kinds of information, if known: (i) the specific event or action to which the records refer; (ii) the name of the unit or program of the Corporation which may be responsible for or may have produced the record; (iii) the date of the record or the date or period to which it refers or relates; (iv) the type of record, such as an application, a grant, a contract, or a report; (v) personnel of the Corporation who may have prepared or have knowledge of the record; (vi) citations to newspapers or publications which have referred to the record.

(3) The Corporation is not required to create a record to satisfy a request for information. When the information requested exists in the form of several records at several locations, the requesting party should be referred to those sources if gathering the information would unduly burden or materially interfere with operations of the Corporation.

(4) All requests for records under this section shall be made in writing, with the envelope and the letter clearly marked: “Freedom of Information Request.” All such requests shall be addressed to the records officer at the headquarters of the Corporation or at any regional records office. Any request not marked and addressed as specified in this sub-paragraph will be so marked and addressed as soon as it is properly identified, and forwarded immediately to the records officer. A request improperly addressed will not be deemed to have been received for purposes of the time period set forth in paragraph (e) of this section until forwarding to the appropriate office has been effected. On receipt of an improperly addressed request, the records officer shall notify the requesting party of the date on which the time period commenced to run.

(5) A person desiring to secure copies of records by mail should write to the records officer at the headquarters in Washington, D.C. The request must identify the records of which copies are sought in accordance with the requirements of this paragraph, and should indicate the number of copies desired. Fees may be required to be paid in advance in accordance with §1602.13. The requesting party will be advised of the estimated fee, if any, as promptly as possible. If a waiver of fees is requested, the grounds for such request should be included in the letter.

(6) The records officer, upon request for any records made in accordance with this Part, shall make an initial determination of whether to comply with or deny such request and dispatch such determination to the requesting party within 10 days (excepting Saturdays, Sundays, and legal public holidays) after receipt of such request, except for unusual circumstances in which case the time limit may be extended for not more than 10 working days by written notice to the requesting party setting forth the reason for the extension and the date on which a determination is expected to be dispatched. In determining whether to issue a notice of extension of time for a response to a request beyond the 10-day period, Corporation officials shall consult with the Office of the General Counsel. As used herein, “unusual circumstances” are limited to the following, but only to the extent reasonably necessary to the proper processing of the particular request:

(1) The need to search for and collect the requested records from field facilities or other establishments that are separate from the office processing the request;

(2) The need to search for, collect, and appropriately examine a voluminous amount of separate and distinct records which are demanded in a single request or

(3) The need for consultation, which shall be conducted with all practicable speed, with another agency having a substantial interest in the determination of the request, or among two or more components of the Corporation having substantial subject matter interest therein.

(4) If no determination has been dispatched at the end of the 10-day period, or the last extension thereof, the requesting party may deem his request denied, and exercise a right of appeal in accordance with §1602.12.

When no determination can be dispatched within the applicable time limit for a response to a request, the Corporation shall extend to the requesting party an opportunity to confer with Corporation personnel who are separate from the office processing the request not marked and addressed as specified in this paragraph, the responses denying the request on that ground shall specify the reasons why the request failed to meet the requirements of this paragraph and shall extend to the requesting party an opportunity to confer with Corporation personnel in order to attempt to reformulate the request in a manner that will meet the needs of the requesting party and the requirements of this paragraph.

(c) The records officer, upon request for any records made in accordance with this Part, shall make an initial determination of whether to comply with or deny such request and dispatch such determination to the requesting party within 10 days (excepting Saturdays, Sundays, and legal public holidays) after receipt of such request, except for unusual circumstances in which case the time limit may be extended for not more than 10 working days by written notice to the requesting party setting forth the reason for the extension and the date on which a determination is expected to be dispatched. In determining whether to issue a notice of extension of time for a response to a request beyond the 10-day period, Corporation officials shall consult with the Office of the General Counsel. As used herein, “unusual circumstances” are limited to the following, but only to the extent reasonably necessary to the proper processing of the particular request:

(1) The need to search for and collect the requested records from field facilities or other establishments that are separate from the office processing the request;

(2) The need to search for, collect, and appropriately examine a voluminous amount of separate and distinct records which are demanded in a single request or

(3) The need for consultation, which shall be conducted with all practicable speed, with another agency having a substantial interest in the determination of the request, or among two or more components of the Corporation having substantial subject matter interest therein.

(4) If no determination has been dispatched at the end of the 10-day period, or the last extension thereof, the requesting party may deem his request denied, and exercise a right of appeal in accordance with §1602.12.

When no determination can be dispatched within the applicable time limit for a response to a request, the Corporation shall extend to the requesting party an opportunity to confer with Corporation personnel who are separate from the office processing the request not marked and addressed as specified in this paragraph, the responses denying the request on that ground shall specify the reasons why the request failed to meet the requirements of this paragraph and shall extend to the requesting party an opportunity to confer with Corporation personnel in order to attempt to reformulate the request in a manner that will meet the needs of the requesting party and the requirements of this paragraph.

(d) If no determination has been dispatched at the end of the 10-day period, or the last extension thereof, the requesting party may deem his request denied, and exercise a right of appeal in accordance with §1602.12. When no determination can be dispatched within the applicable time limit for a response to a request, the Corporation shall extend to the requesting party an opportunity to confer with Corporation personnel who are separate from the office processing the request not marked and addressed as specified in this paragraph, the responses denying the request on that ground shall specify the reasons why the request failed to meet the requirements of this paragraph and shall extend to the requesting party an opportunity to confer with Corporation personnel in order to attempt to reformulate the request in a manner that will meet the needs of the requesting party and the requirements of this paragraph.

(e) After it has been determined that a request will be granted, the Corporation will act with diligence in providing a substantive response.

§1602.9 Invoking Exemptions to Withhold a Requested Record.

(a) A requested record of the Corporation may be withheld from public disclosure only if one or more of the following categories exempted by the FOIA apply:

(1) Matter which is related solely to the internal personnel rules and practices of the Corporation;

(2) Matter which is specifically exempted from disclosure by statute;

(3) Trade secrets and commercial or financial information obtained from a person and privileged or confidential;

(4) Inter-agency or intra-agency memoranda or letters which would not be available by law to a party other than an agency in litigation with the Corporation;

(5) Personnel and medical files and similar files, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy;

(6) Investigatory records compiled for enforcing the Act or any other law, but only to the extent that the production of such records would (i) interfere with enforcement proceedings, (ii) deprive a person of a right of a fair trial or an impartial adjudication, (iii) constitute an unwarranted invasion of personal privacy, (iv) disclose the identity of a confidential source and, in the case of a record compiled by a criminal law enforcement authority in the course of a criminal investigation, or by an agency conducting a lawful
national security intelligence investigation, confidential information furnished only by the confidential source, (v) disclose investigative techniques and procedures, or (vi) endanger the life or physical safety of law enforcement personnel.

(b) In the event that one or more of the above exemptions applies, any reasonably segregable portion of a record shall be provided to the requesting party after deletion of the portions that are exempt. In appropriate circumstances, subject to the discretion of Corporation officials, it may be possible to provide a requesting party with: (1) A summary of information in the exempt portion of a record or (2) an oral description of the exempt portion of a record. In determining whether any of the foregoing techniques should be employed in accordance with this paragraph or whether an exemption should be waived in accordance with paragraph (c) of this section, Corporation officials shall consult with the Office of General Counsel. No requesting party shall have a right to insist that any or all of the foregoing techniques should be employed in order to satisfy a request.

(c) Records that may be exempted from disclosure pursuant to paragraph (a) of this section may be made available as a matter of discretion when disclosure is not prohibited by law, if it does not appear adverse to legitimate interests of the Corporation, the public, or any person.

§ 1602.10 Official authorized to grant or deny requests for records.

The General Counsel shall furnish necessary advice to Corporation officials and staff as to their obligations under this Part and shall take such other actions as may be necessary or appropriate to assure a consistent and equitable application of the provisions of this Part by and within the Corporation. Other officials of the Corporation shall consult with the General Counsel before denying requests under this Part, or before granting requests for waiver or modified application of an exemption or for categories of documents which the General Counsel determines may present special or unusual problems. The General Counsel, subject to consultation with him where required, the Records Officer, each Regional Director, and each Regional Records Officer are authorized to grant or deny requests under this Part.

§ 1602.11 Denials.

(a) A denial of a written request for a record that complies with the requirements of § 1602.8 shall be in writing and shall include the following:

(1) A reference to the applicable exemption or exemptions in § 1602.9(a) upon which the denial is based;
(2) An explanation of how the exemption applies to the requested records;
(3) A statement explaining why it is deemed unreasonable to provide segregable portions of the record after deleting the exempt portions;
(4) The name and title of the person or persons responsible for denying the request; and
(5) An explanation of the right to appeal the denial and of the procedures for submitting an appeal, including the address of the official to whom appeals should be submitted.

(b) Whenever the Corporation makes a record available subject to the deletion of a portion of the record, such action shall be deemed a denial of the denial, and providing of paragraph (a) of this section.

(c) All denials shall be treated as opinions and shall be maintained and indexed accordingly, subject only to the necessity of deleting identifying information, however, this limitation should constitute a clearly unwarranted invasion of personal privacy.

§ 1602.12 Appeals of denials.

(a) Any person whose written request has been denied is entitled to appeal the denial within 90 days by writing to the president of the Corporation at the headquarters in Washington, D.C. The envelope and letter should be clearly marked: "Freedom of Information Appeal." An appeal need not be in any particular form, but should adequately identify the denial, if possible, by describing the requested record, identifying the official who made the denial, and providing the date on which the denial was issued.

(b) No personal appearance, oral argument, or hearing will ordinarily be permitted on appeal of a denial. Upon request and a showing of special circumstances, however, this limitation may be waived and an informal conference may be arranged with the president or the president’s specifically designated representative, for this purpose.

(c) The decision of the president on an appeal shall be in writing and, in the event the denial is in whole or in part upheld, shall contain an explanation responsive to the arguments advanced by the requesting party, the matters described in § 1602.11(a)(1)-(4), and the provisions for judicial review of such decision under section 552(a)(4) of the FOIA. The decision shall be dispatched to the requesting party within 20 working days after receipt of the appeal, unless an additional period is justified pursuant to § 1602.8(c) and such period taken together with any earlier extension does not exceed 10 days. The president’s decision shall constitute the final action of the Corporation. All such decisions shall be treated as final opinions under § 1602.5(b).

§ 1602.13 Fees.

(a) Information provided routinely in the normal course of doing business will be provided at no charge.

(b) The records officer may waive or reduce fees where special circumstances, including but not limited to the benefit of the general public, warrant. A records officer shall waive fees where the requesting party is indigent unless the fees would exceed $25 and may waive or reduce fees for the request of an indigent where the fees would exceed $25. These provisions will be subject to appeal in the same manner as appeals from denial under § 1602.12.

(c) There shall be no fee charged for services rendered by the Corporation pursuant to this part, unless the charges, as calculated in paragraph (d) of this section, exceed $8.50. Where the charges are calculated to exceed $8.50, the fee shall be the difference between $8.50 and the calculated charges.

(d) Ordinarily, no fee shall be levied where the records requested are not provided or made available. However, if the time expended in processing the request is substantial, and if the requesting party has been notified of the estimated cost pursuant to paragraph (c) of this section, and has been specifically advised that it cannot be determined in advance whether any records will be made available, fees may be charged.

(e) The schedule of charges for services regarding the production or disclosure of the Corporation’s records is as follows:

(1) Search for records and production of information based on the following schedule of direct labor charges: (a) Analyst=$3.50/quarter hour; (b) Computer time: Actual charge; (c) Copies: (1) Reproduction, duplication, or copying of records: $0.10 per page; (d) Reproduction, duplication, or copying of microfilm: Actual charge as incurred; (e) Certification of true copies: $ each.

(f) Where it is anticipated that the fee chargeable under this part will amount to more than $25, and the requesting party has not indicated in advance his willingness to pay such a fee, the requesting party shall be notified of the amount of the anticipeate fee or such portion thereof as can readily be estimated. In such cases, request will not be deemed to hav
been received until the requesting party is notified of the anticipated cost and agrees to bear it. Such a notification shall be transmitted as soon as possible, but in any event within 5 working days, giving the best estimate then available. The notification shall offer the requesting party the opportunity to confer with appropriate representatives of the Corporation for the purpose of reformulating the request so as to meet his needs at a reduced cost.

(g) Where the anticipated fee chargeable under this part exceeds $25, an advance deposit of 25 percent of the anticipated fee may be required. Where a requesting party has previously failed to pay a required fee, an advance deposit of the full amount of the anticipated fee together with the fee due and payable may be required.

(h) The Corporation reserves the right to limit the number of copies that will be provided of any document to any one party, or to require that special arrangements for duplication be made in the case of bound volumes or other records representing unusual problems of handling or reproduction.

ALICE DANIEL, General Counsel, Legal Services Corporation.
[FR Doc. 78-21009 Filed 7-27-78; 8:45 am]

[6820-35] [45 CFR Part 1620]

PRIORITIES IN ALLOCATION OF RESOURCES

AGENCY: Legal Services Corporation.

ACTION: Proposed amendment.

SUMMARY: The Corporation proposes to revise its regulation concerning the priority-setting procedures for recipients who provide legal assistance. This proposal would require that recipients set priorities in a more systematic way and involve clients in every step. This rule is being proposed after the Corporation has considered public comments which were received in response to a previously published proposed rule.

DATES: Comments must be received on or before September 11, 1978.


FOR FURTHER INFORMATION CONTACT:
Stephen S. Walters, 202-376-5113.

SUPPLEMENTARY INFORMATION: Section 1007(a)(2)(C) of the Legal Services Corporation Act requires the Corporation to insure that recipients adopt procedures for determining and implementing priorities in the allocation of their resources for the provision of legal assistance. Section 9(b)(1) of the 1977 amendments to the Legal Services Corporation Act requires that, in setting and implementing priorities, recipients take into account the relative needs of eligible clients "including particularly the needs for service of the part of significant segments of the population of eligible clients with special difficulties of access to legal services or special legal problems "**". The elderly and handicapped are cited as examples of groups with such problems. The legislative history of this provision makes clear that it was not intended to establish a preference for certain groups of eligible clients. Rather, it is intended to insure that the needs of all significant segments of the client community are considered, and that the consideration addresses the need for expanded access to service as well as substantive problems.

A proposed amendment to part 1620 was published for comment on March 17, 1978 (43 FR 11241). Many of the comments received urged revision of the regulation to require recipients to approach the setting of priorities in a more systematic way, and to involve clients in every step. The Corporation recognizes the validity of these concerns and has made substantial revisions in response to them.

Some comments urged that an additional step be added to the priority-setting process, that is, a requirement that the views of clients be documented and a written statement of reasons be prepared whenever those reasons are departed from. Others view such a requirement as inconsistent with the draft's attempt to set out only the basic elements of priority-setting, leaving the details to be worked out by individual recipients in light of their particular needs. The clients' documentation requirement is set forth in the bracketed provision 1620.2(d). The Corporation is particularly interested in receiving comments on the wisdom and helpfulness of including or excluding that section.

At present, Part 1620 reads as follows:

PROPOSED RULES 32831

PART 1620—PRIORITIES IN ALLOCATION OF RESOURCES

Sec. 1620.1 Purpose.
1620.2 Procedure.

AUTHORITY: Sec. 107(a)(2); 42 U.S.C. 2996(a)(2).

§1620.1 Purpose.

This Part is designed to insure that a recipient, through policies adopted by its governing body, takes into account the views of eligible clients, the staff and other interested persons in establishing priorities for allocating its resources in an economical and effective manner, consistent with the purposes and requirements of the Act and other provisions of Federal law.

§1620.2 Procedure.

(a) A recipient shall adopt procedures for establishing priorities in the allocation of its resources. The procedure adopted shall:

(1) Provide for an assessment of the needs of eligible clients in the geographic area served by the recipient, and their relative importance, based on comments from eligible clients solicited in a manner reasonably calculated to reflect the attitudes of all significant segments of the eligible client population. The assessment shall determine the need for outreach, training of the recipient's eligible clients, and support services, as well as substantive legal problems; and

(2) Insure participation by all significant segments of the client community and the recipient's employees in the setting of priorities, in the development of the work plan required by subsection (c), and in the review required by section 1620.3, and provide the opportunity for comment by interested members of the public.

(b) The following factors shall be among those considered by the recipient in establishing priorities:

(1) The needs assessment described in subsection (a)(1) above;
ACTION: Further Notice of Inquiry.
SUMMARY: In the June 27, 1978 issue of the Federal Register (43 FR 27888), the FCC published a Notice of Inquiry and Interim Policy Statement permitting ex parte communications in most informal (notice and comments) rulemaking proceedings, but requiring that such contacts be publicly disclosed. This document gives further notice of inquiry and contains five minor modifications or clarifications of the original notice: Those clarifications or modifications are:
1. The reference to "channel allocations" is changed to "channel assignments".
2. The definition of participants in rulemaking is changed to "all interested persons".
3. Memoranda from outsiders must include the substance of proposed discussion, not just lists of topics, and
4. No due date for response to ex parte presentation will be established.
5. No prior notice of cut off.

DATES: Non-applicable.
FOR FURTHER INFORMATION CONTACT:
Keith H. Fagan, Office of General Counsel, 202-632-7112.

ORDER AND FURTHER NOTICES OF INQUIRY
Adopted: July 17, 1978.
Released: July 18, 1978.

In the matter of: Policies and procedures regarding Ex Parte Communications during informal rulemaking proceedings, Gen. Docket No. 78-187.

In reviewing our original Notice of Inquiry in this docket, FCC 78-405, released June 14, 1978, some matters have come to our attention which we believe require clarification or modification. These are as follows:

1. In paragraphs 3, 10, and 15, we referred to cases involving FM or TV channel allocations. We should have said channel assignments. Both under our former procedures and our proposed new procedures, ex parte contacts are prohibited only in those rulemakings involving changes in the FM or TV table of assignments. Such contacts are not barred (although they must now be disclosed) in rulemakings involving spectrum allocation.
2. In paragraph 17, we stated that the persons outside the Commission to be governed by the new procedures included "Participants in the rulemaking, i.e., those filing or intending to file formal comments." It has been pointed out that this definition is too narrow, since not all participants in rulemakings do file formal comments.

Accordingly, we are substituting for the above language the words "Participants in the rulemaking, i.e., all interested persons." It should be noted, however, that this category still includes public as well as private entities.

Also, the representatives of these interested persons, as well as interceders on their behalf, are still covered by the new procedures.

3. In paragraph 18, we stated that a person wishing to discuss the merits of a proceeding with a Commissioner or staff member should bring with him a "memorandum of the subjects he wishes to discuss." One of the purposes of this requirement is to make it possible for other interested persons to comment on the matters discussed at such meetings. Therefore, this memo should not simply be a list of the topics to be discussed; rather, it should reflect the substance of what the writer actually intends to say about these topics.

4. In paragraph 23, we said that we would give notice of a "date certain" by which responses to ex parte presentations should be made. Upon further reflection, we have decided that it is unnecessary to require that responses be made within a certain time. Accordingly, responses to ex parte presentations will be permissible at any time prior to cutoff.

5. In paragraph 24, we stated that there would be "short prior notice" of the date after which ex parte contact would be cut off. Upon reconsideration, we have determined that any prior notice would defeat the purpose of the cutoff requirement. Therefore, our notice for each docket will simply state that ex parte contacts have been cut off as of the date of the notice.

It is ordered, That the Notice of Inquiry, FCC 78-405, released June 14, 1978, is amended in accordance with the preceding paragraphs.

FEDERAL COMMUNICATIONS COMMISSION,
WILLIAM J. TRICARICO,
Secretary.

[FEDERAL REGISTER Vol. 43, No. 145—FRIDAY, JULY 22, 1978]

[6712-01]

FEDERAL COMMUNICATIONS COMMISSION

[47 CFR Part 1]

[Gen. Docket No. 78-187; FCC 78-517]

POLICIES AND PROCEDURES REGARDING EX PARTE COMMUNICATIONS DURING INFORMAL RULEMAKING PROCEEDINGS

Proposed Reformulation and Extension of Time

AGENCY: Federal Communications Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: Action taken herein proposes the assignement of a class A FM channel to Conway, Ark. It also de-
it was a class C channel from Conway and reassigned to Jacksonville, Ark., to reflect the fact that it already is being used there.

DATES: Comments must be received on or before September 15, 1978, reply comments must be received on or before October 5, 1978.


FOR FURTHER INFORMATION CONTACT:
Mildred B. Nesterak, Broadcast Bureau, 202-522-7792.

SUPPLEMENTARY INFORMATION:
In the matter of amendment of §73.202(b), table of assignments, FM broadcast stations. (Mayflower and Conway, Ark; BC Docket No. 78-220, RM-35885, Notice of Proposed Rulemaking.

Adopted: July 17,1978.

Released: July 24, 1978.

By the Chief, Broadcast Bureau:
1. Petitioner, proposal, comments. (a) Notice of Proposed Rulemaking is given, concerning amendment of section 73.202(b) of the Commission's rules as concerns Mayflower, and Conway, Ark.

(b) Petition for rulemaking was filed by Michael D. Harrison ("petitioner"), requesting the assignment of FM channel 224A to Mayflower, Ark. No responses to the petition were made.

2. Community Data. (a) Location—Mayflower, in Faulkner County, is located approximately 27 kilometers (17 miles) northwest of Little Rock, Ark.
(b) Population—Mayflower—459; Faulkner County—31,578.
(c) Present local aural service—There is no local aural broadcast service in Mayflower.

3. Economic data. Petitioner states that Mayflower is primarily an agricultural area whose major industries are food packing, microfilm and manufacturing. He asserts that there is a particular need for providing local weather information to the farmers and workers. In addition, he states that a local facility would fill an important need for coverage of general events in the community such as nighttime sports, musical programs, school announcements, and discussion of controversial subjects of interest and importance to the community. We are told that Mayflower is served by no local newspapers.

4. Conclusion study. Projection would occur only on the cochannel in two areas: one small area contains the proposed transmitter site and Conway which has an FM assignment; the other is a larger area surrounding Hot Springs, Ark., which has three FM stations.

5. Other considerations. In order to avoid short-spacing to station KOTN-FM, channel 222, Pine Bluff, Ark., a channel 224A station at Mayflower would have to use a site 12.8 kilometers (8 miles) north of Mayflower. This would place the station 1.6 kilometers (1 mile) southwest of Conway, Ark. (pop. 15,510), which has two class C assignments (channels 262, 266) with one of the assignments used at Jacksonville, Ark., some 38 kilometers (24 miles) distant.

6. Although petitioner proposes the assignment of channel 224A to the small community of Mayflower, Conway, seat of Faulkner County, is clearly the population center for this area. It appears that, with transmitter site restriction, the proposed channel's principal service area is Conway rather than Mayflower. We believe, therefore, that it might be more appropriate to assign channel 224A to Conway. This, however, does not forclose use of the channel at Mayflower, since the proximity of the two communities would permit the channel to be licensed as a Mayflower facility under the provisions of §73.203(b), the "10-mile rule."

7. The proposed assignment appears to raise the question of whether a second assignment to a community of 15,510 population would be warranted. However, since one of the presently assigned channels is used at Jacksonville, Conway only really has one FM station. Therefore, we are proposing to amend the FM table to reflect the current usage of the channel at Jacksonville. Conway is large enough to qualify for assignment of a second channel under the Commission's population guidelines. However, assignment of the proposed class A channel would result in the intermixing of class C assignments. In the absence of availability of class C assignments, the Commission has permitted such intermixtures if an interest has been shown to operate under such conditions. Yakima, Wash., 45 FCC 2d 548, 550 (1973); Key West, Fla., 45 FCC 2d 142, 146 (1974). Petitioner should indicate his willingness to operate a class A FM station.

8. Since a second FM assignment is being proposed for Conway, petitioner should submit in his comments a Rouse study showing the number of people who would receive a first or second FM service. In addition, petitioner should show the extent of nighttime service provided by standard broadcast stations so that we can determine whether any first and second aural service would be provided. Anamosa-Iowa City, Iowa, 46 FCC 520 (1974).

9. Comments are invited on the proposal to amend the FM table of assignments (§73.202(b) of the rules), as follows:

City and Channel No.


Jacksonville, Ark; Present: —; Proposed: 226.

10. The Commission's authority to institute rulemaking proceedings; showings required; cutoff procedures used; and filing requirements are set forth below and are incorporated herein. NOTE: A showing of continuing interest is required by paragraph 2 below before a channel will be assigned.

11. Interested parties may file comments on or before September 15, 1978, and reply comments on or before October 5, 1978.

FEDERAL COMMUNICATIONS COMMISSION.
WALLACE E. JOHNSON,
Chief, Broadcast Bureau.

1. Pursuant to authority found in sections 4(d), 5(d)(1), 303 (g) and (r), and 309(b) of the Communications Act of 1934, as amended, and §0.281(b)(b) of the Commission's rules, it is proposed to amend the FM table of assignments, §73.202(b) of the Commission's rules and regulations, as set forth in the Notice of Proposed Rulemaking to which this appendix is attached.

2. Showings required. Comments are invited on the proposal discussed in the Notice of Proposed Rulemaking to which this appendix is attached. Proponent(s) will be expected to answer whatever questions are presented in initial comments. The proponent of a proposed assignment is also expected to file comments even if it only resubmits or incorporates by reference its former pleadings. It should also restate its present intention to apply for the channel if it is assigned, and, if authorized, to build the station promptly. Failure to file may lead to denial of the request.

3. Cutoff procedures. The following procedures will govern the consideration of filings in this proceeding.

(a) Counterproposals advanced in this proceeding itself will be considered, if advanced in initial comments, subject to the terms of this proceeding. Petitioner may comment on them in reply comments. They will not be considered if advanced in reply comments. (See §1.420(d) of Commission rules.)

(b) With respect to petitions for rulemaking which conflict with the proposal(s) in this notice, they will be considered as comments in the proceeding, and public notice to this
FOR FURTHER INFORMATION CONTACT:
Mildred B. Nesterak, Broadcast Bureau, 202-632-7723.

SUPPLEMENTARY INFORMATION:
In the matter of amendment of § 73.302(b), table of assignments, FM broadcast stations. (Atlanta, Mich.), BC Docket No. 78-221, RM-3060.
Notice of Proposed Rulemaking.
Adopted: July 17, 1978.
Released: July 24, 1978.

1. Petitioner, proposal, comments.
(a) Petition for rulemaking filed January 5, 1978, by Edward S. Solomon, Wilderness Broadcasting, Inc. ("petitioner"), proposing the assignment of class C FM channel 223 to Atlanta, Mich. (b) This channel could be assigned without interfering with any existing FM assignments.
(c) Petitioner, the only responding party, states it will apply for the channel if assigned.
(b) Population—Atlanta—800; Montmorency County—5,247.
(c) Local aural service—There is no local aural broadcast service in Atlanta.
3. Economic considerations. Petitioner states that, according to the Northeast Michigan Council, Atlanta's economy is primarily devoted to governmental activities and related services. We are informed that forest related activities, tourism, and some minimal agricultural activity are also factors in the area's economy. Petitioner adds that the largest industrial enterprise in the Atlanta area is Essex Wire Corp. which employs about 400 employees.
4. Additional considerations. Petitioner asserts that the counties of Montmorency, Oscoda, and Alcona have no local aural broadcast service. It claims that the proposed station would cover the news and community affairs of this area.
5. Preclusion study. Assignment of class C channel 223 to Atlanta, Mich., would cause preclusion to two communities in Michigan with populations greater than 1,000, namely, St. Ignace (pop. 2,892) and Onaway (pop. 1,262). St. Ignace has an FM station on its own assignment. Onaway does not have an assigned channel. Petitioner should indicate in its comments whether an alternate FM channel is available for assignment to Onaway.

6. In this case where the community has a population of only 800 persons, it would be the usual practice to assign a class A channel. However, the petitioner requested a class C channel. Such an exception has been made where the class C proposal would bring service to unserved or underserved areas. However, before the Commission is able to determine whether the requested assignment would be in the public interest, additional information is needed. Petitioner should submit in its comments a Roanoke Rapids-Goldsboro, N.C., 9 FCC 2d 672 (1967), studying the figures for the area and number of people who would receive a first and second FM service from a class C station in Atlanta. In addition, petitioner should show the extent of nighttime service provided by standard broadcast stations in the context of first and second aural services. Anamosa-Iowa City, Iowa, 46 FCC 2d 581 (1974). Both first and second FM and first and second aural services should be shown apart from any non-commercial educational FM stations.
7. Comments are invited on the following proposal to amend the table of assignments with regard to the community of Atlanta, Mich.

City and Channel No.
8. The Commission's authority to institute rulemaking proceedings; showings required; cut-off procedures used; and filing requirements are set forth below and are incorporated herein.

Note—A showing of continuing interest is required by paragraph 2 below before a channel will be assigned.
7. Interested parties may file comments on or before September 15, 1978, and reply comments on or before October 5, 1978.

[7 CFR Part 73]
[BC Docket No. 78-221; RM-3060]
FM BROADCAST STATION IN ATLANTA, MICH.

Proposed Changes in Table of Assignments

AGENCY: Federal Communications Commission.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: Action taken herein proposes the assignment of a class C FM channel to Atlanta, Mich. Petitioner, Wilderness Broadcasting, Inc., states the proposed channel would bring the first local broadcast service to a three county area.

DATES: Comments must be filed on or before September 15, 1978, reply comments must be filed on or before October 5, 1978.

expected to file comments even if it only resubmits or incorporates by reference its former pleadings. It should also restate its present intention to apply for the channel if it is assigned, and, if authorized, to build the station promptly. Failure to file may lead to denial of the request.

3. Cut-off procedures. The following procedures will govern the consideration of filings in this proceeding.

(a) Counterproposals advanced in this proceeding itself will be considered, if advanced in initial comments, so that parties may comment on them in reply comments. They will not be considered if advanced in reply comments. (See § 1.420(d) of Commission rules.)

(b) With respect to petitions for rulemaking which conflict with the proposal(s) in this Notice, they will be considered as comments in the proceeding, and public notice to this effect will be given as long as they are filed before the date for filing initial comments herein. If they are filed later than that, they will not be considered in connection with the decision in this docket.

4. Comments and reply comments; service. Pursuant to applicable procedures set out in §§ 1.418 and 1.420 of the Commission's rules and regulations, interested parties may file comments and reply comments on or before the dates set forth in the Notice of Proposed Rulemaking to which the proposal is attached. All submissions by parties to this proceeding or persons action on behalf of such parties must be made in written comments, reply comments, or other appropriate pleadings. Reply comments shall be served on the person(s) who filed comments to which the reply is directed. Such comments and reply comments shall be accompanied by a certificate of service. (See § 1.420 (a), (b), and (c) of the Commission rules.)

5. Number of copies. In accordance with the provisions of § 1.420 of the Commission's rules and regulations, an original and four copies of all comments, reply comments, pleadings, briefs, or other documents shall be furnished the Commission.

6. Public presentation of filings. All filings made in this proceeding will be available for examination by interested parties during regular business hours in the Commission's Public Reference Room at its headquarters, 1919 M Street NW., Washington, D.C. (FPR Doc. 78-20238 Filed 7-27-78; 8:45 am)

PROPOSED RULES

[6712-01]

[47 CFR Parts 81 and 83]

[Gen. Docket No. 78-208; FCC 73-43T]

PROVIDING FOR THE USE OF SINGLE SIDEBAND EMISSION A3J (SUPPRESSES CARRIER) ON THE MARITIME MOBILE SERVICE RADIO TELEPHONE FREQUENCY 2182 KHz

Proposed Rulemaking

AGENCY: Federal Communications Commission.

ACTION: Proposed rulemaking.

SUMMARY: Amendment of the rules to provide for the use of single sideband emission A3J (suppressed carrier) on the maritime mobile service radiotelephone frequency 2182 KHz, effective November 1, 1978. This action completes a Commission program to shift from double sideband (DSB) to single sideband emission in the band 2000-2850 KHz, initiated in 1968, except for certain communications (see supplementary information). This amendment also provides improvement in the maritime mobile service radio distress system.

DATES: Comments must be received on or before August 28, 1978, and reply comments must be received on or before September 8, 1978.


FOR FURTHER INFORMATION CONTACT:

Walter E. Weaver, Safety and Special Radio Services Bureau, 202-632-7197.

SUPPLEMENTARY INFORMATION:

Adopted: July 12, 1978.


In the matter of amendment of parts 81 and 83 to provide for the use of single sideband emission A3J (suppressed carrier) on the maritime mobile service radiotelephone frequency 2182 KHz, effective November 1, 1978, Gen. Docket No. 78-208.

1. Notice of proposed rulemaking in the above-captioned matter is hereby given.

2. In this notice of proposed rulemaking the Commission is proposing amendment of parts 81 and 83 to provide for the use of single sideband (SSB) emission A3J (suppressed carrier) on the maritime mobile service radiotelephone frequency 2182 KHz, effective November 1, 1978. Effective on that date use of SSB emission A3E (full carrier) on 2182 KHz will be discontinued, except for communications:

(1) Between a coast station and vessels of foreign registry;
(2) Between a ship station and foreign coast stations;
(3) Between a ship station and vessels of foreign registry; and (4) between survival craft and coastal or ship stations. Matters pertinent thereto are discussed in the paragraphs which follow:

BACKGROUND—CURRENT STATUS

3. In the proceedings in dockets Nos. 17287, 18307, 18332, and 18333 of the Commission, in 1967 and 1968, initiated a two-part program to effect needed improvements in radio-telephony communications in the maritime mobile service. One part concerned the use of VHF, replacing 2 MHz for short distance communications, and channel splitting to approximately double the number of VHF channels. The second part concerned conversion of the 2 MHz frequencies from double sideband (DSB) to single sideband (SSB).

4. The objectives of the 2 MHz part of the program were concisely stated by the Commission in its notice of proposed rulemaking (docket No. 18307, FCC 68-894, 33 FR 14121), excerpted as follows:

14. ** * * to increase the number of channels, to reduce congestion and interference, to establish VHF as the short-distance communication system in U.S. waters, to effect needed improvements in communications, to enhance the maritime radio safety system, and to provide for future use of radiotelephony by vessels unable to fulfill their communication needs by use of VHF * * * * * *

5. In the proceedings of docket 21089 to implement an Inter-Governmental Maritime Consultative Organization’s (IMCO) resolution pertaining to the Safety of Life at Sea Convention, the continued use of A3 emission was authorized for distress and safety purposes of 2182 KHz under certain conditions. These conditions provided for portable survival craft equipment, and DSB transmitters authorized prior to January 1, 1972, as described in §§ 83.132(a) and 83.132(c)(2). The continued use of A3 emission is primarily responsive to emergency needs when beyond range of VHF communications, and where outdated DSB equipment may be available only for distress and safety communications.

6. In the intervening 9 years since implementing the objectives of the 2 MHz and VHF programs, substantial improvements have been achieved particularly by enhanced service provided through VHF and the shift of users to VHF for coastal and inland communications. In addition, an engineered safety system has been installed by

the U.S. Coast Guard to provide VHF coverage around the periphery of the United States, and on the Great Lakes and major U.S. waterways. The serious congestion on 2 MHz radiotelephone which made it literally ineffective in 1968 has been greatly alleviated by this two-part program, and the longer range capabilities of 2 MHz frequencies made more dependable for those maritime users beyond VHF range who require 2 MHz coverage.

7. While these programs have substantially improved 2 MHz operations, they are not in our opinion satisfactory as concerns the maritime radio system on 2182 kHz. The current difficulties result from transitional measures in using SSB with carrier (A3H) in order to permit intercommunications between various configurations of received and transmitted emissions and receiver detectors. This compromise solution was necessary during the period of SSB implementation, and to satisfy the requirement to intercommunicate with those foreign ships in U.S. coastal areas and survival equipment that still employ A3 emission. The current difficulties affect 2182 kHz safety service through two impacts:

(1) Decreased communications range.

(2) Decreased intelligibility where one station transmits on DSB and the other receives on a SSB receiver.

It is our view that measures must be implemented to correct these difficulties as early as practicable.

CURRENT DIFFICULTIES

8. In examining the two general type complaints referred to above, it is appropriate to note that they both occur when the transitional (A3H) mode of operation is in use, that is, to effect the shift from DSB to SSB. It was necessary to provide a mode of operation (A3H) whereby a vessel fitted with SSB can communicate with vessels fitted with DSB. The A3H SSB mode was selected because the DSB receiver can demodulate the A3H SSB signal and, conversely, the SSB receiver, set in the A3H mode, can demodulate the DSB signal. (The DSB signal must be on frequency, or close thereto.) The A3H SSB mode is not relatively efficient, as compared to the A3A or A3J modes, nor are there any merits to its use other than that it provides a necessary technical vehicle to effect transition from DSB to SSB. An analysis conducted by the Coast Guard indicated that A3H transmissions on 2182 kHz suffer severe degradations at even moderate distances. For example, if a ship is capable of transmitting 80 nautical miles by SSB (A3J), the corresponding predicted coverage by A3H would be 26 nautical miles. These coverage estimates are being validated by the Coast Guard during day-to-day operations. Thus, if confined to A3H emission, the resulting service range of 2182 kHz merely duplicates the distress and safety coverage being provided by DSB instead of those intended users beyond VHF range in the offshore area.

9. In the first case listed above, decreased communications range, transmission on SSB (A3H), reception on a DSB receiver:

The SSB signal suffers in excess of a 3 dB noise power degradation in the DSB receiver. (The DSB receiver bandwidth is more than twice that required to pass the SSB signal.) The SSB (A3H) signal is demodulated by the envelope detector in the DSB receiver, resulting in a 3 dB power loss over that of the corresponding DSB ((A3J) emission on a DSB receiver suffers at least a 6 dB degradation, as compared to reception of DSB on the same receiver.

10. In the second case listed above, lack of or decrease in intelligibility, transmission on DSB, reception on a SSB (A3H) receiver:

With voice communications, when the DSB carried is off-frequency (different from the reinserted carrier), there is an equal and corresponding shift in voice level.

Frequency tolerances, ITU radio regulations, permit ship stations to depart from 2182 kHz by ±436.4 Hz, or survival craft and EPIRB's to depart ±654.6 Hz.

Speech will be unintelligible when DSB carrier is off-frequency by a value of substantially less than 436 Hz. A departure of this magnitude may be beyond the range of the receiver "clarifier" control, or, if provided, circuitry in receivers for automatic frequency control. Distortion and unintelligibility occur also under a number of other conditions, dependent upon the selectivity, detection, and audio systems employed in the particular receiver under consideration, for example: When the DSB sideband is only partially within the pass band of the SSB receiver; or when the DSB carrier falls within the SSB receiver pass band, etc.

In summary, in order to be intelligible on a SSB (A3H) receiver, the carrier of the DSB transmission on 2182 kHz must be within reasonable proximity to the frequency 2182 kHz.

It is apparent that both of the above types of difficulty will disappear once all ships employ the same mode of operation. While this was not possible prior to January 1, 1977, due to the large number of DSB users, it will be possible to do so now as concerns vessels operating in the U.S. coastal areas.

11. The major impediment to U.S. implementation of A3J operation on 2182 kHz is the impact this action may have upon those remaining users not yet converted (waivered U.S. vessels (FCC docket 21089), non-SSB equipped foreign vessels, survival craft radios, and emergency position indicating radio beacons (EPIRB's)). It should be noted that SSB (A3J) emission is authorized on all other MF and HF maritime radiotelephone frequencies. Further, those vessels that transmit A3J (single sideband with carrier) as presently authorized on 2182 kHz do so by electrically reinserting the carrier to the output of the single sideband circuits internal to the equipment. This connection is included in the channel selection switch that automatically provides for reinsertion when set to 2182 kHz, by the emission mode switch. At issue is whether to proceed with full implementation of single sideband in U.S. waters to realize its improved performance in distress and calling coverage on 2182 kHz, or to continue to delay this achievable improvement in U.S. waters until all potential foreign and U.S. DSB users are fully converted. In this respect, the final dates for which A3 or A3H may continue to exist pursuant to international agreement are interpreted as final targets in the International Implementation program rather than a prohibition to orderly implementation. The decisions are influenced by the extent of non-SSB equipment in U.S. waters, and the relative risks in detection of emergency non-SSB transmissions. In any case, the ultimate world conversion to SSB (A3J) on 2182 kHz is being pursued. The following subsections discuss the rationale and impacts pertinent to implementing A3J operation on 2182 kHz.

U.S. Waters

12. The rule amendments adopted by the Commission in the above referred proceedings provide:

(1) That the use of DSB on 2182 kHz, and on other 2 MHz frequencies, be discontinued aboard U.S. registry vessels effective January 1, 1977, and all U.S. coast and shipboard transmitters type accepted for SSB radiotelephony be capable of operation in all three SSB modes, that is for A3A, A3H, and A3J transmissions. Thus, with the exception of DSB equipment retained for emergency and safety use within the provisions of docket 21089, equipment fitted aboard any U.S. registry vessel for use on 2 MHz after January 1, 1977, is capable of SSB operation and of adjustment to one or the other of all three SSB modes. As of the implementation date of this rulemaking, shore stations of the U.S. Coast Guard and Federal Communications Commission licensed public coast stations will be fitted with SSB equipment (receivers) capable of receiving the SSB operating modes.

13. The rule amendments in the above-referred proceedings also provide:

*Not applicable to those public coast stations which have outstanding a rule waiver of the requirement to guard 2182 kHz.
vide, generally, the vessels within VHF range of shore will use VHF and that vessels at greater distances will use the 2 MHz frequencies. The communication range over which VHF is usable is subject to a number of variables, however, a rounded figure of 20 nautical miles is used here to coincide with the distance designed into VHF shore facilities to the U.S. Coast Guard (USCG), which serve the VHF maritime radio safety system on 156.3 MHz. With the VHF maritime radio safety system extending out from shore for a distance of 20 nautical miles, it is reasonable to assume that any vessel in need of assistance will call the USCG on VHF if less than 20 nautical miles from shore or on 2182 kHz if more than 20 nautical miles from shore.

COAST

14. Population estimates of civil ships and vessels beyond 20 nautical miles but within 200 nautical miles offshore of the continental United States on an average day approximate 1750. The statistical distribution* of this population by class and flag is estimated as follows:

<table>
<thead>
<tr>
<th>Type/class</th>
<th>Total</th>
<th>United States</th>
<th>Foreign</th>
</tr>
</thead>
<tbody>
<tr>
<td>Commercial ships</td>
<td>750</td>
<td>500</td>
<td>250</td>
</tr>
<tr>
<td>Fishing vessels</td>
<td>200</td>
<td>700</td>
<td>350</td>
</tr>
<tr>
<td>Recreational and party</td>
<td>100</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td><strong>Totals</strong></td>
<td>1,750</td>
<td>1,300</td>
<td>450</td>
</tr>
<tr>
<td><strong>Percent</strong></td>
<td>.74</td>
<td></td>
<td>.26</td>
</tr>
</tbody>
</table>

These estimates may vary by season, geography, and operational research methodology; however, they are considered generally valid as an average projection. For example, fishing vessels move widely in following particular fish species and foreign fishing vessels may concentrate offshore of New England to increase observed populations in particular areas. Recreational boating similarly may concentrate in offshore areas but normally are centered within the 0.1 percent are beyond approximately 20 nautical miles of shore. Commercial ships in international transit generally are outfitted to utilize high frequency voice and/or telegraph because of extended ranges of movement. Foreign commercial ships primarily call to major ports such as Boston, New York, Norfolk/Baltimore, New Orleans, Galveston/Houston, Los Angeles, San Francisco, and Seattle. As a result, predominant commercial carriage along the U.S. coasts in the zone of interest is by U.S. ships.

15. Whereas essentially all U.S. ships and vessels are SSB equipped pursuant to the program covered by these rules, the population in the offshore zone that may have DSB-only capabilities is unknown other than the assumption that the majority are foreign ships. Based on the 26 percent estimated foreign ships within the offshore zone as reported in DOs examination of all 2182 kHz distress or guard calls to be received on DSB in the last year. Accordingly, the DSB-equipped population offshore of the U.S. coasts is indeed a low percentage and considered less than 5 percent. 16. Accordingly, as we assess the situation at this time, an overwhelming majority (95 percent) of the vessels involved are capable of operating in the SSB A3J mode and the remaining 5 percent are not capable of operating in that mode. If we continue to retain the DSB watch on 2182 kHz for the minority, the majority will receive an inferior service from decreased range and intelligibility difficulties will be removed. The technical benefits of SSB can be realized. In brief, it is our opinion that regardless of the approach taken to solve the needs of the minority, the public interest cannot be served by disregarding the needs of, or by foreing an inferior service upon, the majority. We believe that the public interest demands that first consideration be given to providing a satisfactory service to the large majority of 95 percent. We are, therefore, proposing that effective November 1, 1978, all FCC licensed coast stations involved shift the guard on 2182 kHz to the SSB A3J mode. The DSB user situation (foreign vessels, waiver of the U.S. vessels, etc.) in the 20-200 nautical mile area is discussed below.

17. A coast station fitted with an SSB A3J mode receiver will be able to satisfactorily demodulate DSB transmissions if the carrier is 2152 kHz. A ship station fitted with a DSB receiver, it should, however, be able to receive the SSB A3J mode transmissions from the coast station. In general, we expect that the majority (about 62 percent) of foreign registry vessels will be close enough to 2182 kHz (within approximately 45 Hz) to be clearly demodulated by an SSB A3J mode receiver. Most of the remaining 40 percent also will be within an acceptable range and can be satisfactorily demodulated by the U.S. vessel A3J receiver. In regard to waivered U.S. vessels, the provisions of docket 21809 that permit retention of DSB equipment authorized prior to January 1, 1972, do not include means to evaluate the compatibility of such equipment with an SSB (A3J) system. Accordingly, the Coast Guard will accept short communication checks on 2182 kHz from boaters who continue to rely upon DSB equipment for emergency purposes. However, it should be noted that in 2-month evaluation of watchkeeping using only A3J reception concluded September 30, 1977, by the Third and Fifth Coast Guard Districts, no major problem were detected or reported. Similar tests show that false alarms are totally recognizable from DSB transmissions noting that the Coast Guard uses operator guards rather than autoalarm receivers. In regard to EPIRB's of foreign vessels, the Coast Guard has never experienced a 2182 kHz EPIRB case in U.S. responsible waters. However, tests have shown them to be extremely stable and therefore detectable with DSB receivers. In testing with DSB, further signals as detected by Coast Guard receivers, signals are either understandable or provide sufficient alerting to permit receiver shifts as appropriate.

*Provided by the U.S. Coast Guard.

The trend in the use of 2182 kHz by foreign vessels to the Coast Guard is as follows: Year and Number of distress calls—1971, 164; 1972, 146; 1973, 150; 1974, 94; 1975, 50; and 1976, 55.

The U.S. Coast Guard suggests the shift be made on July 1, 1978. To provide time in which to consider the effect of this change, we have changed that date to November 1, 1978.

FEDERAL REGISTER, VOL 43, NO. 146—FRIDAY, JULY 28, 1978
PROPOSED RULES

INTERNATIONAL WATERS AND NATIONAL WATERS OF OTHER COUNTRIES

18. The situation in international waters is expected to differ from the situation in U.S. waters in regard to the proportion of foreign registry to U.S. registry vessels, that is, the number of foreign registry vessels will substantially increase as compared to the number of U.S. registry vessels. Thus, the number of vessels fitted with DSB may be proportionally greater than the number of SSB-fitted vessels. As far as intership communications and the capability to communicate is concerned, the situation will be unchanged from that described in paragraph 17, above.

19. In national waters of other countries, the situation in regard to intership communications is unchanged from that described in paragraph 17, above. As concerns communication between U.S. registry vessels fitted with SSB and the coast stations of the concerned foreign administration, a situation probability with SSB A3H mode transmitters and DSB receivers, we doubt that any such station will be off-frequency from 2182 kHz by a sufficient amount to present difficulty in demodulating the coast SSB transmission in the ships SSB A3J receiver. As discussed above, it will be necessary that the ship station transmit to these coast stations using the SSB A3H mode.

INTERNATIONAL RADIO REGULATION

20. The radio regulations in No. 1323.1 permit where coast stations provide a watch on 2182 kHz for receiving A3A and A3J emissions, that ship stations may call for safety purposes on A3A and A3J after first calling using A3 or A3H emission. In this proceeding we are recommending that A3J be used for safety purposes or otherwise, in U.S. waters. This would not be in conformity with the procedures set forth in No. 1323.1 of the radio regulations. This is based on a choice between two basic situations: First, whether to serve the needs of the majority of affected vessels using a system which is technically capable of providing communications over the range (2 to 200 miles); or second, to attempt to serve the minority of affected vessels using a system which is technically not capable of providing effective communications. The Commission, of course, does not take lightly international procedures; however, when a situation is clearly inimical to safety we must choose a course of action which will provide greater safety. As discussed herein the U.S. Coast Guard also recognizes the need for our present proposed changes. It must be recognized that the Commission in its MF radiotelephone conversion program to SSB starting in 1968 and completed in 1977, except for 2182 kHz, has been keeping pace with the state of the art while international procedures reflect something less than current technology and were not intended for an SSB environment.

RELATED MATTERS

21. The International Radio Consultative Committee (CCIR), of the International Telecommunication Union, prepared document 8/1063-E which was adopted at the CCIR XIII Plenary Assembly, 1974, on the subject of "Equivalent Powers of Double-Sideband and Single-Sideband Radiotelephone Emissions (Maritime Mobile Service)." This document represents the technically coordinated and agreed opinion on the relative merits of the various DSB and SSB emissions. The benefits from use of SSB emission A3J, as compared to DSB emission A3 and SSB emission A3H, is readily apparent. It is also apparent that if the maritime mobile service is to have a first class safety system on 2182 kHz, that system must be converted to SSB emission A3J.

22. The 1974 WSMARC adopted resolution MAR 2-20 which includes the following:

Resolves (1) That study of the use of class A3A and A3J emissions for distress and safety purposes is required; (2) That this study should be completed in time for a decision on the date for the final conversion to class A3A and A3J emissions on the carrier frequency 2182 kHz to be made by the next competent World Administrative Radio Conference;

Requests the C.C.I.R. to study the above-mentioned subject as a matter of urgent and, if possible, to issue Recommendations sufficiently in advance of the above mentioned conference;

Invites the Inter-Governmental Maritime Consultative Organization to consider the matter as part of the study currently being undertaken of the maritime distress and safety system.

23. It will be noted that the matter of emissions and frequencies to be provided in survival craft equipment has not been treated in the proposed rule amendments. That matter is under continuing study and will be treated at a future date.

24. The proposed amendments to the rules, as set forth in the appendix are issued pursuant to the authority contained in section 305 (c), (f), (g), and (r) of the Communications Act of 1934, as amended.

25. Pursuant to applicable procedures set forth in § 1.415 of the Commission's rules, interested persons may file comments on or before August 28, 1978, and reply comments on or before September 8, 1978. All relevant and timely comments and reply comments will be considered by the Commission before final action is taken in this proceeding, the Commission may also take into account other relevant information before it, in addition to the specific comments invited by this notice.

26. In accordance with the provisions of § 1.419 of the Commission's rules, an original and five copies of all statements, briefs, or comments filed shall be furnished to the Commission. Responses will be available for public inspection during regular business hours in the Commission's public reference room at its headquarters in Washington, D.C.

FEDERAL COMMUNICATIONS COMMISSION,
WILLIAM J. TRICARICO, Secretary.

Parts 81 and 63 of chapter I of title 47 of the Code of Federal Regulations are amended as follows:

PART 81—STATIONS ON LAND IN THE MARITIME SERVICES AND ALASKA-PUBLIC FIXED STATIONS

1. Section 81.104, paragraphs (b) and (d) are amended to read as follows:

§ 81.104 Facilities required for coast stations.

(b) Each coast station using radiotelephony on frequencies in the band 1605–3500 kHz shall be equipped and licensed to transmit on the frequency 2182 kHz and at least one working frequency in that band.

(d) Each coast station licensed to transmit on frequencies in the band 1605–3500 kHz shall be capable of receiving A3J emission on the frequency 2182 kHz and at least one working frequency in that band.

2. In § 81.132, paragraph (a)(2)(i) is amended to read as follows:

§ 81.132 Authorized classes of emission.

(b) Coast stations using radiotelephony;

(d) For frequencies below 29 MHz in § 81.304(a): 2182 kHz—A3J as specified in § 81.304(c) and (d).

3. In § 81.304, paragraphs (c)(5) and (d)(5) are amended to read as follows:

§ 81.304 Frequencies available.

(b) Each coast station using radiotelephony on frequencies in the band 1605–3500 kHz shall be equipped and licensed to transmit on the frequency 2182 kHz and at least one working frequency in that band.

§ 81.304(a) (c) •

FEDERAL REGISTER, VOL. 43, NO. 146—FRIDAY, JULY 28, 1978
§ 83.104 Authorized classes of emission.

(a) • • • • Frequency Band and Classes of Emission

(b) • • • • Stations using radiotelephony:

(1) For frequencies below 23 MHz designated in § 83.351a(4) 2182 kHz A3J.

4. In § 83.201, paragraph (b) is amended to read as follows:

§ 83.201 Watch required during silence periods.

(b) Except for stations on board vessels required by law to be fitted with radiotelegraph equipment, each ship station licensed to transmit by telephony on one or more frequencies within the band 1605 to 3500 kHz shall, during its hours of service for telephony, maintain an efficient watch for the reception of A3J emissions on the authorized carrier frequency 2182 kHz, whenever such station is not being used for transmission on that frequency or for communication on other frequencies in this band. Such watch shall, insofar as is possible, be maintained at least twice each hour for 3 minutes commencing at x h. 00 and x h. 30, Greenwich mean time. Except for messages of distress, urgency, and vital navigational warnings, ship stations shall not transmit on 2182 kHz during the silence periods.

5. In § 83.233, the table is amended to read as follows:

§ 83.233 Frequencies for use in distress.

In case of distress, mobile stations shall, in the bands set forth below, use the frequencies specified when requesting assistance from the maritime service. The preferred types of emission are shown. When a ship station cannot transmit on the designated frequency, it shall use any available frequency on which attention might be attracted.

<table>
<thead>
<tr>
<th>Frequency band</th>
<th>Emission</th>
<th>Carrier frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>405-515 kHz</td>
<td>A2</td>
<td>500 kHz</td>
</tr>
<tr>
<td>1605-3500 kHz</td>
<td>A3J, A3J</td>
<td>2182 kHz</td>
</tr>
<tr>
<td>116-135 kHz</td>
<td>A2, A3, A9</td>
<td>121.5 MHz</td>
</tr>
<tr>
<td>156-162 MHz</td>
<td>F3</td>
<td>156.8 MHz</td>
</tr>
<tr>
<td>225-399.9 MHz</td>
<td>A9</td>
<td>243 MHz</td>
</tr>
</tbody>
</table>

The maximum transmitter power obtainable shall be used.

$\text{§}$ 83.242 Transmission of distress message by a station not itself in distress.

(a) • • • • (b) The transmission of a distress message under the conditions prescribed in paragraph (a) of this section shall be made on either or all of the international distress frequencies (500 kHz radiotelegraph; 2182 kHz or 156.8 MHz radiotelephone) or on any other available frequency on which attention might be attracted.

7. In § 83.248, paragraph (a) is amended to read as follows:

§ 83.248 Urgency message.

(a) The urgency signal and call, and the message following it, shall be sent on one of the international distress frequencies (500 kHz radiotelegraph; 2182 kHz or 156.8 MHz radiotelephone). However, stations which cannot transmit on a distress frequency may use any other available frequency on which attention might be attracted.

8. In § 83.249, paragraph (d) is amended to read as follows:

§ 83.249 Safety signals.

(d) The safety signal and call shall be sent on one of the international distress frequencies (500 kHz radiotelegraph; 2182 kHz or 156.8 MHz radiotelephone). However, stations which cannot transmit on a distress frequency may use any other available frequency on which attention might be attracted.

9. In § 83.365, subparagraph (d) of paragraph (a) is amended to read as follows:

§ 83.365 Procedure in testing.

(a) • • • • (d) Testing of transmitters shall, insofar as practicable be confined to working frequencies without two-way communications; however, 2182 kHz and 156.8 MHz may be used to contact other ship or coast stations when signal reports are necessary. U.S. Coast Guard stations may be contacted on 2182 kHz for test purposes only.

1. In § 83.204, paragraph (b)(2)(D) is deleted.

2. In § 83.106, paragraph (a) is amended to read as follows:

§ 83.106 Required frequencies for radiotelephony.

(a) Each ship radiotelephone station licensed to operate in the band 1605 to 3500 kHz shall be able to transmit and receive A3J emission on the carrier frequency 2182 kHz, and, if the station is used for other than safety communication, it shall be capable also of transmitting and receiving class A3J emission on at least two other frequencies within that band.

3. In § 83.132, paragraph (a)(2)(I) is amended to read as follows:

§ 83.132 Authorized classes of emission.

4. In § 83.360, paragraphs (a)(1)(iii) and (v) are amended to read as follows:

§ 83.360 Frequencies available below 4000 kHz.

(a) • • • •

(1) • • • • (iii) Except as provided in § 81.142(d), the capability of using A3J emission;

5. In § 81.708, paragraph (b)(7) is amended to read as follows:

§ 81.708 Frequencies available.

(b) • • • •

7. In § 83.246, paragraph (a) is amended to read as follows:

§ 83.246 Authorized classes of emission.

(a) • • • •

5. In § 81.708, paragraph (b)(7) is amended to read as follows:

§ 81.708 Frequencies available.

(b) • • • •

8. In § 83.365, paragraph (d) of paragraph (a) is amended to read as follows:

§ 83.365 Procedure in testing.

(a) • • • • (d) Testing of transmitters shall, insofar as practicable be confined to working frequencies without two-way communications; however, 2182 kHz and 156.8 MHz may be used to contact other ship or coast stations when signal reports are necessary. U.S. Coast Guard stations may be contacted on 2182 kHz for test purposes only.

1. Ship stations are, additionally, authorized to receive and transmit using emission A3F for communication with foreign coast stations and with vessels of foreign registry.

2. Ship stations are, additionally, authorized to receive and transmit using emission A3H for communication with foreign coast stations and with vessels of foreign registry.
as "FCC" or "technical" and logged accordingly; or
(ii) (As an interim measure pending final resolution in Docket No. 21089).
When short tests, by vessels which continue to rely upon the use of DSB equipment for distress and safety purposes, are required as a means to evaluate the compatibility of that equipment with an SSB emission A3J system.

10. In §83.484, paragraphs (a) and (d)(2) are amended to read as follows:

§83.484 Radiotelephone transmitter.
(a) The transmitter shall be capable of effective transmission of A3H and A3J emissions on 2182 kHz, 2638 kHz, in accordance with §83.351, and at least two other frequencies within the band 1605 to 2850 kHz available for ship-to-shore or ship-to-ship communication.

(d) The transmitter shall be capable of complying with the range requirement specified in paragraph (c) of this section when:
(1) **

(2) The transmitter has been demonstrated, or is of a type which has been demonstrated, to the satisfaction of the Commission as capable, with normal operating voltages applied, of delivering not less than 50 watts peak envelope power for A3H and A3J emissions on each of the frequencies 2182 and 2638 kHz into either an artificial antenna consisting of a series network of 10 Ohms effective resistance and 200 picofarads capacitance or an artificial antenna of 50 Ohms nominal impedance. Provided, however, that an individual demonstration of the power output capability of the transmitter, with the radiotelephone installation normally installed on board ship, may be required whenever in the judgment of the Commission this is deemed necessary.

11. In §83.488, paragraph (a) is amended to read as follows:

§83.488 Radiotelephone receivers.
(a) The receiver used for maintaining the watch required by §83.202(b) and §83.503(b) shall be capable of effective reception of A3H and A3J emissions, shall be connected to the antenna system specified by §83.494, and shall be present to, and capable of accurate and convenient selection of, the frequencies 2182 kHz, 2638 kHz, and the receiving frequencies associated with the transmitting frequencies provided pursuant to §83.484(a).

12. In §83.514, paragraph (a)(1) is amended to read as follows:

§83.514 Radiotelephone installation.
(a)(1) The radiotelephone installation shall include a transmitter capable of effective reception of A3H and A3J emissions and a receiver capable of effective reception of A3H and A3J emissions within the band 1605 to 2850 kHz; or alternatively, if the vessel is within communication range of a public coast station or U.S. Coast Guard station operating in the band 156 to 162 MHz which maintains an efficient watch for the reception of F3 emission on 156.8 MHz at all times, the vessel shall be capable of effective reception of F3 emission within the band 156 to 162 MHz.

13. In §83.517, paragraphs (a) and (c)(2) are amended to read as follows:

§83.517 Medium frequency transmitter.
(a) The transmitter shall have a peak envelope output power of at least 50 watts for A3H and A3J emissions on 2182 kHz, in accordance with §83.351, and at least one ship-to-shore working frequency within the band 1605 to 2850 kHz enabling communication with a public coast station serving the region in which the vessel is navigated.

(c) **

(2) The transmitter has been demonstrated, or is of a type which has been demonstrated, to the satisfaction of the Commission as capable, with normal operating voltages applied, of delivering not less than 50 watts peak envelope power for A3H and A3J emissions on each of the frequencies 2182 and 2638 kHz into either an artificial antenna consisting of a series network of 10 Ohms effective resistance and 200 picofarads capacitance or an artificial antenna of 50 Ohms nominal impedance. Provided, however, that an individual demonstration of the power output capability of the transmitter, with the radiotelephone installation normally installed on board ship, may be required whenever in the judgment of the Commission this is deemed necessary.

14. In §83.519, paragraph (a) is amended to read as follows:

§83.519 Radiotelephone receiver.
(a) If a medium frequency radiotelephone installation is provided, the receiver used for maintaining the watch required by §83.202(c) shall be capable of effective reception of A3H and A3J emissions, shall be connected to the antenna system specified by §83.526, and shall be present to, and capable of accurate and convenient selection of, the frequencies 2182 kHz, 2638 kHz, and the receiving frequency(s) associated with the ship-to-shore transmitting frequency(s) provided pursuant to §83.517(a).
DATES AND ADDRESSES: Hearings are open to the public and will be held in accordance with the following schedule:

1978 Date, Location and Time

- **August 14,** Marine Resources Center, Pine Knoll Shores, Morehead City, N.C., 7:30 p.m.-9 p.m.
- **August 15,** Downtowner Motor Inn, 201 West Oglethorpe Ave., Savannah, Ga., 7:30 p.m.-9 p.m.
- **August 16,** Ramada Inn, Highway A1A, Treasure Island, Fort Pierce, Fla., 7:30 p.m.-9 p.m.
- **August 21,** Texas A&M University, Agriculture Research and Extension Center, Texas Highway 44, 5 miles west of Corpus Christi, Corpus Christi, Tex., 7-10 p.m.
- **August 21,** Quality Inn, Lake Wright, 6280 Northampton Boulevard, Box 2945, Norfolk, Va. 23502, 7:30 p.m.
- **August 22,** City Council Chambers, City Hall, 1300 Perdido, New Orleans, La., 7-10 p.m.
- **August 23,** City Commission Meeting Room, City Hall, 9 Harrison Ave., Panama City, Fla., 7-10 p.m.
- **August 23,** South Carolina Wildlife and Marine Resources, Department Building, Fort Johnson Rd., Charleston, S.C., 7:30 p.m.-9 p.m.

Written comments should be submitted to the contact person listed below prior to September 2, 1978, to receive full consideration in the amendment process.

FOR FURTHER INFORMATION CONTACT:


WINFRED H. MORRELL, Associate Director, National Marine Fisheries Service.

[FR Doc. 78-20345 Filed 7-27-78; 8:45 am]
DEPARTMENT OF AGRICULTURE
Federal Grain Inspection Service

GRAIN STANDARDS

Request for Transfer of Designation by the Cedar Rapids Chamber of Commerce Grain Service, Inc., Cedar Rapids, Iowa

AGENCY: Federal Grain Inspection Service.

ACTION: Notice.

SUMMARY: Notice that the Cedar Rapids Chamber of Commerce Grain Service, Inc., Cedar Rapids, Iowa, has requested transfer of its designation as an official agency to perform grain inspection services under the authority of the U.S. Grain Standards Act, as amended, to Mr. Florian E. Polaski, who has filed an application for such designation. This notice also notes comments on the proposed transfer and invites other interested persons to make application for designation as an official agency at Cedar Rapids.

DATE: Comments and/or applications must be received by August 29, 1978.

FOR FURTHER INFORMATION CONTACT:

Edith A. Christensen, Federal Grain Inspection Service, Compliance Division, Delegation and Designation Branch, 201 14th Street SW., Room 2405, Auditor Building, Washington, D.C. 20250, 202-447-8525.

SUPPLEMENTARY INFORMATION:
The U.S. Grain Standards Act, as amended (7 U.S.C. 71 et seq.) thereinafter the "act"), has been amended to extensively modify the official grain inspection system. Pursuant to sections 7 and 7A of the act, the Administrator of the Federal Grain Inspection Service (FGIS) has the authority to designate any State or local governmental agency, or any person, as an official agency for the conduct of all or specified functions involved in official inspection (other than appeal inspection), weighing and supervision of weighing of grain, at inland locations where the Administrator determines there is a need for such services (7 U.S.C. 79 and 7 U.S.C. 79a). Under the act, such designation shall terminate triennially but may be renewed in accordance with the criteria and procedure prescribed (7 U.S.C. 79(g)(1) and 79a(c)).

The Cedar Rapids Chamber of Commerce Grain Service, Inc. (Chamber of Commerce), Cedar Rapids, Iowa, has requested that its designation under the act to operate as an official agency at Cedar Rapids, Iowa, be transferred to Mr. Florian E. Polaski, the present Chief Inspector of the Chamber of Commerce. Mr. Florian E. Polaski has applied for designation in accordance with section 7(f)(1) of the act (7 U.S.C. 79(f)(1)) to operate as the official agency at Cedar Rapids, Iowa, to be known as the Cedar Rapids Grain Service, Inc. This application does not preclude other interested persons from making similar applications.

Note.—Section 7(f)(2) of the act (7 U.S.C. 79(f)(2)) provides that not more than one official agency shall be operative at one time for any geographic area as determined by the Administrator.

Interested persons are hereby given opportunity to submit written views or comments with respect to the requested transfer of official agency designation. All views or comments should be submitted in writing, in duplicate, and mailed to the Director's Office, Compliance Division, Federal Grain Inspection Service, 201 14th Street SW., Room 2405, Auditor Building, Washington, D.C. 20250, not later than August 28, 1978.

Under the provisions of section 7(f)(1), interested persons are also given opportunity to make application for designation to operate as an official agency at Cedar Rapids, Iowa, pursuant to the requirements in section 7(f)(1)(A) of the act, as amended (7 U.S.C. 79(f)(1)(A)) and § 26.96 of the regulations (7 CFR 26.96). Persons wishing to apply for designation to operate as an official agency at Cedar Rapids should contact the Compliance Division, Federal Grain Inspection Service, U.S. Department of Agriculture, Washington, D.C. 20250, for the appropriate forms and mail their applications to the Director's Office at the above cited address, not later than August 28, 1978.

Consideration will be given to the views and comments filed and to any applications submitted and to all other information available to the U.S. Department of Agriculture before a final determination is made with respect to the official agency designation. All views, comments and applications submitted pursuant to this notice will be made available for public inspection at the above office of the Director during regular business hours (7 CFR 1.27(b)).


L. E. Bartelt,
Administrator.

[FR Doc. 78-20844 Filed 7-27-78; 8:45 am]

Forest Service

BURLINGTON NORTHERN INC. LAND EXCHANGE PROPOSAL OFFERED LANDS; BEAVERHEAD AND GALLATIN NATIONAL FOREST'S SELECTED LANDS; WESTERN MONTANA

Northern Region—U.S.F.S. Intent to Prepare an Environmental Statement

Pursuant to 102(2)(c) of the National Environmental Policy Act of 1969, the Forest Service, Department of Agriculture, will prepare an environmental statement for Burlington Northern Inc. (BN) proposal to offer its approximately 177,000 acres of land within the Gallatin and Beaverhead National Forests in exchange for national forest lands in western Montanas.

In an April 1977 news release, BN Vice President Bud Merryman says the trade is sought since BN is inhibited from developing its timber resources because of its checkboard pattern of ownership mingled with public lands mainly in the Madison and Gallatin Mountain ranges of southwest Montana. Issues and concerns identified thus far are: effect on programed allowable timber harvest; effect on county revenues; effect on resources; effect on existing rights (mining claims, special uses, etc.); effect on public use; and social effects.

Forest Service Chief John McGuire is the responsible official; Robert Torhelm is the regional forester, northern region; and Vic Standa is the project leader working with personnel from the Bitterroot, Custer, Gallatin, Beaverhead, Lolo, Flathead, and Kootenal National Forests.

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NOTICES

The draft environmental statement is scheduled for completion by July 1979, with a 60-day review period, and the final environmental statement is scheduled for filing in December 1979.

Comments on the notice of intent or on the land exchange proposal should be sent to Robert Torheim, Regional Forester, Northern Region, Federal Building, Missoula, Mont. 59807.

JAMES E. REDD,
Acting Regional Forester,
Forest Service, Northern Region.

[FR Doc. 79-20869 Filed 7-27-78; 3:45 am]

Office of the Secretary

PRIVACY ACT OF 1974

Notice of Systems of Records

Notice is hereby given that the Department of Agriculture, in accordance with 5 U.S.C. 552a(e)(4) and (11), intends to amend the notice of an existing system of records as set forth below.

This notice was originally published in the Federal Register Apr 1979 (August 27, 1975). All the proposed amendments are administrative and are based on operational experience under the Privacy Act. The changes will provide more accurate information for the public.

The amendments to the notice will be adopted July 28, 1978.

System USDA/FS-14, Grazing Permits, Individual, National Forest System, is amended to adequately describe system location, category of records in the system, policies and practices for storing and retrieving records in the system, and record source categories.

The paragraphs are amended to read:

Security location: The records in this system are maintained in the Regional Forester's office as pertains to special limits of some grazing permittees, in the headquarters office of the Forest Supervisors for all permittee records, and offices of District Rangers for duplicate records of those kept by Forest Supervisors. Records are also stored on magnetic tape at the Fort Collins Computer Center. The addresses for Regional Foresters and Forest Supervisors are listed in 36 CFR 200.2, Subpart A, and the addresses for District Rangers are in the telephone directory of the applicable locality under the heading, U.S. Government, Department of Agriculture, Forest Service.

Categories of records in the system: The system contains information on names and post office addresses of permittees; number, kind, and brands of livestock owned; acres, by kind, of land owned which is declared as base property; number and kinds of livestock permitted; race and sex of permittee; type of permits, periods of use, grazing allotments (areas) involved, and whether or not an escrow waiver of term permit privileges exists.

Also included are acres of land owned or leased in addition to base property; tons of dry feed produced or purchased, Bureau of Land Management permits held by Forest Service permittees (number and kind of livestock permitted; race and sex of permittee; type of permits, periods of use, grazing allotments (areas) involved, and whether or not an escrow waiver of term permit privileges exists.

Categories of individuals covered by the system:

Parties who hold permits to graze livestock on Forest Service administered lands are included in this system of records.

Categories of records in the system:

The system contains information on property and post office addresses of permittees; number, kind, and brands of livestock owned; acres, by kind, of land owned which is declared as base property; number and kinds of livestock permitted; race and sex of permittee; type of permits, periods of use, grazing allotments (areas) involved, and whether or not an escrow waiver of term permit privileges exists.

Also included are acres of land owned or leased in addition to base property; tons of dry feed produced or purchased, Bureau of Land Management permits held by Forest Service permittees (number and kind of livestock permitted; race and sex of permittee; type of permits, periods of use, grazing allotments (areas) involved, and whether or not an escrow waiver of term permit privileges exists.

Authority for maintenance of the system:

5 U.S.C. 301; 36 CFR 222.3.

Routine uses of records maintained in the system, including categories of users and the purposes of such uses:

None.

Policies and practices for storing, retrieving, accessing, retaining, and disposing of records in the system:

Storage:

Records are maintained in file folders and on magnetic tape.

Retrievability:

Records in file folders are indexed by name of permittee; records on magnetic tape are retrievable by name, by identification number assigned by Forest Supervisor, characteristics of permittee, or type of grazing use.

Record source categories:

Information in the system comes from individual grazing permittees, or grazing associations, and from Forest Service records of permittees, grazing allotments, and permitted livestock. Race and sex of permittee is included by District Ranger based on observation.

In consideration of the foregoing, notice is hereby given that the revised system will read as set forth below.


BOB BESLAND,
Secretary.
USDA/FS-14

System name:
Grazing Permits, Individual, National Forest System, USDA/FS.

Security location:
The records in this system are maintained in the Regional Forester's office as pertains to special limits of some grazing permittees, in the headquarters offices of the Forest Supervisors for all permittee records, and offices of District Rangers for duplicate records of those kept by Forest Supervisors. Records are also stored on magnetic tape at the Fort Collins Computer Center. The addresses for Regional Foresters and Forest Supervisors are listed in 36 CFR 200.2, Subpart A, and addresses for District Rangers are in the telephone directory of the applicable locality under the heading, U.S. Government, Department of Agriculture, Forest Service.
NOTICES

BURTON S. KOLKO,
Administrative Law Judge.
[FR Doc. 78-20939 Filed 7-27-78; 8:45 am]

[6320-01]
(Order No. 78-7-56; Docket Nos. 32617, 32618)

PAN AMERICAN WORLD AIRWAYS, INC.
Order To Show Cause and Granting Exemption


By application dated May 5, 1978, Pan American seeks authority to carry local traffic between Detroit and Washington, D.C., on flights serving London. On the same date, it asked for exemption authority to carry fill-up passengers on one daily round trip pending final action on its 401 application. Pan American has also petitioned for an order to show cause why its certified application should not be granted. In support of its applications, Pan American asserts that on May 1, 1978, it inaugurated one daily Detroit-Washington (Dulles)-London round trip, and that it is economically inefficient to operate the Detroit-Washington portion of the flights without carrying local traffic; it can no longer route its Detroit-London flights over Boston, as it has in the past, because it no longer has Boston-London authority; in order to continue its Detroit-London one-stop service economically it must operate over a strong intermediate point and the new routing insures continuation of a service greatly benefiting Detroit-London/Europe passengers; since there is no fill-up service to Washington's Dulles International Airport, the proposed fill-up service will fill a gap in the existing Detroit-Washington/Northern Virginia service pattern and will cause little or no diversion from the incumbents, all of whom serve National Airport or BWI; and it will offer a range of stimulative low fares in the market. The Commonwealth of Virginia supports the application.

United Air Lines opposes our grant of the application by means of show-cause proceedings, alleging that the Board cannot legally act on it in this way. United also opposes Pan American's request for exemption, stating that it would not be in the public interest; the proposed operations are not of limited extent since they will increase the frequency of service in the market by approximately 10 percent; and Pan American has not demonstrated any unusual circumstances indicating a need for the requested exemption.

Pan American filed a motion for leave to file an unauthorized document, accompanied by a reply to United's answer. Because Pan American has not provided adequate justification for our receiving the reply, we have decided to deny the motion.

We tentatively conclude that the public convenience and necessity require the issuance of an order to show cause why we should not grant Pan American fill-up authority in this market. We will also grant the carrier an exemption to carry fill-up passengers on one daily round trip pending our final action on the section 401 application.

Our tentative conclusion to issue a show cause order is supported by the following tentative findings. The requested authority will benefit Pan American by enabling it to fill some of its empty seats. It will also benefit the traveling public by providing them with first Detroit service to and from Dulles International Airport, and at low fares. We recognize that Pan American does not have a history of Detroit-Washington operations, and most of our previous orders have considered fill-up rights only in markets in which the applicants have provided service for a sustained period of time. On the basis of Pan American's previous Detroit-Boston-London operations, however, we are confident that the carrier is providing Detroit-London one-stop service primarily to serve the needs of international traffic rather than Detroit domestic passengers. As a result of circumstances beyond its control, Pan American can no longer serve the Boston-London market.

1 In its motion, Pan American did not raise any new facts nor did it demonstrate that United's answer contained new material it could not have anticipated.
2 See Orders 77-10-16, October 6, 1977 and 78-4-138, April 27, 1978. See, however, Order 78-1-135, January 31, 1978 (made final by Order 78-5-26, May 5, 1978) where we granted Delta fill-up rights between Houston and New Orleans, on flights serving Venezuela, in advance of Delta's inauguration of the Houston extension of its New Orleans-Venezuela flights. We based our decision on the facts that Delta already had domestic authority between Houston and New Orleans and that the extension of its New Orleans-Venezuela flights to improve Houston would primarily serve the needs of international traffic.
3 Pan American has served the Detroit-Boston-London market for approximately three decades.

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American's Detroit-Boston-London
Policy and Conservation Act of
the meaning of the National Environmental
duration fill-up authority. We tentatively find
that our action does not constitute a major
service the positions listed
under the provisions of title
13, United States Code, sections 182,
224, and 225, to conduct a 1978
organization survey. It is designed
to collect information on the number
of employees, payrolls, receipts,
geographic location, current
status, and kind of business for the
establishments of multiestablishment
companies.
Consideration for Surveys
Notice is hereby given that the
Bureau of the Census is considering a
proposal under the provisions of title
13, United States Code, sections 182,
224, and 225, to conduct a 1978
organization survey. It is designed
to collect information on the number
of employees, payrolls, receipts, geo-
market, so it must find another inter-
mediate point for its Detroit-London
operations. Accordingly, we believe
that we should extend to it this fill-up
authority.
Our decision to grant an exemption
is justified by the unusual circum-
stances surrounding the loss of Pan
American's Detroit-Boston-London
routings. Enforcement of section
401 of the act, to the extent it
would otherwise prevent Pan Ameri-
can from providing the services au-
thorized here, would be an undue
burden on it by reason of the unusual
circumstances surrounding its oper-
ations and is not in the public interest.
We will give interested persons 30
days following adoption of this order
to show cause why the tentative find-
ings and conclusions we have stated
here should not be made final. We
expect such persons to support their
objections with detailed economic
analysis. Any objector requesting an
oral evidentiary hearing should state,
in detail, why such a hearing is neces-
sary and what relevant and material
facts it would expect to establish
through such a hearing that it cannot
establish by written pleadings. We will
not entertain general, vague, or unsup-
supported objections.4
Accordingly, it is ordered, That:
1. All interested persons be directed
to show cause why the Board should
not issue an order making final the
tentative findings and conclusions we
have reached in this order and author-
ize Pan American World Airways to
transport persons, property, and mail
in interstate air transportation be-
tween Detroit and Washington, D.C.,
on flights in overseas or foreign air
transportation;
2. Any interested persons who object
to the issuance of an order making
final the proposed findings, conclu-
sions, and certificate amendments set
forth here shall, within 30 days after
the date of adoption of this order, file
and serve on all persons listed in para-
graph 7 below a statement of objec-
tions together with a summary of tes-
timony, statistical data, and such evi-
dence they expect to rely on to sup-
port the stated objections; answers
may be filed 10 days after that;
3. If timely and properly supported
objections are filed, we will consider
all the matters and issues raised in
them before taking further action;7
4. In the event no one files objec-
tions, all further procedural steps will
be deemed to have been waived, and
the case will be submitted to the Board
for final action;
5. Pan American be exonerated from
section 401 of the Act and the terms,
conditions, and limitations of its certif-
icate to transport persons, property,
and mail in interstate air transportation
between Detroit and Washington, D.C.,
on one daily round trip in overseas or
International air transportation;
6. The authority granted in para-
graph 5 above shall be effective imme-
diately and continue until 60 days
after final Board decision in Docket
32617;
7. The motion of Pan American for
leave to file an unauthorized docu-
ment be denied; and
8. This order shall be served on Pan
American World Airways, United Air
Lines, and the Commonwealth of Vir-
ginia.
This order shall be published in the
FEDERAL REGISTER.
By the Civil Aeronautics Board.*

PHYLIS T. KAYLOR,
Secretary.
(FR Doc. 78-20940 Filed 7-27-78; 8:45 am)

[6325-01]
CIVIL SERVICE COMMISSION
DEPARTMENTS OF HEALTH, EDUCATION AND
WELFARE, TRANSPORTATION, HOUSING
AND URBAN DEVELOPMENT
Grant of Authority to Make Noncareer
Executive Assignment
Under authority of § 9.20 of Civil
Service rule LX (5 CFR 9.20), the Civil Service Commission authorizes the follow-
ing agencies to fill by noncareer executive assignment the positions listed below:
Department of Health, Education, and Welfare—(1) Deputy Assistant Secretary for Health Policy, Research
and Statistics, Immediate Office, Office of Health Policy, Research and

*All motions or petitions for reconsider-
ation shall be filed within the period al-
lowed for filing objections and we will ent-
ter no further oral requests or peti-
tions for reconsideration of this order.
*All Members concurred.
NOTICES

graphic location, current status, and kind of business for the establishment of multiestablishment companies. The information will be used to update company and establishment changes to the multiestablishment companies in the Standard Statistical Establishment List. The data will have significant application to the needs of the public and to governmental agencies, and are not publicly available from nongovernmental or governmental sources.

The survey, if conducted, shall begin not earlier than December 1, 1978.

Copies of the proposed forms are available on request to the Director, Bureau of the Census, Washington, D.C. 20233.

Any suggestions or recommendations concerning the subject matter of the proposed survey submitted to the Director in writing on or before August 28, 1978, will receive consideration.


MANUEL D. Plotkin,
Director
Bureau of the Census.

[3510–25]

Industry and Trade Administration

DARTMOUTH COLLEGE, ET AL.

Applications for Duty Free Entry of Scientific Articles

The following are notices of the receipt of applications for duty-free entry of scientific articles pursuant to section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89-651; 80 Stat. 987). Interested persons may present their views with respect to the question of whether an instrument or apparatus of equivalent scientific value for the purposes for which the article is intended to be used is being manufactured in the United States. Such comments must be filed in triplicate with the Director, Statutory Import Programs Staff, Bureau of Trade Regulation, U.S. Department of Commerce, Washington, D.C. 20230, on or before August 17, 1978.

Regulations (15 CFR 301.9) issued under the cited act prescribed the requirements for comments.

A copy of each application is on file, and may be examined between 8:30 a.m. and 5 p.m., Monday through Friday, in Room 6886C of the Department of Commerce Building, 14th and Constitution Avenue NW., Washington, D.C. 20230.

Docket No. 78-00287. Applicant: Dartmouth College, Chemistry Department, Steeles Hall, Hanover, N.H. 03755. Article: Temperature Jump Apparatus, Model 120-S. Manufacturer: Hartley Measurements, Ltd., United Kingdom. Intended use of article: This article was used in the course Chem 72—Chemical Dynamics to train chemistry major juniors and seniors in theory and practice of chemical kinetics. Application received by Commissioner of Customs: June 26, 1978.

Docket No. 78-00288. Applicant: University of California, San Diego Scripps Institute of Oceanography, Deep Sea Drilling Project A-031, La Jolla, Calif. 92038. Article: ROCK-EVAL Source Rock Analyzer, EPC FINA Process and Spare Parts. Manufacturer: Technip Geoproduction, France. Intended use of article: The article is intended to be used to determine the genetic potential of sampled rocks to produce hydrocarbons thereby providing a measure useful for safety considerations which are primary in those drilling operation areas which are deemed to have a geologic setting conducive to hydrocarbon generation and/or accumulation. Application received by Commissioner of Customs: June 26, 1978.

Docket No. 78-00289. Applicant: Cornell University, 161 Day Hall, Ithaca, N.Y. 14853. Article: Transmission Electron Microscope, Model HB5 and accessories. Manufacturer: Vacuum Generators, United Kingdom. Intended use of article: The article is intended to be used for the study of polymeric resists, silicon based and compound semiconductor structures, superconductors (niobium, lead), insulators (oxides) and structures at the submicrometer scale. The phenomena to be investigated will include chemical and electronic structure at spatial structures at pattern down to 5 Å and interaction of electrons with materials as preparatory to electron beam lithography. Application received by Commissioner of Customs: June 26, 1978.

Docket No. 78-00290. Applicant: Professional Staff Association of the L.A. County Harbor General Hospital, 1124 West Carson Street, Torrance, Calif. 90010. Article: HN A200 Electrophoresis Apparatus Safety Model complete with accessories. Manufacturer: V. Holm, Denmark. Intended use of article: The article is intended to be used to separate serum and brain protein in an electric field during the study of immunological responses to the nervous system to viral infection. Application received by Commissioner of Customs: June 21, 1978.

Docket No. 78-00292. Applicant: Bureau of Drugs Food and Drug Administration, Building 29, Room 514, 8800 Rockville Pike, Bethesda, Md. 20014. Article: HI-5010 Scanning Attachment for Electron Microscope. Manufacturer: Mahl, Basel, Switzerland. Intended use of article: The article is an accessory to an electron microscope which is being used in conducting ultrastructural studies pertinent to control and research activities concerned with biological products including viral, rickettsial and bacterial vaccines, allergenic products, blood and blood fractions and diagnostic reagents. Application received by Commissioner of Customs: June 23, 1978.

Docket No. 78-00294. Applicant: University of California, Los Angeles, 405 Hilgard Avenue, Los Angeles, Calif. 90024. Article: Gas Chromatograph Mass Spectrometer, Model MS25 and accessories. Manufacturer: KRA07S, Inc., United Kingdom. Intended use of article: The foreign article is intended to be used in research studies in environmental chemistry and insect pheromones. This article will also be used by graduate students in their educational advance toward a Ph. D. degree. Application received by Commissioner of Customs: June 26, 1978.

Docket No. 78-00303. Applicant: College of Medicine of the Burlington Medical Center, 2015 N. Riverside, P.O. Box 10146, Newark, N.J. 07101. Article: LKB 2128-010 Ultratome IV Ultramicrotome and Accessories. Manufacturer: LKB Producter AB, Sweden. Intended use of article: The article is in use for the preparation of cut sections for electron microscopy of biological material including plant, animal and fungal specimens. Normal and disease biological tissues will be embedded in hardened epoxy resins, and other biological materials for sectioning. Investigations will include chiefly ultrastructural studies of the morphology of normal and diseased plant and animal tissues, and electron cytochemical studies aimed at detecting and localizing certain proteins in diseased tissue. The major cytochemical studies proposed are designed to: (a) Detect vascular damage and (b) precisely localize immunoglobulins in natural and experimental autoimmune disorders of the kidney and central nervous system using the immuno-peroxide technique. The article will also be used in the courses Ultrastructure and Cytochemistry which will involve a study of general principles on techniques and the use of the electron microscope to study the fine structure of cells and various cellular organelles and the employment of cytochemical staining methods to localize various enzymes. The objectives of these courses will be to train students in the use and application of electron microscopy and to use the electron microscope in solving individual research problems. Application received by Commissioner of Customs: June 26, 1978.

Docket No. 78-00306. Applicant: University of California at Los Angeles, School of Engineering and Applied Science, 405 Hilgard Avenue, Los Angeles, Calif. 90024. Article: Lumonics
TEA 600A, CO₂ Laser. Manufacturer: Lumonics Research Ltd., Canada. Intended use of article: The article is intended to be used for far-infrared lasers development, a program which consists of using CO₂ lasers to optically pump molecular gases such as Methyl Fluoride, Deuterium Oxide and obtain laser output. These far-infrared lasers are to be used for Takomak plasmas diagnostics. This is part of a line of research in an attempt to find an alternative to oil and other fossil fuels as a source of electrical power. Application received by Commissioner of Customs: June 28, 1978.

Docket No. 78-00307. Applicant: University of Chicago, Operator of Argonne National Lab., 9700 South Cass Avenue, Argonne, Ill. 60439. Article: No. 512 Euluerian Cradle (Huber) with offset Phi circle, and accessory. Manufacturer: Robert Huber, Disstraktion, West Germany. Intended use of article: This article is intended to be used for measurement of Bragg intensities during studies of single crystal inorganic and organic materials, e.g., plutononacidade complexes, TCNQ derivatives, etc. Application received by Commissioner of Customs: June 29, 1978.

Docket No. 78-00308. Applicant: University of Washington, Department of Ophthalmology RJ-10, RR 735 RSB, Seattle, WASH 98105, as a source of ultramicrotome, Model LKB 8800A and accessories. Manufacturer: LKB Produkter AB; Sweden. Intended use of article: The article is intended to be used to prepare brain, nerve and eye specimens for ultrastructural studies on normal physiological tissues, developmental studies on animal systems, cyto and histochemical studies on enzyme and subcellular organelle localization in cells and tissues, morphology, interfaces, and changes in the structure and function of cells induced by changes in their biochemical and physical environments. The article will also be used in courses to train students in the use and application of electron microscopy and to use the electron microscope in solving individual research problems. Application received by Commissioner of Customs: June 29, 1978.

Docket No. 78-00309. Applicant: Indiana University, Department of Biology, Bloomington, Ind. 47401. Article: Ultramicrotome, Model LKB 2128-10 and accessories. Manufacturer: LKB Produkter AB, Sweden. Intended use of article: The article is intended to be used for ultrastructural studies on normal and pathologic plant tissues, developmental studies on laticifer cell systems, cyto and histochemical studies on enzyme and subcellular organelle localization in cells and tissues, membrane interactions at organelle-cytomembrane interfaces, and subcellular changes in cells induced by changes in their biochemical and physical environments. This research will be conducted to further basic knowledge on cell and tissue ultrastructure and to reveal, at the ultrastructural level, the enzyme localization and distributions and interpenetration of cells and tissues developing under normal and pathological conditions. In addition, the article will be used in the course Cell Ultrastructure and Cell Cytochemistry which will involve a study of general principles and techniques and the use of the electron microscope to study the fine structure of cells and various subcellular organelles and the employment of cytochemical staining methods to localize various enzymes and other cellular compounds. Application received by Commissioner of Customs: June 29, 1978.

Docket No. 78-00310. Applicant: St. Francis Hospital, 2230 Lilha Street, Honolulu, Hawaii 96817. Article: Electron Microscope, Model EM 95-2. Manufacturer: Carl Zeiss, West Germany. Intended use of article: The article is intended to be used as an integral part of a training program for undergraduate, graduate, and medical students as well as pathology residents. The article is needed for electron microscopic instruction in the following courses: Courses 601 and 602 in Human Pathology which provide a comprehensive review of the pathologic basis of disease, and Course 699 entitled "Directed Research" provides an in-depth study of the pathology of aging, nutrition, alcoholism, and immunology. Application received by Commissioner of Customs: June 29, 1978.

(Catalog of Federal Domestic Assistance Program No. 11.165, Importation of Duty-Free Educational and Scientific Materials.)

RICHARD M. SEPPA
Director, Statutory Import Programs Staff.

[3510-25]

JOHNS HOPKINS UNIVERSITY
Decision on Application for Duty-Free Entry of Scientific Article

The following is a decision on an application for duty-free entry of a scientific article pursuant to section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89-651, 80 Stat. 897) and the regulations issued thereunder as amended (15 CFR 301).

A copy of the record pertaining to this decision is available for public review between 8:30 a.m. and 5 p.m. in Room 1008E Commerce Building, 14th and Constitution Avenue NW, Washington, D.C. 20229.

Docket No. 78-00410. Applicant: The Johns Hopkins University, Department of Anatomy, 725 North Wolfe Street, Baltimore, Md. 21205. Article: Scanning Electron Microscope, Model JSM-35U, JEOL, Japan. Intended use of article: The article is intended to be used to study biological specimens drawn from the blood, blood producing tissues, and immune system tissues in experiments to be conducted using animals in which these tissues will be selectively treated with drugs, chemicals, and irradiation. In addition, diseases tissues from humans and animals will be studied to gain an understanding of the structure and function of these tissues and to obtain information necessary for treatment and cure of leukemia, anemia, multiple myeloma, and related diseases. The article will also be used in graduate and professional courses in cell biology and histology.

Comments: No comments have been received with respect to this application. Decision: Application denied. An instrument or apparatus of equivalent scientific value to the foreign article; for such purposes as this article is intended to be used, was being manufactured in the United States at the time the foreign article was ordered (August 28, 1976). Reasons: This application is a reapplication of application 76-00165-33-46070 which was denied without prejudice to resubmission on April 1, 1976, for Informational deficiencies. In reply to question 8 in this application the applicant alleged that the structure and function of these tissues and to obtain information necessary for treatment and cure of leukemia, anemia, multiple myeloma, and related diseases. The article will also be used in graduate and professional courses in cell biology and histology.

I. A new standard option Lanthanum Hexaboride (LaB₆) electron gun source which provides a guaranteed resolution of 50A resolution.

II. A new longlife LaB₆, electron source (500 hours) with an ability to be easily changed (filament change takes about half an hour and can be done by most users) and aligned by students.

III. Electronic systems for astigmatism, focusing, and brightness and contrast control which enables the user to get the maximum performance from the article.

IV. Reliability.

The National Bureau of Standards (NBS) advises in its memoranda dated February 8, 1977, and January 25, 1978, respectively that only resolution (feature I above) is pertinent to the applicant's intended use. As amended (15 CFR 301), the regulations issued thereunder as amended (15 CFR 301).

A copy of the record pertaining to this decision is available for public review between 8:30 a.m. and 5 p.m. in Room 1008E Commerce Building, 14th and Constitution Avenue NW, Washington, D.C. 20229.

FEDERAL REGISTER, VOL. 43, NO. 146—FRIDAY, JULY 28, 1978
NOTICES

In response to question 8, in the order listed above, the following is noted:

I. Resolution. The CWIC Model 50A provides a guaranteed resolution of 500A with its broil gun which more than matches the foreign article. In its recommendation NBS discusses the resolution for the foreign such as electron and this statement is very close to the theoretical limit of a thermionic instrument (as opposed to a field emission system) and upon reviewing the issue, found no evidence of the resolution being obtained through the use of an LaB, source on biological material. We know of no evidence to the contrary. Based on the foregoing the Department finds that the CWIC Model 50A matches the foreign article with respect to this pertinent feature.

II. Longlife 50A. Source in the initial submission, Docket No. 76-00195 35-46070, the applicant alleged that the article's long life time (500+ hrs) is a definite teaching aid, because "students cannot be expected to be able to change the tip" and must summon the technician to replace it. In this submission (Docket No. 76-491) the applicant repeats verbatim his response to question 7 in the first submission and in his response to question 8 states, "A point which was made in the original application but which must be emphasized here is that we require an instrument which can be heavily used by both advanced researchers and by medical and veterinary students, graduate students, clinicians, and post-doctoral fellows. From our own experience with the Coates and Welter machines (50A) we learned that a filament change and subsequent realignment takes about 7 hours and can only be performed by highly trained personnel. This is due to the bake time and cooling period required by the Vac-Ion pumps and the complex tip installation procedure. [The article] does not employ Vac-Ion pumps and tip alignment is electromagnetic, and so that equivalent procedure takes about half an hour and can be done by most users." Further, in response to question 8 the applicant alleges that "the extraordinary lifetime of the LaB, tip (500+ hours) and its ability to be easily changed and aligned by students" (emphasis added) is an important advantage of the article.

The Department notes that in the denial without prejudice to resubmission of the initial submission the applicant was informed that the CWIC Model 50A provided a matching guaranteed resolution and that other features cited were not shown to be pertinent, because although they might relate to the operation of the SEM they were not related to the scientific requirements for performance of the work. As noted above, the applicant in this second submission did not add any additional details to the description of his purposes, for example, how the intended research can be performed on the CWIC, in support of justification for duty-free entry. Moreover, the Department notes a significant difference in the applicant's two submissions. In the second submission, the applicant no longer alleges that a technician is necessary to replace the article's long life tip but now states that it can be easily changed and aligned by students.

In accordance with subsection 301.11(k) of the regulations, the determination of scientific equivalency is based on a comparison of the guaranteed specifications of the article and the most closely comparable domestic instrument for these specifications. It must be pointed out that the article nor the model 50A specify guaranteed times for a filament change and subsequent realignment or specify that these operations can be done by most users. However, the Department has learned that these functions can be performed in both instruments in 15 to 20 minutes with the help of convenient external tip alignment controls for the X, Y, Z, axis by personnel who are not highly trained (i.e., prior demonstration is sufficient training for skill in tip replacement). The domestic instrument's literature also indicates that automatic bakeout for convenient tip replacement is provided. Since significant breakdowns will precede actual failure, the importers can plan for an automatic overnight pumpdown with bakeout.

The Department also notes that both instruments provide built-in features which are conducive to usage by large numbers of investigators. The domestic Model 50A provides a prealigned permanent "stay clean" aperture, permanent scintillator, ultra-clean ultra-high vacuum system which provides a three minute pumpdown time with normal specimens, and a long life (2 months to 1 year) field emission gun which operates at room temperature. The article provides a heated aperture, vacuum system which pumps down in 10 minutes, and a long life LaB, gun (500+hours). NBS advises that the life expectancy of any electron source is essentially a factor of how many such as vacuum, current saturation, temperature control, alignment, quality of materials and aperture control. NBS advises that the service and maintainability of the LaB, tip in the article is a convenience feature within the meaning of Subsection 301.2 (n) of the regulations and not pertinent for the described work.

Finally, the applicant's claims concerning an SEM loafed by CWIC must be addressed. The applicant states that "while the Coates and Welter Co. offered the same resolution, their microscope was consistently unable to perform to specifications even with the constant maintenance company." This statement implies that the applicant loaned a CWIC Model 50A SEM, (the only CWIC instrument with a 50A guarantee available at that time). The Department has determined that the applicant was actually loaned a Model 104A, a less expensive instrument with lower capability than the article and a guaranteed resolution of 50A. Apparently, this particular instrument is more likely to break down (and possible abuse) as a demonstrator in various areas of the country. It was in the applicant's possession for less than 2 months.

Although the applicant's experience (7 hour filament change with realignment) has been covered above, it must be noted that this experience was gained on an instrument that might not be expected to perform nearly so well as one that has been accepted as meeting specifications after purchase (as had been the case with many CWIC instruments). In any event, while an institution's previous experience with the products of a particular manufacturer may enter into its buying decisions, such experience is not an objective criterion that the Department can rely on in making the requisite equivalency determination under Pub. L. 89-651.

III. Astigmatism, Focus, Brightness and Contrast.

A. Astigmatism and Focus.—The CWIC Model 50A provides for rapid correction of astigmatism to an acceptable level (less than 2 months) and focus which are immediately observable on a 12-inch CRT monitor. This feature helps enable users with varying experience to obtain maximum performance from the Coates and Welter Model 50A. Further, NBS advises that an electronic system for astigmatism control is provided (but not essential) and, therefore, not pertinent within the meaning of Subsection 301.2 (n) of the regulations in adjusting astigmatism to an acceptable level for high quality micrographs (high resolution). In this connection, NBS points out that the ability to correct the causes of astigmatism as aperture contamination, applied kilovolts, working distance, specimen interaction, and lens adjustment are all factors which may relate to the importation of the optical field with operator control. But aside from the question of pertinency, NBS advises that the CWIC Model 50A is a precision instrument which is capable of providing a high depth of focus and astigmatism control matching that of the foreign article. NBS reinforces this advice by pointing out that micrographs of biological material available from CWIC show excellent quality, which is directly related to astigmatism and focusing. Thus, the Department finds that the astigmatism and focusing aspects of feature III are not grounds for duty-free entry.

B. Brightness and Contrast.—The Model 50A provides an Automatic Gain Control (AGC) amplifier that automatically sets the brightness and contrast to accommodate a wide range of specimen characteristics, manual overrides on the gamma control, edge enhancer as well as brightness and contrast controls which provide the operator with the capability to optimize electron micrograph parameters. Thus, the Department finds that the Model 50A matches the technical with respect to brightness and contrast control. Moreover, the Department notes that the optional automatic contrast and brightness (ACB) control the only system for controlling brightness and con-
trast in the literature supplied by the applicant, was not ordered with the foreign article. Therefore, in accordance with Subsections 301.2(d) and 301.6(a)(3) of the regulations, this feature cannot be a factor in our deliberation.

IV. Reliability.—In response to Question 8, the applicant describes his “on loan” use for about 2 months before the article was ordered as evidence on which not get publication quality pictures. The applicant summarizes this experience by stating that while CWIC offered the same resolution (as the article) the CWIC SEM was consistently unable to perform to specifications, even with constant maintenance by the domestic firm which was unable to correct serious problems with the loan instrument’s photographic and stage assemblies. As noted in our coverage of feature II above the loan instrument was the Model 104A. As previously stated, the loan instrument which had poor guaranteed resolution than the article, might be expected to have problems not found in a new instrument accepted after purchase as meeting its guaranteed specifications. In this connection, it is noted that this has been the case with many CWIC SEM’s, including the Model 59A. Also, NBS advises that micrographs of biological materials available from the domestic manufacturer show excellent quality.

In a prior case, Docket No. 75-00213, 58-46070, it was held that all applications (including CWIC) were not reliable, NBS advised that the applicant’s claims regarding the unreliability of domestic manufacturers’ SEM’s are not found in fact and are not a matter of general understanding in the field of scanning electron microscopy. In connection with this prior case, our scientific consultants at HEW pointed out that reliability is a cost of ownership associated with the level of maintenance and is not a pertinent specification within the meaning of Subsection 301.2(n) of the regulations. This position is one which has been consistently followed by the Department over the years.

In the general information which can lead to a direct quantitative comparison of the reliability (i.e., ability to conform to specifications without excessive breakdown) of two instruments is seldom available. When a specifications is “guaranteed” by the manufacturer is stating, in effect, that necessary steps have been taken to verify ability to meet this obligation. Thus a guaranteed specification presupposes a determination of reliability to some “engineered” CWIC SEM. CWICs may manufacturers neither issue quantitative specifications on reliability nor guaranteed reliability.

Without strong and substantive support for our conclusion on the record, which is not available here, that the reliability of the two instruments were measurably different and the difference in reliability precluded performance of the work intended, reliability cannot be considered a justifiable basis for duty-free entry under Pub. L. 89-651. While reputations with respect to reliability which are derived from personal experience or word-of-mouth claims may enter into a person’s decision to buy a particular instrument, such cannot serve as objective basis for duty-free entry.

Based on the foregoing considerations, the NBS advice and our own review of the application, as well as other factual information in our possession (specifications, textbooks, etc.), we find that at the time the foreign article was ordered the CWIC Model 50A was of equivalent scientific value to the foreign article for such purposes as the foreign article is intended to be used.

(Ratalog of Federal Domestic Assistance Program No. 11.16x, Importation of Duty-Free Educational and Scientific Materials.)

RICHARD M. SEPPA,
Director, Statutory Import
Programs Staff.

[FR Doc. 78-20941 Filed 7-27-78; 8:45 am]

[3510-25] NORTH CAROLINA STATE UNIVERSITY, ET AL.
Applications for Duty-Free Entry of Scientific Articles

The following are notices of the receipt of applications for duty-free entry of scientific articles pursuant to section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 90-651; 80 Stat. 897). Interested persons may present their views with respect to the question of whether an instrument or apparatus of equivalent scientific value for the purposes for which the article is intended to be used is being manufactured in the United States. Such comments must be filed in triplicate with the Director, Statutory Import Programs Staff, Bureau of Customs, Department of Commerce, Washington, D.C. 20230, on or before August 17, 1978.

Regulations (15 CFR 301.9) issued under the cited act prescribe the requirements for comments. A copy of each application is on file, and may be examined between 8:30 a.m. and 5 p.m., Monday through Friday, in Room 6866C of the Department of Commerce Building, 14th and Constitution Avenue NW., Washington, D.C. 20230.

Docket No. 78-00311. Applicant: North Carolina State University, Department of Geosciences, 228 Withers Hall, Raleigh, N.C. 27695. Article: Find (5) recording electronic microprobes, model 4. Manufacturer: Aardena Instruments Co., Norway. Intended use of article: The article is intended to be used for studies of Gulf Stream meanders and eddies along the North Carolina continental shelf and slope. The phenomena to be investigated will include current patterns derived from personal experience or word-of-mouth claims may enter into a person’s decision to buy a particular instrument, such cannot serve as objective basis for duty-free entry.

Based on the foregoing considerations, the NBS advice and our own review of the application, as well as other factual information in our possession (specifications, textbooks, etc.), we find that at the time the foreign article was ordered the CWIC Model 50A was of equivalent scientific value to the foreign article for such purposes as the foreign article is intended to be used.

(Ratalog of Federal Domestic Assistance Program No. 11.16x, Importation of Duty-Free Educational and Scientific Materials.)

RICHARD M. SEPPA,
Director, Statutory Import
Programs Staff.

[FR Doc. 78-20941 Filed 7-27-78; 8:45 am]

[3510-25] NORTH CAROLINA STATE UNIVERSITY, ET AL.
Applications for Duty-Free Entry of Scientific Articles

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Regulations (15 CFR 301.9) issued under the cited act prescribe the requirements for comments. A copy of each application is on file, and may be examined between 8:30 a.m. and 5 p.m., Monday through Friday, in Room 6866C of the Department of Commerce Building, 14th and Constitution Avenue NW., Washington, D.C. 20230.

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Based on the foregoing considerations, the NBS advice and our own review of the application, as well as other factual information in our possession (specifications, textbooks, etc.), we find that at the time the foreign article was ordered the CWIC Model 50A was of equivalent scientific value to the foreign article for such purposes as the foreign article is intended to be used.

(Ratalog of Federal Domestic Assistance Program No. 11.16x, Importation of Duty-Free Educational and Scientific Materials.)

RICHARD M. SEPPA,
Director, Statutory Import
Programs Staff.

[FR Doc. 78-20941 Filed 7-27-78; 8:45 am]
Docket No. 78-00317. Applicant: Ellis Fischel State Cancer Hospital, 115 Business Loop 70 West, Columbia, Mo. 65201. Article: LKB 8800A Ultratome III Ultramicrotome. Manufacturer: LKB Produkt AB, Sweden. Intended use of article: The article is intended to be used to prepare tissue specimens for the study of cellular structure of various cancer tumors. Application received by Commissioner of Customs: July 5, 1978.

Docket No. 78-00318. Applicant: Southern California College of Optometry, 2001 Associated Road, Fullerton, Calif. 92631. Article: Nageo Anatomoscope. Manufacturer: Schmidt and Haensch, West Germany. Intended use of article: The article is intended to be used to identify persons with deficiencies of color vision through quantitative assessment of the type and degree of severity of a color vision deficiency. The article will be used in Visual Science 322, a course devoted to the theories, experimental basis, and testing of human color vision. In addition, the article will be used in the teaching clinics of the college for diagnosis of color vision anomalies. Application received by Commissioner of Customs: July 5, 1978.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials.)

RICHARD M. SEPPA, Director, Statutory Import Programs Staff.

[FR Doc. 78-20942 Filed 7-27-78; 8:45 am]

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

BILATERAL TEXTILE NEGOTIATIONS WITH THE GOVERNMENT OF INDIA

Soliciting Public Comment


On April 21, 1974, the Committee for the Implementation of Textile Agreements published a notice in the Federal Register (39 FR 13307) conveying the Committee's intention to announce, and solicit comment on, U.S. Government actions implementing the GATT Arrangement Regarding International Trade in Textiles and the bilateral textile agreements entered into thereunder.

Pursuant to the terms of the Arrangement and the Bilateral Cotton, Wool and Man-Made Fiber Textile Agreement of December 30, 1977, as amended, between the Governments of the United States and India, the Committee anticipates holding consultations with the Government of India beginning early in September 1978. Any party wishing to express a view or provide data or information with regard to the treatment of any product under the bilateral agreement and any other aspects thereof, or comment on production or availability of domestic textile products, is invited to submit such in ten copies to Mr. Robert E. Shepherd, Chairman of the Committee for the Implementation of Textile Agreements and Deputy Assistant Secretary for Domestic Business Development, U.S. Department of Commerce, Room 3025, 14th Street and Constitution Avenue NW., Washington, D.C. 20230.

Views, data or information submitted under this procedure will be available for public inspection in the Office of Textiles, Room 2015, U.S. Department of Commerce, 14th and Constitution Avenue NW., Washington, D.C. 20230, and may be obtained upon written request. Whenever practicable, public comment may be invited concerning views, comments or information received from the public in any instance. The Committee for the Implementation of Textile Agreements considers appropriate for further consideration.

The solicitation of comments on any negotiation, consultation, market disruption or any other matter pursuant to this notice is not a waiver in any respect of the exemption contained in 5 U.S.C. 553(a)(1) and 554(a)(4) relating to matters which constitute "a foreign affairs function of the United States."

ROBERT E. SHEPHERD, Chairman, Committee for the Implementation of Textile Agreements, and Deputy Assistant Secretary for Domestic Business Development.

[FR Doc. 78-20912 Filed 7-27-78; 8:45 am]

COMMITTEE FOR PURCHASE FROM THE BLIND AND OTHER SEVERELY HANDICAPPED

PROCUREMENT LIST 1978

Proposed Additions

AGENCY: Committee for Purchase from the Blind and Other Severely Handicapped.

ACTION: Proposed additions to procurement list.

SUMMARY: The Committee has received proposals to add to Procurement List 1978 commodities to be produced by workshops for the blind and other severely handicapped.

COMMENTS MUST BE RECEIVED ON OR BEFORE: August 30, 1978.

ADDRESS: Committee for Purchase from the Blind and Other Severely Handicapped, 330 Independence Avenue, S.W., Washington, D.C. 20230.
NOTICES

DEPARTMENT OF ENERGY

ISSUANCE OF DECISIONS AND ORDERS BY THE OFFICE OF HEARINGS AND APPEALS

Week of June 5 through June 9, 1978

Notice is hereby given that during the week of June 5 through June 9, 1978, the decisions and orders summarized below were issued with respect to appeals and applications for exception or other relief filed with the Office of Hearings and Appeals of the Department of Energy. The following summary also contains a list of submissions which were disapproved by the Office of Hearings and Appeals and the basis for the dismissal.

APPEALS


R. D. Bowerman d.b.a. Executive Center Gulf (Bowerman) appealed from a Remedial Order which was issued to the firm by FEA Region VI on May 21, 1974 which required FEA Region VI found that during the period November 1, 1973 through July 24, 1974 Bowerman sold motor gasoline to its customers at prices which exceeded the maximum permissible levels calculated in accordance with 10 CFR 212.33. In its Appeal, Bowerman challenged the Remedial Order on several procedural grounds. Bowerman's first claim was that any action by the DOE to collect the overcharges was barred by the Texas statute of limitations. The DOE found that although the Emergency Petroleum Allocation Act (EPAA) did not contain a relevant statute of limitations, the application of a 3 year statute of limitations to enforcement action of this type would be inconsistent with the national policy expressed in the EPAA. In this connection, the DOE found that its enforcement activities, a crucial element of the regulatory program which was intended to achieve the EPAA's policy objectives, would be seriously jeopardized if the agency were precluded from instituting compliance actions as a result of peculiarities and differences among the states. In its Reply, Bowerman requested that the firm have access to the records of FEA with respect to the exceptions filed. The DOE found that the enforcement proceeding against Bowerman was part of a program which was designed to further the objective of preventing distribution of petroleum products at equitable prices among all regions of the country. Moreover, the DOE noted that the public itself would be the direct beneficiary of the enforcement action inasmuch as the Remedial Order required Bowerman to offer for sale all grades of gasoline at reduced prices. Consequently, the DOE held that the Texas statute of limitations was not applicable to the enforcement action against Bowerman. Bowerman also claimed that he never received the Notice of Probable Violation (NPV) which was issued to him by the FEA prior to the issuance of the Remedial Order and as a result was not accorded the full procedural safeguards to which he was entitled. The DOE rejected this contention, noting that Bowerman had signed a United States Postal Service receipt indicating that Bowerman had received the NPV. Finally, Bowerman contended that the DOE previously made a determination not to proceed against him for violating the price regulations and therefore should be barred from reopening this matter in the absence of a showing that the agency now possessed new information regarding these violations. This argument was rejected. The DOE determined that even though an investigation of a firm's compliance with the price regulations during a particular period may have been closed, the agency's regulations permitted a further investigation at any time that circumstances so warranted. The DOE concluded that in the present proceeding the circumstances justified the reissuance of the NOPV. Accordingly, the Bowerman Appeal was denied.

Gulf Oil Corp., Tulsa, Okla., D.EE--2612, crude oil

Gulf Oil Corp. filed an Application for Exception from the provisions of 10 CFR, Part 212, Subpart D which, if granted, would permit Gulf to sell the crude oil produced from the Kiefer Unit located in Creek County, Okla., at upper tier ceiling prices. In considering the exception application, the DOE found that the cost of producing crude oil from the Kiefer Unit was increased to a level where it now exceeds the revenue that the firm can obtain from the sale of the crude oil at the lower tier ceiling price. The DOE therefore concluded that Gulf had no economic incentive to continue to produce crude oil from the property, and that it was highly unlikely that the crude oil from the Kiefer Unit could be recovered by any other firm in the absence of exception relief. The DOE therefore concluded that the application of the ceiling price rule resulted in a gross inequity to Gulf and the other working interest owners. In order to provide the working interest owners with an incentive to continue to produce, the DOE granted exception relief which permits Gulf to sell 34.88 percent of the crude oil produced from the Kiefer Unit for the benefit of the working interest owners at upper tier ceiling prices for a six month period of time.


Texaco, Inc. (Texaco) appealed from a partial denial by the Information Access Officer (IAO) that Texaco, Inc. had withheld from the IAO all copies of the documents from which it had submitted under the Freedom of Information Act (FOIA). In its Appeal, Texaco requested that the DOE order the release of the documents which the Information Access Officer had withheld from the firm. The Information Access Officer denied the firm access to those documents on the grounds that they are intra-agency memoranda which are exempt from mandatory public disclosure under the provisions of 5 U.S.C. 552(b)(4). In considering the Appeal, the DOE found that the documents which were withheld from the firm generally contained information of a confidential nature. The DOE also determined that the material which was withheld is precisely the type of information which Exception 5 of the FOIA was designed to protect from disclosure. In addition, the DOE determined that there were no portions of the documents which contain
purely factual material which could be easily segregated from the policy discussions contained in the documents and released to Texas. Finally, the DOE determined that the Information Access Officer's response to the Texaco Request for Information adequately set forth the grounds upon which the Stay Order was held. Accordingly, the Texaco Appeal was denied.

**Texas Gas Exploration Corp., Washington, D.C., FEE-4460, propane**

Texas Gas Exploration Corp. (Exploration) filed an Application for Exception from the provisions of 10 CFR 212.165 for propane which, if granted, would permit the firm to increase the banks of unrecovered product costs which it is generally permitted to reflect in price increases in future months. In its Application, Exploration stated that because of the ambiguity surrounding the correct application of the definition of "transaction" prior to issuance of Ruling 1977-5, it incorrectly calculated its May 15, 1978, weighted average selling price for propane which was below the maximum permissible selling price under the Price Regulations, and a consequent loss of substantial revenues on its sales of this product during the period from 1975 through 1977. Exploration requested that its banks of unrecovered product costs be increased by an amount equal to the revenues which it lost during the 1975-1977 period.

In considering the Exploration request, the DOE noted that in **Quincy Oil Co., Inc., 1 DOE Par. 80,222 (Mar. 15, 1978),**, it had held that due to the confusion surrounding the proper application of the term "transaction" to variable-price contracts, the standard for retroactive relief should not be applied in evaluating applications for exception from the definition of transaction set forth in Ruling 1977-5. The DOE determined that the application of the transaction definition to the fixed-price contract in the present case was ambiguous as well. The DOE further found that Exploration had adopted a reasonable interpretation of the Price Regulations and had thereby charged lower prices than it was lawfully permitted to charge under the Regulations. The DOE also determined that market conditions during the relevant period would have permitted the firm to charge the lawful higher prices. Under these circumstances, the DOE concluded that the firm should be permitted to recover the revenues which it had foregone. However, since only one customer was undercharged as result of the firm's misinterpretation of the exception relief approved was limited to the prospective prices charged to that customer.

**REQUESTS FOR EXCEPTION**

**Charter Oil Co., Jacksonville, Fla., DEX-0491, Crude oil**

Charter Oil Co. (Charter) filed an Application for Exception from the provisions of 10 CFR 211.67 (the Entitlement Program) which, if granted, would relieve the firm of its obligation to purchase entitlements beginning with the quarter which would prevent it from receiving either its historical profit margin or its historical return on invested capital (ROIC). The DOE determined that the exception relief was warranted under the criteria set forth in Delta Refining Co., 2 FEA Par. 57-11 (Oct. 7, 1975), Delta Refining Co., 2 FEA Par. 57-6 (June 8, 1975). The DOE found that Charter's projections indicated that even if the firm were relieved of its entire entitlement purchase obligation for the current fiscal year it would still not attain either its historical profit margin or ROIC. Accordingly, in a Proposed Decision and Order issued to the firm on Mar. 28, 1978, the DOE tentatively granted Charter an exception which relieved it of any obligation to purchase entitlements during the 6-month period Mar. 31 through Aug. 31, 1978. Since no Notice of Objection was filed to the Proposed Decision in accordance with the regulations which govern exception matters, this order was issued to Charter in final form on Mar. 20, 1978.

**Standard Oil Co. (Indiana), Chicago, IL, FEX-4813, Natural Gas Liquids**

On Oct. 28, 1977, the DOE issued a Proposed Decision and Order to the Standard Oil Co. (Indiana) (Standard) which denied the firm's request for an extension of relief permitted under the provisions of 10 CFR 212.105. The Proposed Decision refused to extend the exception relief which Standard had previously been granted. Instead, it increased its selling prices for the natural gas liquids produced at its Elmwood plant. In a subsequent Proposed Decision and Order issued to the firm on Mar. 15, 1978, the DOE held that Standard's future nonproduct cost levels warranted another extension of relief, and granted exception relief permitting Standard to increase its Elmwood natural gas liquids selling prices for the three calendar quarters ending June 30, 1977. On Dec. 8, 1977, Standard filed a Statement of Objections to the Proposed Decision. Standard contended that it did not seek an extension of relief but instead wanted relief based upon the most recently completed six month period for purposes of the June 30, 1977, Proposed Decision. Standard argued in its current application should have been construed by DOE as an initial request for exception and that the calculation of the amount of relief should be based upon a comparison of only the most recently completed quarter's costs with those of the base period. In considering the firm's contentions, the DOE noted that it had previously considered and rejected a virtually identical argument in Shell Oil Co., 1 DOE Par. 80,222 (Mar. 15, 1978). As indicated in the Shell Decision, if the permitted firms to selectively utilize their costs from interim periods to justify the magnitude of the exception relief which it sought, an amount of relief granted could be unrepresentatively high because of factors such as the timing of accounting record entries. In order to avoid this potential problem, the DOE only determines the amount of unrecovered nonproduct costs which have been incurred at a point in time which is related to the comparison of base quarter costs with those incurred during a current period which encompasses all of the quarters which have elapsed since a previous grant of exception relief. Since Standard failed to present any convincing evidence that the principles of the Shell Decision should be reversed the DOE concluded that the calculation of the amount of relief which would be appropriate in this case was inappropriate. Accordingly, the Proposed Decision and Order was issued in final form.

**Sun Co., Inc. Dallas, Tex., FXE-4780, FXE-4785, FXH-4820, FXH-4823, FXF-4825, FXF-4828, FXF-4847, Natural Gas Liquids**

On Sept. 30, 1978, the Sun Co., Inc. (Sun) was issued a Proposed Decision and Order which tentatively extended previously granted exception relief. Sun contended that it should be permitted to increase its selling prices above maximum levels permitted under 10 CFR 212.165 for natural gas liquids and natural gas liquid products which it produced at several of its natural gas processing plants. On Nov. 15, 1977, Sun filed a Statement of Objections to the Proposed Decision and Order. In its Statement of Objections, Sun contended that the DOE erred in utilizing the most recently completed six month period for purposes of the June 30, 1977, Proposed Decision. In that Decision the DOE stated that utilization of the most recent 3-month period results in a better approximation of the firm's future nonproduct cost levels in which the relief is intended to defray. In considering Sun's contentions, the DOE noted that it had previously rejected an argument that was predicated on the filing of an Appeal involving exception relief granted to other of its plants. See Sun Company, 1 DOE Par. 80,557 (Nov. 15, 1977). In that Decision the DOE stated that the utilization of a 6-month period is rational since it takes into consideration all of the data which can reasonably be used in the previous grant of exception relief. Since Sun failed to present any convincing evidence that the use of a 6-month period is erroneous or that its application to this case is inappropriate, the DOE issued the Proposed Decision and Order in final form on June 5, 1978.

**SUPPLEMENTAL ORDERS**

**Arizona Fuels Corp., Salt Lake City, Utah, DEX-0075, Crude Oil**

On Jan. 16, 1978, the DOE issued a Proposed Decision and Order to the Arizona Fuels Corp. (Arizona Fuels) which tentatively concluded that an Application for Exception which the firm had submitted from the provisions of 10 CFR 211.67 (the Entitlement Program) should be granted. On Jan. 17, 1978, the DOE issued a Further Decision and Order to the firm staying its obligation to purchase entitlements to the extent specified in the Proposed Decision and Order. Arizona Fuels subsequently filed a Statement of Objections to the January 16 Proposed Decision. No final determination had as yet been issued with respect to the Proposed Decision. However, under the specific terms of the January 17 Stay Order Arizona Fuels was required to commence to pay the stay relief even though the 6-month exception relief period specified in the Proposed Decision and Order had expired. Accordingly, the January 17 Stay Order was amended to specify that the stay relief was applicable only to the 6-month period January 1–June 30, 1978.
through June 1978 pending the issuance of a final determination with respect to the Proposed Decision and Order.

Laketon Asphalt Refining, Inc., Evansville, Ind., DEX-0076, Crude Oil

On Feb. 10, 1978, the DOE issued a Proposed Decision and Order to Laketon Asphalt Refining, Inc. (Laketon) which tentatively concluded that an Application for Exception which the firm had submitted from the provisions of 10 CFR 211.67 (the Entitlement Program) should be granted. On Feb. 10, 1978, the DOE issued a further Decision and Order to the firm stating its obligation to purchase entitlements to the extent specified in the Proposed Decision and Order. Laketon subsequently filed a Statement of Objections to the February 10 Proposed Decision. No final determination has as yet been issued with respect to the Proposed Decision. However, under the specific terms of the February 10 Stay Order, Laketon would continue to receive stay relief even though the 6-month exception relief period specified in the Proposed Decision and Order had expired. Accordingly, the February 10 Stay Order was amended to specify that the stay relief was applicable only to the six month period February through July 1978 pending the issuance of a final determination with respect to the Proposed Decision and Order.

Newhall Refining Co., Inc., Dallas, Tex., DEX-0077, Crude Oil

On February 10, 1978, the DOE issued a Proposed Decision and Order to Newhall Refining Co., Inc. (Newhall) which tentatively concluded that an Application for Exception which the firm had submitted from the provisions of 10 CFR 211.67 (the Entitlement Program) should be granted. On Feb. 10, 1978, the DOE also issued a Decision and Order to the firm stating its obligation to purchase entitlements to the extent specified in the Proposed Decision and Order. Newhall subsequently filed a Statement of Objections to the February 10 Proposed Decision. No final determination had as yet been issued with respect to the Proposed Decision. However, under the specific terms of the February 10 Stay Order, Newhall would continue to receive stay relief even though the six month exception relief period specified in the Proposed Decision and Order had expired. Accordingly, the February 10 Stay Order was amended to specify that the stay relief was applicable only to the six month period February through July 1978 pending the issuance of a final determination with respect to the Proposed Decision and Order.

No. 2 (Home) Heating Oil, Washington, D.C., DEX-0092 through DEX-0098, Evidentiary Hearing Home Heating Oil

The Office of Hearings and Appeals of the Department of Energy recently received 11 Petitions to Intervene submitted by organizations that wish to participate in an evidentiary hearing which will be held in August 1978 concerning No. 2 (home) heating oil. These Petitions were filed pursuant to Rule 2 of the rules of procedure which the Office of Hearings and Appeals adopted on an interim basis on Apr. 18, 1978. In a previous Decision and Order, the Office of Hearings and Appeals granted the Petitions of three organizations, the Energy Policy Task Force of the Consumer Federation of America, the American Petroleum Institute, and the Antitrust Division of the Department of Justice. Accordingly, these petitioners were designated as parties to the August 1978 evidentiary hearing. The Office of Hearings and Appeals also held a conference on June 8, 1978 in order to allow the remaining petitioners to comment further on the reasons why they should be accorded party status. After considering the views which were presented at the June 6 conference and reviewing the eight pending Petitions to Intervene, the DOE determined that two of the petitioners, the National Oil Jobsers Council (NOJC) and the Atlantic Refiners Company, should be accorded party status in this proceeding. In this regard, the DOE found that the written petitions and oral presentations made by NOJC and ARCO at the June 6 conference indicated that their participation in the evidentiary hearing would contribute substantially to the purpose and scope of the hearing. With respect to the remaining petitioners, the Office of Hearings and Appeals determined that they should not be accorded party status at the evidentiary hearing.

SUMMARY DECISIONS

In the following case, stay relief from the provisions of 10 CFR, Part 212 which had previously been granted to sellers of Gasohol in the State of Illinois and to members of FS Services and Affiliated Companies that sell Gasohol in the States of Iowa and Wisconsin was extended to all sellers of Gasohol in the State of Iowa: Iowa Development Commission, Des Moines, Iowa, DES-0094.

DISMISSAL

The following submissions were dismissed following a statement by the applicant indicating that the relief requested was no longer needed: City of Long Beach Dept. of Oil Properties, Long Beach, Calif., FMR-014; Lezest Oil & Gas Co., Austin, Tex., DEX-945 & DEX-946.

Copies of the full text of these Decisions and Orders are available in the Public Docket Room of the Office of Hearings and Appeals, Room B-120, 2000 M Street NW., Washington, D.C. 20461, Monday through Friday, between the hours of 9 a.m. and 5 p.m., e.d.t., except Federal holidays. They are also available in Energy Management: Federal Energy Guidelines, a commercially published loose leaf reporter system.

RICHARD T. TEBROW, Acting Director, Office of Hearings and Appeals.


(IFR Doc 78-20671 Filed 7-27-78; 8451)

[3126-01]

CASES FILED WITH THE OFFICE OF HEARINGS AND APPEALS

Week of July 7 Through July 14, 1978

Notice is hereby given that during the week of July 7 through July 14, 1978, the appeals and applications for exception or other relief listed in the appendix to this notice were filed with the Office of Hearings and Appeals of the Department of Energy.

Under the DOE's procedural regulations, 10 CFR, part 205, any person who will be aggrieved by the DOE action sought in this case may file with the DOE written comments on the application within 10 days of service of notice, as prescribed in the procedural regulations. For purposes of those regulations, the date of service of notice shall be deemed to be the date of publication of this notice or the date of receipt by an aggrieved person of actual notice, whichever occurs first. All such comments shall be filed with the Office of Hearings and Appeals, Department of Energy, Washington, D.C. 20461.


THOMAS L. WIEKER, Acting Director, Office of Hearings and Appeals.

FEDERAL REGISTER, VOL. 43, NO. 146—FRIDAY, JULY 28, 1978

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APPENDIX.—List of cases received by the Office of Hearings and Appeals
(Week of July 7 through July 14, 1978)

<table>
<thead>
<tr>
<th>Date</th>
<th>Name and location of applicant</th>
<th>Case No.</th>
<th>Type of submission</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do.</td>
<td>Warrier Asphalt Co. of Alabama, Washington, D.C.</td>
<td>DEX-0093</td>
<td>Supplemental order. If granted: The DoE would review the entitlements exception relief granted to Warrier Asphalt Co. of Alabama during its 1978 fiscal year in order to determine whether the level of relief accorded the firm was appropriate.</td>
</tr>
<tr>
<td>July 10, 1978</td>
<td>L. W. Babcock, Bakersfield, Calif.</td>
<td>DEX-1408</td>
<td>Price exception (as sec. 212.72). If granted: L. W. Babcock would be permitted to sell the crude oil produced from the Union Avenue field at upper-tier ceiling prices.</td>
</tr>
<tr>
<td>Do.</td>
<td>Cities Service Co., Tulsa, Okla.</td>
<td>DEX-1410</td>
<td>Price exception (as sec. 212.105). If granted: Cities Service Co. would be permitted to increase its prices to reflect increased costs in excess of $0.005 per gallon for natural gas liquid products produced at the Natomas, Selling, and Thunder Creek plants.</td>
</tr>
<tr>
<td>Do.</td>
<td>Keener Oil Co., Tulsa, Okla.</td>
<td>DEX-1407</td>
<td>Extension of relief granted in Keener Oil Company, 1 DOE Par. 01,008 (Mar. 7, 1978). If granted: Keener Oil Co. would be permitted to sell the crude oil produced from its Little-Grigil well No. 1 located in Seminole County, Okla., at upper-tier ceiling prices.</td>
</tr>
<tr>
<td>Do.</td>
<td>Lerner Oil Co., Inc., Gardenia, Calif.</td>
<td>DSC-0124</td>
<td>Request for special redress. If granted: An NOPV which was issued to Gardner Ink-Free Oil Co. by DoE region IX and subsequently withdrawn would be reissued.</td>
</tr>
<tr>
<td>Do.</td>
<td>Sidney E. Pinkston, Jr., Adams County, Miss.</td>
<td>DEX-1409</td>
<td>Price exception (sec. 212.73). If granted: Sidney E. Pinkston, Jr., would be permitted to sell the crude oil produced in the Beaver Branch field at upper-tier ceiling prices.</td>
</tr>
<tr>
<td>Do.</td>
<td>Wyoming Refining Co., Denver, Colo.</td>
<td>DEX-0085</td>
<td>Motion for discovery. If granted: Wyoming Refining would be entitled to discovery in connection with its statement of objections to a proposed decision and order issued to Little Ameron Refining Co.</td>
</tr>
<tr>
<td>Do.</td>
<td>Allied Chemical Corp., Houston, Tex.</td>
<td>DEX-1413</td>
<td>Price exception (sec. 212.128). If granted: Allied Chemical Corp. would be permitted to increase its prices to reflect nonproduct cost increases in excess of $0.005 per gallon for natural gas liquid products produced at the Burnet N. Feiten, N. Terbrouse-Tebora, and S. Fullerton plants.</td>
</tr>
<tr>
<td>Do.</td>
<td>Econ-o-Gas, Inc., Temple, Tex.</td>
<td>DEX-1416</td>
<td>Exception to change supplier. If granted: Econ-o-Gas, Inc., would be entitled to its application for exception which the firm had filed (case No. DBC-0009).</td>
</tr>
<tr>
<td>Do.</td>
<td>Powerine Oil Co., Los Angeles, Calif.</td>
<td>DXC-1027</td>
<td>Motion for discovery. If granted: Powerine Oil Co. would be permitted to sell the crude oil produced from its Salt Lake City, Utah, at upper-tier ceiling prices.</td>
</tr>
<tr>
<td>July 12, 1978</td>
<td>E. C. Johnson Co., Longview, Tex.</td>
<td>DEX-1418</td>
<td>Price exception (sec. 212.165). If granted: E. C. Johnson Co. would be permitted to increase its prices to reflect nonproduct cost increases in excess of $0.005 per gallon for natural gas products produced at the H. M. Stephens plant.</td>
</tr>
<tr>
<td>Do.</td>
<td>No. 2 (Home) Heating Oil (Wisconsin), Washington, D.C.</td>
<td>DEX-0069</td>
<td>Request for evidentiary hearing. If granted: The State of Wisconsin would be permitted to submit written comments to the Office of Hearings and Appeals in connection with an evidentiary hearing being held with respect to No. 2 (home) heating oil.</td>
</tr>
<tr>
<td>July 13, 1978</td>
<td>Arizona Fuels Corp., Salt Lake City, Utah</td>
<td>DEX-0094</td>
<td>Supplemental order. If granted: Arizona Fuels Corp. would receive a stay of a portion of its entitlement purchase obligations pending a final determination on its application for exception.</td>
</tr>
<tr>
<td>Do.</td>
<td>DeMartin Truck Lines, Inc., Bakersfield, Calif.</td>
<td>DRA-0198</td>
<td>Appeal of revised remedial order issued June 29, 1978. Stay request. If granted: The decisions and order issued to Powerine Oil Co. on April 11, 1977, and July 7, 1977, would be modified with respect to the level of relief from purchases of entitlements to be afforded the firm during 1978.</td>
</tr>
<tr>
<td>Do.</td>
<td>Northland Oil &amp; Refining Co., Tulsa, Okla.</td>
<td>DEX-0089</td>
<td>Motion for discovery. If granted: Northland Oil &amp; Refining Co. would be granted a stay of any entitlements purchase obligations pending a decision on its application for exception.</td>
</tr>
<tr>
<td>Do.</td>
<td>John Wight, Billings, Mont.</td>
<td>DEX-1417</td>
<td>Exception to entitlements program. If granted: Northland Oil &amp; Refining Co. would be granted a stay of any entitlements purchase obligations pending a decision on its application for exception.</td>
</tr>
<tr>
<td>July 14, 1978</td>
<td>Champlin Petroleum Co., Fort Worth, Tex.</td>
<td>DRB-0912</td>
<td>Interlocutory order. If granted: The DoE would establish procedures with regard to an evidentiary hearing which might be held in connection with the decision of the March 29, 1978, proposed remedial order issued to the firm.</td>
</tr>
<tr>
<td>Do.</td>
<td>Nerco Oil Co., Cheboygan, Mich.</td>
<td>DRH-0064</td>
<td>Request for evidentiary hearing. If granted: An evidentiary hearing would be convened in connection with the Nerco Oil Co.'s objections regarding the March 29, 1978, proposed remedial order issued to the firm.</td>
</tr>
<tr>
<td>Do.</td>
<td>Texas City Refining, Inc., Washington</td>
<td>DEI-1418</td>
<td>Exception to entitlements program. If granted: Texas City Refining, Inc., would be granted a stay of any entitlements purchase obligations.</td>
</tr>
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</table>

Notices of objection received
(Week of July 7 through July 16, 1978)

<table>
<thead>
<tr>
<th>Date</th>
<th>Name and location of applicant</th>
<th>Case No.</th>
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</thead>
<tbody>
<tr>
<td>Do.</td>
<td>Lunday-Thagard Oil Co, Washington, D.C.</td>
<td>DEX-1019</td>
</tr>
<tr>
<td>Do.</td>
<td>San Joaquin Refining Co. Bakersfield, Calif.</td>
<td>DEX-1017</td>
</tr>
</tbody>
</table>

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NOTICES OF OBJECTION—CONTINUED

[Week of July 7 through July 16, 1978]

<table>
<thead>
<tr>
<th>Date</th>
<th>Name and location of applicant</th>
<th>Case No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>July 10, 1978</td>
<td>Robert E. Hanson, Riverton, Wyo.</td>
<td>DEE-0320</td>
</tr>
<tr>
<td>July 12, 1978</td>
<td>Jack Halbert, Tyler, Tex.</td>
<td>DEE-1369</td>
</tr>
<tr>
<td>July 13, 1978</td>
<td>Saber Refining Co., Houston, Tex.</td>
<td>DRO-0079</td>
</tr>
<tr>
<td>July 10, 1978</td>
<td>Woodward Drilling Co., Columbus, Ohio</td>
<td>DRO-0080</td>
</tr>
<tr>
<td>July 12, 1978</td>
<td>Crystal Petroleum Co., Corpus Christi, Tex.</td>
<td>DRO-0081</td>
</tr>
<tr>
<td>July 7, 1978</td>
<td>Gene L. Poll, d/b/a, Gene Poll's Chevron Station Philmont, Ore.</td>
<td>DRO-0082</td>
</tr>
</tbody>
</table>

SUPPLEMENTARY INFORMATION:

I. Narrative statement describing FEA-23, as required by the Privacy Act of 1974 and OMB Circular A-108.

II. Comment Procedures.

I. Narrative statement as required by the Privacy Act of 1974 and OMB Circular A-108.

Background: This Report on New Systems is submitted by the Department of Energy (DOE), as required by the Privacy Act of 1974, 5 U.S.C. 552a(o), and paragraph 2(a) of Transmittal Memorandum No. 1 to Office of Management and Budget (OMB) Circular A-108. OMB Circular A-108 required that a government agency publish a Report on New Systems whenever a new system of records is proposed or there occurs a change in the number or types of individuals about whom information is maintained; an expansion in the type or categories of information maintained; an alteration in the manner in which the records are organized, indexed, or searched so as to change the nature or scope of those records; an alteration in the purposes for which the information is used; or a change in the equipment configuration on which the system is operated so as to create the potential for either greater or easier access. In this case, the amendments would alter the number of individuals covered and the types of information contained, as more fully described below.

The DOE was estimated by the Department of Energy Organization Act (Pub. L. 95-91) (the Act), which was made effective October 1, 1977, by Executive Order 12008, dated September 13, 1977 (42 FR 6297, September 15, 1977). The act transfers to, and vests in, the DOE and the independent collegial body within the DOE, the Federal Energy Regulatory Commission (FERC), the functions of the former Federal Energy Administration, the former Energy Research and Development Administration, the former Federal Power Commission, and certain functions previously performed by several other departments and programs. The departments, agencies, and commissions, or components thereof, which, prior to the act, discharged the functions which the act vests in the DOE, established and proposed certain systems of records in accordance with the Privacy Act of 1974 and other authority vested in them. Those systems of records (or portions thereof) either in existence or proposed prior to October 1, 1977, which relate to the functions of any entity which was transferred to the DOE by the act to either the Secretary or to the FERC (or delegated to the FERC by the Secretary) were formally transferred to the Secretary and to the FERC, as appropriate to their respective functions (42 FR 54555, October 11, 1977).

The system designated as FEA-23, telephone numbers of FEA officials, is a system of records created and noticed in 42 FR 52485, September 29, 1977. The system contains the home telephone numbers of senior staff officials of the Federal Energy Administration (FEA). The proposed amendments to FEA-23 would expand both the number and types of phone numbers covered by the system and the type of information contained therein. These proposed amendments to FEA-23 are therefore being noticed in the Federal Register in accordance with section 3(e)(11) of the Privacy Act of 1974, 5 U.S.C. 552a(e)(11).

B. Purpose: The system designated as FEA-23 was originally established as a necessary precaution to guard against an emergency situation during which the number of personnel available to support senior officials by

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carrying out secretarial and administrative duties arising as a result of emergency situations. Additionally, the home addresses of all of the individuals covered are proposed to be included in aid in determining the relative availability and accessibility of officials and employees in the event of an emergency. As a result of these changes, the system will be renamed FEA-23, telephone numbers and addresses of DOE senior and support staff.

C. Authority: Section 641 of the Department of Energy Organization Act authorizes the Secretary, to the extent necessary or appropriate in performing any function transferred by that act, to exercise any authority or part thereof available by law to the official or agency from which such function was transferred. Section 301 of the act transfers to the Secretary, among other functions, all of the functions vested by law in the Administrator of FEA. The authority for the FEA Administrator to amend systems of records was based upon the authority vested in him pursuant to Section 7(a) of the Federal Energy Administration Act of 1974 (Pub. L. 93-275) to promulgate such rules, regulations, and procedures as necessary to carry out his functions. Therefore, as a result of the transfer of functions pursuant to Section 301 of the DOE Organization Act, the Secretary of DOE is vested with authority to amend systems of records which was previously vested in the FEA Administrator.

Additionally, 5 U.S.C. 301 and section 644 of the Department of Energy Organization Act authorize the Secretary of the DOE to prescribe such procedural and administrative rules and regulations as he may deem necessary or appropriate to administer and manage functions vested in him. Therefore, these provisions are also authority for the proposed amendments.

D. Potential consequences on individual privacy. Although the amendments would expand the categories of individuals and the type of information under this system, DOE does not deem that the maintenance of the amended FEA-23 will have any substantial effect on the privacy and other personal or property rights of individuals. No information is or will be retained in the system other than that which is given voluntarily to the agency by an individual. The use of FEA-23 is totally internal to DOE operations, with no access to information contained therein allowed to any persons other than those with with a need to know for the purpose of conducting official DOE business. With DOEs stringent access controls and limited use of the records contained in the FEA-23, the operation of the system will have minimal effect on individual privacy and other personal or property rights.

E. Safeguards against unauthorized access. The risk of unauthorized access has been minimized by locating FEA-23 in a lockable container within a secure room in the DOE building. Neither authorized users nor the system manager is present. Control over these facilities is given only to the system manager and those qualifying for access under the routine uses listed in the accompanying proposed amended system notice. The lower risk alternative of maintaining the system in a locked cabinet within secured rooms was considered; however, the presence of responsible DOE personnel was considered to be sufficient to prevent unauthorized access to the systems. No higher risk alternatives were considered.

II. Comment Procedures:

As provided by section 3(e)(11) of the Privacy Act of 1974 (5 U.S.C. 552a(e)(11)), interested persons are invited to submit written data, views, or arguments related to these proposals to Public Hearing Management, Department of Energy, Box SW, 2000 M Street, Room 2133, Washington, D.C. 20585. Hand carried comments may be delivered to that same office between the hours of 8 a.m. to 4:30 p.m., Monday through Friday, except on legal public holidays.

Comments should be identified on the outside of the envelope and on the documents submitted to DOE with the designation "FEA-23, Privacy Act System of Records". Fifteen copies should be submitted. All comments received on or before August 28, 1978, will be available for public inspection in the DOE Reading Room, Room 2107, Federal Building, 12th and Pennsylvania Avenue NW., Washington, D.C., between the hours of 8 a.m. and 4:30 p.m., Monday through Friday, except on legal public holidays. These comments and all other relevant information will be considered by DOE before the amended system is adopted in its final form.

Any information or data considered by the person furnishing it to be confidential must be so identified and submitted in writing, one copy only. The DOE reserves the right to determine the confidential status of the information or data and to treat it according to that determination.

It is the intent of DOE to operate the amended system of records as proposed at the expiration of the comment period if no comments to the contrary are received.

A room secured when neither an employee of DOE nor a customer of DOE was present was considered to be sufficient to prevent unauthorized access to confidential information. Any information or data considered by the person furnishing it to be confidential must be so identified and submitted in writing, one copy only. The DOE reserves the right to determine the confidential status of the information or data and to treat it according to that determination.

The system of records described is totally internal to DOE operations, with no access to information contained therein allowed to any persons other than those with a need to know for the purpose of conducting official DOE business. With DOEs stringent access controls and limited use of the records contained in the FEA-23, the operation of the system will have minimal effect on individual privacy and other personal or property rights.

In consideration of the foregoing, the amendments to FEA-23 as described above are proposed. An amended system description incorporating the proposed amendments is set forth below.


WILLIAM P. DAVIS,
Deputy Director of Administration.

FEA-23

System name: Telephone numbers and addresses of DOE officials and support staff.


System location: Office of the Secretary, Department of Energy, Forrestal Building, Washington, D.C. 20585.

Categories of individuals covered by the system: DOE senior staff officials and support staff.

Categories of records in the system: Name, home telephone number, and home address.

Authority for maintenance of the system: 5 U.S.C. 301; Federal Energy Administration Act of 1974; Executive Order 11790; Department of Energy Organization Act; Executive Order 12009.

Routine uses of records maintained in the system, including categories of users and the purposes of such uses:

The records are available only to DOE staff within the office of the Secretary and the energy policy staff within the Executive Office of the President. Telephone numbers will be given out on an individual basis from the list to those DOE officials or energy policy staff with a demonstrated need for the information in the course of their duties.

Policies and practices for storing, retrieving, accessing, retaining, and disposing of records in the system:

Storage: Paper records.

Retrievability: Name of DOE official or support staff.

(Federal Register, Vol. 43, No. 146—Friday, July 28, 1978)
NOTICES

ENIRONMENTAL PROTECTION AGENCY

[FRl. 990-61]

IDENTIFICATION OF CONVENTIONAL POLLUTANTS

Publication

Notice is hereby given that the Environmental Protection Agency is publishing on this date a list of four conventional pollutants in accordance with subsection 304(a)(4) of the Clean Water Act, 33 U.S.C. 1251 et seq. These four pollutants are required to be listed by the act and are therefore published as a final list. Three additional pollutants are proposed today as conventional pollutants and public comment is invited.

Pursuant to section 304(a)(4) of the act, the Administrator is required within 90 days to publish information identifying conventional pollutants including but not limited to, pollutants classified as biodegradable, suspended solids, fecal coliform bacteria and pH. The thermal component of any discharge is not to be identified as a conventional pollutant under section 304(a)(4).

For conventional pollutants, the applicable technology-based limitations for point sources are defined on the basis of the "best conventional pollution control technology" (BCT) pursuant to section 301(b)(4)(B) and section 301(b)(2)(E) of the act, and section 301(b)(2)(E) provides that such limitations must be established no later than July 1, 1984. The reasonableness assessment required under section 301(b)(4)(B) and section 301(b)(2)(E) may result in effluent limitations less stringent than those established based upon "best available technology economically achievable." However, in no case should BCT limitations be less stringent than those based on "best practicable technology currently available."

The act and its legislative history state that the economic and water quality criteria must be established to provide a permittee with effluent limitations less stringent than BCT based on a case-by-case evaluation of economic or water quality concerns. Thus, establishment of BCT may result in more stringent limitations which are more stringent than necessary for protection of local water quality. Since BCT will always be equal to or less stringent than BAT, BCT may be less protective of water quality. Such cases would result in a greater reliance on water quality standards.

Criteria considered and accepted

Because the act is silent on the definition of conventional pollutants, the Agency was allowed a great deal of discretion in determining criteria factors. However, the Agency tried to determine the act's intent and used the act and the legislative history as a guide to establishing criteria which were used in the selection of conventional pollutants. Based on these considerations the Agency has identified three classes of substances which may contain conventional pollutants: oxygen demanding substances, solids, and nutrients.

The overriding consideration in the Agency's selection process is the environmental effect of classes of pollutants. The legislative history indicates that conventional pollutants are generally those pollutants which are naturally occurring, biodegradable, oxygen demanding materials, and solids and which have similar characteristics to naturally occurring biodegradable substances. This criterion is supported by Congress' designation of BOD and TSS as conventional pollutants. These classes of pollutants impact water quality and aquatic life and therefore are an appropriate criterion to be used in the selection of conventional pollutants.

The second criterion the Agency established concerned those classes of pollutants that traditionally have been the primary focus of wastewater control. This criterion is supported in the act and establishes fecal coliform as conventional pollutants, neither of which is oxygen demanding or a solid. The Agency believes this is an appropriate criterion and is in keeping with the intent of the act.

Using these criteria, three classes of conventional pollutants have been identified: oxygen demanding substances, solids, and nutrients.

Criteria considered and rejected

There were two other criteria that were considered in the selection process, but ultimately rejected.

First, although the cost and level of reduction of conventional pollutants from the discharge of publicly owned treatment works (POTW) is one factor used to establish the "reasonableness" of BCT limitations, the Agency concluded that this does not require that a pollutant be regulated at secondary treatment levels in POTW in order to be identified as conventional. Although most of the pollutants that Congress specified are treated by the secondary treatment, this is not true for every pollutant. For example, fecal coliform was included by Congress although EPA does not require the control of fecal coliform as part of secondary treatment standards. Additionally, there is not necessarily a direct link between secondary treatment levels and environmental impacts, thus the criteria is inappropriate.

Further, the concept of secondary treatment is nowhere identified by Congress as a requirement in defining this reasonableness test. If a pollutant is normally treated by the primary treatment by POTW, the Agency can use these costs and effluent reduction benefits as the basis of comparison for establishing BCT limitations.

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If the three pollutants that EPA is proposing to add to the conventional pollutant list, phosphorus is the only pollutant which is not commonly treated by secondary treatment technology. It should be emphasized that in determining the reasonableness of BCT limitations for phosphorus, the Agency intends to use POTW tertiary control costs and reduction as the basis for comparison to industrial point source dischargers of phosphorus, while for BOD and TSS, secondary treatment costs and reductions will be the basis for comparison.

Finally, although the act specifies that one factor in determining BCT limitations is the cost and efficient reduction of conventional pollutants at POTW; it does not prohibit the Agency from using other tests to determine the reasonableness of BCT limitations. Thus, if a pollutant is not commonly treated by POTW technology but would otherwise meet the criteria for a conventional pollutant, it may be designated as a conventional pollutant. The Agency believes that the treatability of a conventional pollutant by a POTW should not be a factor in the selection of conventional pollutants.

The second criterion that the Agency considered and rejected was that the conventional pollutants are those not specified by the EPA Administrator to specify conventional pollutants. The legislative history indicates that conventional pollutants are not toxic, the Agency does not interpret this to mean that because pollutants have toxic properties that they are precluded from being on the conventional pollutant list. If a pollutant meets the criteria for conventional pollutants and incidentally is toxic, the Agency believes that it has the flexibility to weigh the pollutant's toxic properties against its conventional properties and assign the pollutants to the list (conventional pollutant list or toxic list) which the Agency deems more appropriate.

The major impact of assigning a pollutant to the conventional list rather than the toxic list is that the BCT limitations for conventional pollutants must meet the added test of reasonableness, while the limitation for a toxic pollutant must meet BAT. Therefore, the control of a conventional pollutant may be less than that of a toxic pollutant.

Because the selection criteria are the major factors in the choice of conventional pollutants, other than those mandated by the act, the Agency encourages interested parties to comment on these and other criteria and their appropriateness in selecting conventional pollutants. It must be emphasized that these criteria are the essential elements in the selection process. Public comments should emphasize the appropriateness of the criteria as well as the appropriateness of a candidate pollutant.

**Conventional Pollutant List**

The act identifies four pollution parameters as conventional:

- Biochemical oxygen demand (BOD)
- Chemical oxygen demand (COD)
- Total suspended solids (TSS)
- Total dissolved solids

BOD may not provide such data. Phosphorus is regarded as a nutrient and the growth enhancement of aquatic plants and the resultant environmental degradation are well recognized. Phosphorus is regarded as a controlling factor in chemically characterizing wastewater treatment works. Fecal coliform bacteria are measured to identify the bacteria which are normally present in the intestinal tract of warm-blooded animals including humans and are recognized universally as indicators of sanitary water quality. Fecal coliform bacteria are conventionally held to indicate the potential presence of pathogenic intestinal organisms.

The term pH is a designation for the negative logarithm of the hydrogen ion concentration in water and is a measure of acidity and alkalinity achieved by various dissolved compounds, salts and gases. It is an important factor in chemically characterizing water systems since changes in pH affect the degree of dissociation of weak acids or bases. This in turn affects the toxicity and solubility of many compounds including metals and metallic salts. Biological systems are affected by the pH of the water. pH is widely recognized as a necessary measurement in the control of chemical and biological wastewater treatment systems.

**Section 304(a)(14)** authorizes the Administrator to specify conventional pollutants in addition to the four parameters identified as conventional by the act, and the Agency is now proposing chemical oxygen demand (COD), phosphorus, and oil and grease as candidate designations as conventional pollutants.

Chemical oxygen demand (COD) is a standard test typically used to characterize certain industrial waste loads and for control of wastewater treatment works. This determination provides a measure of the carbonaceous portion of the organic matter present that is susceptible to oxidation by a strong chemical oxidant such as potassium dichromate. Thus, like BOD, COD is a measure of an oxygen demanding fraction in wastewater streams. However, with certain waste chemical treatments, COD provides a means of determining the organic demand for oxygen where BOD may not provide such data.

Phosphorus also is a pollutant which traditionally has been of concern in wastewater treatment and phosphorus is a nutrient and the growth enhancement of phosphorus on aquatic plants is well recognized. Phosphorus is regarded as a controlling factor in chemically characterizing wastewater treatment works. Substances which traditionally represent oxygen demanding material are of concern in wastewater treatment.

Concentrations of BOD, COD, TSS, and oil and grease may in some cases exceed any local ordinances for conventional pollutants in a wastewater. Where available data support this relationship, it is the Agency's intent that it may specify one or more of these parameters as an indicator of a toxic pollutant. Effluent limitations for such indicators of toxic pollutants will be established pursuant to the provisions of best available treatment technology, pretreatment, new source performance standards, and best management practices of the act. When a conventional pollutant is used as an indicator for a toxic pollutant or for a group of toxic pollutants in effluent limitations, such conventional pollutants will be treated as a toxic pollutant for purposes of effluent limitations.

In high concentrations some conventional pollutants may adversely affect the biological treatment process in publicly owned wastewater treatment plants. Thus, there is no intent to supersede any local ordinances for control of any of these conventional pollutants through pretreatment requirements.

In summary, the pollutants and measurements of pollutants listed and proposed today as conventional pollutants include:
2. Analysis of Kaltrim’s financial data reveals that $64,328 will be required to construct the proposed facility and operate for one year, without revenue, itemized as follows:

<table>
<thead>
<tr>
<th>Equipment (including interest)</th>
<th>$2,324</th>
</tr>
</thead>
<tbody>
<tr>
<td>Building</td>
<td>9,494</td>
</tr>
<tr>
<td>Land allowances</td>
<td>3,669</td>
</tr>
<tr>
<td>Working capital (first year)</td>
<td>40,000</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>$64,283</td>
</tr>
</tbody>
</table>

To attempt to meet this requirement, Kaltrim relies upon a stockholder loan of $55,000 from George E. Benko. However, the loan commitment does not state the rate of interest, the collateral required, if any, or the terms of repayment as required by section III, Paragraph 4(a) of the application. Therefore, the Commission is unable to find that the proposed loan is available. Moreover, Mr. Benko’s balance sheet submitted in support of his ability to honor the loan commitment is more than one year old. Without a current balance sheet, we are unable to determine whether Mr. Benko has the financial ability to comply with loan agreement. Accordingly, since Kaltrim has not shown any funds available, a financial issue will be specified.

3. Kaltrim has failed to comply with the Commission’s Primer on Ascertainment of Community Problems by Broadcast Applicants, 27 FCC 2d 650, 21 RR 2d 1501 (1971). Question and Answer 9 of the Primer requires that applicants show that they have determined the composition of their communities by submitting “such data as is necessary to indicate the minority, racial, or ethnic breakdown of the community, its economic activities, governmental ‘activities, public service organizations, and any other factors or activities that make the particular community distinctive.” Kaltrim has failed to provide a statement relating to its public service organizations. Evaluation of the applicant’s list of community leaders in light of the demographic information submitted shows that not all significant groups have been consulted. Voice of Dixie, Inc., 45 FCC 2d 1027, 29 RR 2d 1124 (1974).

For example, Kaltrim’s list of community leaders contacted includes no identifiable leaders of industry, labor, educational organizations, the elderly, and the professions. Furthermore, the applicant has not provided a sufficient description of the methodology it employed in making the list of the general public for the Commission to determine whether genuinely random sample was achieved, in compliance with Question and Answer 13(b) of the Primer. An ascertainment issue will therefore be specified.

4. Analysis of Peninsula’s financial data reveals that it will require, $76,650 to construct its proposed facility and operate for 1 year, without revenue, itemized as follows:

<table>
<thead>
<tr>
<th>Equipment</th>
<th>$29,650</th>
</tr>
</thead>
<tbody>
<tr>
<td>Building</td>
<td>1,250</td>
</tr>
<tr>
<td>Miscellaneous</td>
<td>6,000</td>
</tr>
<tr>
<td>Working capital (first year)</td>
<td>30,650</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>$76,650</td>
</tr>
</tbody>
</table>

To meet this requirement, Peninsula plans to rely on $10,000 in stock subscriptions and $60,000 in loans from two of its principals, Roy Henderson and Roger Watson. Peninsula has not satisfactorily established the availability of the proposed commitment from Roy Henderson. Mr. Henderson relies on two bank loans from the Cadillac State Bank to support his $40,000 commitment. Since the bank commitment letter has expired, the Commission is unable to find these funds available. Moreover, the Commission notes that while the Cadillac State Bank commitment letter requires Mrs. Henderson’s cosignature for the loans and contemplates the pledge of certain assets of the corporate applicant and its stockholders, no indication of Mrs. Henderson’s agreement to co-sign the note or any agreement to the collateralization requirements have been presented. Since Peninsula has, therefore, shown the availability of only $50,000 to meet a $76,650 requirement, a financial issue will be specified.

5. Peninsula proposes independent programming, while Kaltrim, should its pending AM application be granted, proposes to duplicate the programming of that station during 62 percent of its broadcast time. Therefore, evidence regarding program duplication will be admissible under the standard comparative issue in the event that the AM application is granted before the hearing in this proceeding has been terminated. When duplicated programming is proposed, the showing...
NOTICES

mitted under the standard comparative issue will be limited to evidence concerning the benefits to be derived from the proposed duplication which would offset its inherent inefficiency. 

Jones T. Sudbury, 8 FCC 2d 360, 10 RR 114 (1967).

6. Data submitted by the applicants indicates that there would be a significant difference of the areas and populations which would receive service from the proposals. Consequently, for the purposes of comparison, the areas and populations which would receive FM service of 1 mV/m or greater intensity, together with the availability of other primary aural services in such areas will be considered under the standard comparative issue, for the purpose of determining whether a community needs and interests of a comparative issue will be limited to evidence governing the time for filing and other requirements relating to such pleadings.

7. Except as indicated by the issues specified below, the applicants are qualified to construct and operate as proposed. However, because the proposals are mutually exclusive, the applicants herein shall, pursuant to section 311(a)(x) of the Communications Act of 1934, as amended, and § 1.594 of the Commission's rules, give notice of the hearing, either individually or, if feasible and consistent with the rules, jointly, within the time and in the manner prescribed in such rule, and shall advise the Commission of the publication of such notice as required by section 1.594(g) of the rules.

FEDERAL COMMUNICATIONS
COMMISSION
WALLACE E. JOHNSON,
Chief, Broadcast Bureau.

[FR Doc. 78-20846 Filed 7-27-78; 8:45 am]

[6712-01]

TV BROADCAST APPLICATIONS READY AND AVAILABLE FOR PROCESSING

Adopted: July 17, 1978.


By the Chief, Broadcast Facilities Division.

Notice is hereby given, pursuant to § 1.572(c) of the Commission's rules, that on September 8, 1978, the TV broadcast applications listed in the attached appendix will be considered as ready and available for processing. Pursuant to § 1.227(b)(1) and § 1.591(b) of the Commission's rules, an applicant in order to be considered with any application appearing on the attached list or with any other application on file by the close of business on September 7, 1978, which involves a conflict necessitating a hearing with any application on this list, must be substantially complete and tendered for filing at the offices of the Commission in Washington, D.C., by the close of business on September 7, 1978.

The attention of any party in interest desiring to file pleadings concerning any pending TV broadcast application, pursuant to section 309(d)(1) of the Communication's Act of 1934, as amended, is directed to § 1.580(l) of the Commission's rules for provisions governing the time for filing and other requirements relating to such pleadings.

FEDERAL COMMUNICATIONS
COMMISSION
WILLIAM J. THICARICO,
Secretary.

BPCT-5171 (new), Tulsa, Okla., Oklahoma City Broadcasting Co. Channel 23, ERP. Vis. 2838 kW, HAAT: 1,480 ft.

BPCT-5172 (new), Tulsa, Okla., Western Area Bureau of Information Broadcasting Division, Channel 51-E, ERP. Vis. 2100 kW, HAAT: 291 ft.

BPCT-5173 (new), Galveston, Tex., The Old Time Religion Hour, Inc. (The O.T.R.H., Inc.) Channel 48, ERP. Vis. 2500 kW, HAAT: 1,151 ft.

BPCT-5175 WTYX-TV, Ft. Pierce, Fla., Indian River Television, Inc. Channel 34, Change ERP. to Vis. 2846 kW, HAAT: 1,480 ft., change transmitter location.

BPCT-5176 (new), Newark, Ohio, Christian Television of Ohio, Inc. Channel 52, ERP. Vis. 21.5 kW, HAAT: 305 ft.; request waiver of § 73.610(d) of the Commission's rules.

BPCT-5179 (new), Tulsa, Okla., David Livingstone Missionary Foundation, Channel 47, ERP. Vis. 344 kW, HAAT: 630 ft.

BPCT-5180 (new), Hardin, Mont., KOUS TV, Inc. Channel 4. ERP. Vis. 91.45 kW, HAAT: 1,082 ft.

BPCT-5185 (new), West Chicago, Ill., Largo Grande Television Co. Channel 69, ERP. Vis. 2390 kW, HAAT: 1,469 ft.

BPCT-5189 (new), Miami, Fla., Contemporary Television Broadcasting, Inc. Channel 39, ERP. Vis. 2668 kW, HAAT: 949 ft.; request for waiver of § 73.610(d) of the Commission's rules.

BPET-610 (new), Blomarek, N. DAK., Prairie Public Television, Inc. Channel 3* ERP. Vis. 100 kW, HAAT: 1,393 ft.

BPET-611 (new), Minot, N. DAK., Prairie Public Television, Inc. Channel 6. ERP. Vis. 100 kW, HAAT: 1,111 ft.

Application deleted from public notice released May 26, 1978, mimeo No. 1196, 43 FR 24132.

BPET-660 (WNJB-TV), New Brunswick, N.J., New Jersey Public Broadcasting Authority. Channel 56. Change transmitter location; change ERP. Vis. 3640.9 kW, HAAT: 1,419.3 ft.; and request for waiver of § 73.610(d) of the Commission's rules.

[FR Doc. 78-20846 Filed 7-27-78; 8:45 am]

[6210-01]

FEDERAL RESERVE SYSTEM

GUARANTY CORPORATION

Formation of Bank Holding Co.

Guaranty Corporation, Denver, Colorado, has applied for the Board's approval under § 5(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become a bank holding company by acquiring 80 per cent or more of the voting shares of Guaranty Bank & Trust Company, Denver, Colorado. The factors that are considered in acting on the application are set forth in § 3(c) of the act (12 U.S.C. § 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Kansas City. Any person wishing to comment on the application should submit views in writing to the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551 to be received no later than August 15, 1978.


GRiffin L. Garwood,
Deputy Secretary of the Board.

[FR Doc. 78-20897 Filed 7-27-78; 8:45 am]

FEDERAL REGISTER, VOL. 43, NO. 146—FRIDAY, JULY 28, 1978
NOTICES

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Assistant Secretary for Information

COMMENTS ON COLLECTION OF INFORMATION AND DATA ACQUISITION ACTIVITY

Pursuant to Section 406(g)(2)(B), General Education Provisions Act, notice is hereby given as follows:

The U.S. Office of Education has proposed collections of information and data acquisition and budget which will request information from educational agencies or institutions.

The purpose of publishing this notice in the Federal Register is to comply with paragraph (g)(2)(B) of the “Control of Paperwork” amendment which provides that each educational agency or institution subject to a request under the collection of information and data acquisition activity and their representative organizations shall have an opportunity, during a 30-day period before the transmittal of the request to the Director of the Office of Management and Budget, to comment to the Administrator of the National Center for Education Statistics on the collection of information and data acquisition activity.

These data acquisition activities are subject to review by the HEW Education Data Acquisition Council and the Office of Management and Budget.

Descriptions of the proposed collections of information and data acquisition activities follow below.

Written comments on the proposed activities are invited. Comments should refer to the specific sponsoring agency and form number and must be received on or before August 28, 1978 and should be addressed to Administrator, National Center for Education Statistics, ATTN: Manager, Information Acquisition, Planning, and Utilization, Room 3001, 400 Maryland Avenue SW, Washington, D.C. 20202.

Further information may be obtained from Elizabeth M. Proctor of the National Center for Education Statistics, 202-245-1022.

MARIE D. ELDRIDGE,
Administrator, National Center for Education Statistics.

DESCRIPTION OF A PROPOSED COLLECTION OF INFORMATION AND DATA ACQUISITION ACTIVITY

1. TITLE OF PROPOSED ACTIVITY

2. AGENCY/BUREAU/OFFICE

3. AGENCY FORM NUMBER
OE Forms 257, 116-2, -2-1, -2-2.

4. LEGISLATIVE AUTHORITY FOR THIS ACTIVITY
"(16) provides (A) that the applicant will make periodic reports at such time, in such form, and containing such information as the Assistant Secretary may require by regulation, which regulation may require at least—
   (D) In the case of reports relating to performance, that the reports be consistent with specific criteria related to the program objectives, and
   (F) That the reports include information relating to educational achievement of children in the schools of the applicant, and (G) that the applicant will keep such records and afford such access thereto as—
   (1) Will be necessary to assure the correctness of such reports and to verify them, and
   (2) Will be necessary to assure the public adequate access to such reports and other written materials.
   (b) No application under this section may be approved which is not accompanied by the written comments of a committee established pursuant to clauses (2)(B) of subsection (a). The Assistant Secretary shall not approve an application without first affording the committee an opportunity for an informal hearing if the committee requests such a hearing. (Pub. L. 92-318, section 710(a)(16) and section 710(b)); (20 U.S.C. 1809(a)(16) and 1809(b)); (45 CFR 185.13(k)). (Office of Education General Provisions for Programs, 45 CFR Part 160, Subparts P, Q, and R.)

5. VOLUNTARY/OBLIGATORY NATURE OF RESPONSES REQUIRED
Required of grantees.

6. HOW INFORMATION TO BE COLLECTED WILL BE USED
Performance reports (OE 257, OE 116-2, -2-1, -2-2)—information will be used to measure the effectiveness of programs in meeting the objectives.

Financial status report (SF 269)—information will be used to determine the amount of unspent funds that must be returned to the U.S. Treasury.

7. DATA ACQUISITION PLAN
   Frequency: Annually.

8. RESPONDENTS
a. Type: Local educational agencies, institutions of higher education, public agencies and organizations, and private non-profit organizations.
   c. Estimated average man-hours per respondent:
      Program Progress Report: 12 hours.
      Financial Status Report: 2 hours.
      Districtwide Advisory Committee Report: ½ hour.
      Student Advisory Committee Report: ½ hour.

9. INFORMATION TO BE COLLECTED
Program Progress Report: The grantee shall provide for each type of project a list of major events and for each event, provide the planned and actual starting and completion dates, a brief description of actual accomplishments, and the difference between planned and actual accomplishments (where applicable).

Financial Status Report: Provide financial data for each program, function, and activity in the approved budget. Provide the total Federal and non-Federal gross outlays, the total Federal and non-Federal unliquidated obligations, the total cumulative amount of Federal funds authorized and the unobligated balance of Federal funds.

Districtwide Advisory Committee Report: The chairperson of the committee shall provide information about the frequency of committee meetings and visits to the program, the opportunity to make recommendations to school officials, the frequency with which recommendations were carried out, and a description of any advisory committee activity that made a significant contribution to the success of the program.

Student Advisory Committee Final Report: The chairperson of the committee shall provide information about the frequency of committee meetings, the opportunity to make recommendations to school officials, the frequency with which recommendations were carried out, and a description of any advisory committee activity that made a significant contribution to the success of the program.

Description of a Proposed Collection of Information and Data Acquisition Activity

1. TITLE OF PROPOSED ACTIVITY
National direct student loan program semi-annual default loan report.

2. AGENCY/BUREAU/OFFICE

3. AGENCY FORM NUMBER
OE Form 574.

4. LEGISLATIVE AUTHORITY FOR THIS ACTIVITY
Section 463. (a) "An agreement with any institution of higher education for the payment of Federal capital contributions under this part shall: Provide that where a note or written agreement evidencing a note has been in default for (A) one hundred and twenty days, in the case of a loan which is repayable in monthly installments, or (B) one hundred and eighty days, in the case of a loan which is repayable in less frequent installments, notice of such default shall be given to the Commissioner in a report describing the total number of loans from
such fund which are in such default, and made to the Commissioner at least semi-annually.” (Pub. L. 92-218, Sec. 137(b), 20 U.S.C. 1087c, as amended under Sec. 133(c), Pub. L. 94-482, Education Amendments of 1976.)

5. VOLUNTARY/OBLIGATORY NATURE OF RESPONSE
Required to obtain or maintain benefits.

6. HOW INFORMATION TO BE COLLECTED WILL BE USED
Program management: This report will serve to provide information about the capability of the institutions to establish and administer effective collections programs. The data will be used to determine the effectiveness of the loan activities and to determine whether the institutions are following the steps necessary in the performance of due diligence as stipulated in the regulations. It will also be used in the formula to compute delinquency percentages and potential default rates.

Evaluation: (1) Compliance with established regulations pertaining to collection practices, such as regular billing and follow-up procedures, and collection activities; (2) institutional administrative capability; (3) practices and policies established to carry out due diligence.

Research: The data collected may be used for the purposes of (1) establishing default trends in various types of institutions by repayment method; (2) analysis and studies of defaulted loans by educational organizations and OE; (3) comparison of default ratios.

Condition of education: (1) Summaries of categorical information for OE and organizations associated with the Education Community; (2) response to Congressional inquiries; (3) public dissemination.

7. DATA ACQUISITION PLAN
(a) Method of collection: Mail
(b) Time of collection: Winter (December 31) of each year.
(c) Frequency: Annually.

8. RESPONDENTS
(a) Type: Colleges and universities—vocational/technical and proprietary institutions of postsecondary education.
(b) Number: 4,000.
(c) Estimated average man-hours per respondent: 5.

9. INFORMATION TO BE COLLECTED
(1) Number of borrowers in default status. (2) Principal amount outstanding. (3) Principal amount in default.

DESCRIPTION OF A PROPOSED COLLECTION OF INFORMATION AND DATA ACQUISITION ACTIVITY
1. TITLE OF PROPOSED ACTIVITY
Survey of individual educational program plans.

2. AGENCY/BUREAU/OFFICE

3. AGENCY FORM NUMBER
OE-531.

4. LEGISLATIVE AUTHORITY FOR THIS ACTIVITY
“* * * the Commissioner shall conduct a statistically valid survey for assessing the effectiveness of individualized education programs.” Section 618, Pub. L. 94-142, 20 U.S.C. 1418.

5. VOLUNTARY/OBLIGATORY NATURE OF RESPONSE
Voluntary.

6. HOW INFORMATION COLLECTED WILL BE USED
Evaluation: The Survey is one of several evaluation studies authorized under Section 618, Pub. L. 94-142. This section specifically mandates the survey. “* * * the Commissioner shall conduct a statistically valid survey for assessing the effectiveness of individualized education programs.”

The primary but not only objective of all the evaluation studies is to provide information for a national congressional report. The objective of this report is to describe who, where, and how the beneficiaries of Pub. L. 94-142 are served; what administrative mechanisms are used to provide these services; what the consequences are of the law; and the extent the intent of the law is being met.

The specific objective of the survey is to assess the effectiveness of the individualized education program by surveying the mandated program document. First, section 613 mandates that several aspects of a good plan must be included in the program document. Thus, the survey will describe the nature, purpose, and variety of plans to serve handicapped children. Second, the survey will describe the characteristics of the children and associate these characteristics with their plans. Third, the survey will describe the characteristics of schools and associate these characteristics with the plans they have for the handicapped children they serve. And forth, the survey will discuss the adequacy of the public document to account for and communicate the program to all those interested in the education of that handicapped child.

7. DATA ACQUISITION PLAN
a. Method of collection: Site visit.
   c. Frequency: Biennial.

8. RESPONDENTS
a. Type: Teachers, elementary/secondary.
   b. Number: 6,800.
   c. Estimated average man-hours per respondent: 20 minutes.
   a. Type: Principals, elementary/secondary.
   b. Number: 480.
   c. Estimated average man-hours per respondent: 30 minutes.

9. INFORMATION TO BE COLLECTED
(1) Number of borrowers in default status. (2) Principal amount outstanding. (3) Principal amount in default.

DESCRIPTION OF A PROPOSED COLLECTION OF INFORMATION AND DATA ACQUISITION ACTIVITY
1. TITLE OF PROPOSED ACTIVITY
Fiscal-operations report 1977-1978 award period (July 1, 1977 through June 30, 1978) and applications to participate—1978-1980 award period (July 1, 1979 through June 30, 1980)—national direct student loan, supplemental educational opportunity grants, and college work-study programs.

2. AGENCY/BUREAU/OFFICE
Office of Education—Bureau of Student Financial Assistance—Division of Program Operations.

3. AGENCY FORM NUMBER
OE Form 446 (This form is a combination of the fiscal-operations report, EO Form 1152-1, and the tripartite application, OE form 1036).

4. LEGISLATIVE AUTHORITY FOR THIS ACTIVITY
A. “Include such other provisions as may be necessary to protect the financial interest of the United States and promote the purposes of this part as are agreed to by the Commissioner and the institution.” (Pub. L. 92-318, 20 U.S.C. 1087c, subpart 137(b), CFR, section 144.18) national direct student loan program; “include such other provisions as may be necessary to protect the financial interest of the United States and promote the purposes of this subpart.” (Pub. L. 92-318, 20 U.S.C. 1070b-2, section 131(b), CFR section 176.23) supplemental educational opportunity grants program; “include such other provisions as the Commissioner shall deem necessary or appropriate to carry out the purposes of this part.” (Pub. L. 92-318, 20 U.S.C. 2754, section 444(b), CFR section 176.29) college work-study program.

B. “Any institution of higher education desiring to receive payments of Federal capital contributions from the apportionment of the State in which it is located for any fiscal year shall make an agreement under section 463 and shall submit a proposal therefore to the Commissioner, in accordance with the provisions of this part. The Commissioner shall, from time to time, set dates before which such institutions must file applications under this section.” (Pub. L. 92-318, section 137(b), 20 U.S.C. 1087b, CFR 144.3) national direct student loan program; “The Commissioner shall, from time to time, set dates before which institutions in any State must file applications for allocation to such institution, of supplemental grant funds from the apportionment to that State for any fiscal year pursuant to subsection (a)(1).” (Pub. L. 92-318, section 131(b)(1), 20 U.S.C. 1070b-3, CFR 176.6) supplemental educational opportunity grants program; “include such other provisions as the Commissioner shall deem necessary or appropriate to carry out the purposes of this part.” (Pub. L. 90-350, section 444(b), 20 U.S.C. 2754, CFR section 176.5, 6) college work-study program.

5. VOLUNTARY/OBLIGATORY NATURE OF RESPONSE
Fiscal-operations portion required of all institutions which participated in the pro-
NOTICES

**Title:** Final proposed rule on identification of poorly administered operations.

**Description:** The proposed rule includes provisions for the identification of institutions with poor administration, including the development of a nationwide information collection process. The rule also addresses the use of this information for program management, evaluation, and budgeting.

**Implementation:** The proposed rule is scheduled for implementation in Fall 1978.

**Frequency:** Annual.

**Responsibility:** Federal agency and congressional response.

**Information Collected:**
- **Data Collection Plan:**
  - **Method of collection:** Mail.
  - **Time of collection:** Fall 1978.
  - **Frequency:** Annually.

- **Respondents:**
  - **Type:** Heads of accrediting and State approval agencies for postsecondary education.
  - **Number:** 100 (Universe).
  - **Estimated average man-hours per respondent:** 2 hours.

- **Information to be Collected:**
  - **Fiscal data regarding all programs for the period ending June 30, 1978:**
    - Number of students receiving financial aid by ethnic, sex, and income categories.
    - Amount spent by type of student and income categories.
    - Funds authorized and expended by program.
  - **Application data:**
    - Funds needed to operate programs.
    - Historical information regarding total enrollment, cost of attendance, revenue, and other sources of financial aid.

**Evaluation:**
- **Evaluation of the OE criteria for the recognition of accrediting and State approval agencies:** An annual evaluation report will be transmitted to appropriate congressional committees.

**Legislative Authority:**
- **Title:** Final proposed rule on identification of poorly administered operations.
- **Section:** 417.
- **Number:** 3.
- **Description:** The Secretary shall transmit to appropriate congressional committees an annual report on the effectiveness of the proposed rule.

**Voluntary/Obligatory Nature of Response:** Voluntary.

**Other Notes:**
- **Frequency:** One-time.
- **Other Information:**
  - **Publication:** Federal Register, Vol. 43, No. 146—Friday, July 28, 1978.
  - **Number:** 32863.

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**Federal Register, Vol. 43, No. 146—Friday, July 28, 1978**

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**Description:** The proposed rule includes provisions for the identification of institutions with poor administration, including the development of a nationwide information collection process. The rule also addresses the use of this information for program management, evaluation, and budgeting.

**Implementation:** The proposed rule is scheduled for implementation in Fall 1978.

**Frequency:** Annual.

**Responsibility:** Federal agency and congressional response.

**Information Collected:**
- **Data Collection Plan:**
  - **Method of collection:** Mail.
  - **Time of collection:** Fall 1978.
  - **Frequency:** Annually.

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**Voluntary/Obligatory Nature of Response:** Voluntary.

**Other Notes:**
- **Frequency:** One-time.
- **Other Information:**
  - **Publication:** Federal Register, Vol. 43, No. 146—Friday, July 28, 1978.
  - **Number:** 32863.
attributable to the recognition process or independent of it.

Suggestions for modification of the recognition process; extent of agreement within the accreditation community on about 50 suggested changes in the recognition process.

Expert judges of accreditation (State agencies and legislators, Federal agency and congressional staff members, postsecondary school administrators and faculty members, independent experts and critics of accreditation):

Comparative importance of accrediting agency characteristics.

Evidence on the reliability and validity of the OE recognition process.

Chairpersons of accrediting agency commissions or boards:

Evidence on the reliability and validity of the OE recognition process.

DESCRIPTION OF A PROPOSED COLLECTION OF INFORMATION AND DATA ACQUISITION ACTIVITY

1. TITLE OF PROPOSED ACTIVITY

Institutional release of funds/request for additional funds under the supplemental educational opportunity grants and/or college work-study programs.

2. AGENCY/BUREAU/OFFICE


3. AGENCY FORM NUMBER

OE form 1285.

4. LEGISLATIVE AUTHORITY FOR THIS ACTIVITY

The supplemental educational opportunity grants statute states that, "funds allocated to an institution for initial grants which the institution anticipates will not be used by the end of the period for which such funds were made available may be reallocated on an equitable basis to other institutions in that State." Pub. L 95-205 (20 U.S.C. 10706-3), section 406 of the Education Amendments of 1974, Pub. L. 93-380 (88 Stat. 552, 553.) The Council is directed to:

Advise the Commissioner of Education on the implementation of Section 406 of the Education Amendments of 1974, sections 331-336 of the Education amendments of 1978, and the Career Education Incentive Act and carry out such advisory functions as it deems appropriate, including reviewing the operation of these sections and all other programs of the Division of Education pertaining to the development and implementation of career education, evaluating their effectiveness in meeting the needs of career education throughout the United States, and in determining the need for further legislative remedy in order that all citizens may benefit from the purpose of career education as described in section 406 and in the Career Education Incentive Act.

The Council with the assistance of the Commissioner conducted a survey and assessment of the current status of career education programs, projects, curricula and materials in the United States and submitted to Congress a report on such survey.

The Assistant Secretary shall, to the extent practicable, seek the advice and assistance of the Council concerning the lifelong learning activities authorized by section 133, Part B, Title I of the Higher Education Act of 1965, as amended.

The meeting of the Council shall be open to the public. The meeting will be held on Monday, August 28, 1978 and will begin at 9 a.m. and end at 4:30 p.m. The meeting will be held at the Federal Office Building No. 6 (FOB No. 6), located at 400 Maryland Avenue SW. (room 3000), Washington, D.C. 20202.

The proposed agenda includes:

2. Legislative Update.
3. Recent Developments in Career Education.
4. Subcommittee and Task Force Reports.
5. New Business.

Records shall be kept of all Council proceedings and shall be available 14 days after the meeting for public inspection at the Office of Career Education located at Seventh and D Streets SW., room 3100, FOB No. 3, Washington, D.C. 20202.


JOHN LINDIA,
Delegate, National Advisory Council for Career Education.

[FR Doc. 78-20893 Filed 7-27-78; 8:45 am]

[4110-02]

Office of Education
NATIONAL ADVISORY COUNCIL FOR CAREER EDUCATION
Meeting
AGENCY: Office of Education, National Advisory Council for Career Education.

ACTION: Notice.

SUMMARY: This notice sets forth the schedule and proposed agenda of forth coming meeting of the National Advisory Council for Career Education. It also describes the functions of the Council. Notice of the meeting is required pursuant to Section 10 (a) (2) of the Federal Advisory Committee Act (Pub. L. 92-463.) This document is intended to notify the general public of their opportunity to attend.


ADDRESS: Room 300, FOB No. 6, 400 Maryland Avenue, SW., Washington, D.C.20202.

FOR FURTHER INFORMATION CONTACT:

The National Advisory Council for Career Education is established under section 406 of the Education Amendments of 1974, Pub. L. 93-380 (88 Stat. 552, 553.) The Council is directed to:

Advise the Commissioner of Education on the implementation of Section 406 of the Education Amendments of 1974, sections 331-336 of the Education amendments of 1978, and the Career Education Incentive Act and carry out such advisory functions as it deems appropriate, including reviewing the operation of these sections and all other programs of the Division of Education pertaining to the development and implementation of career education, evaluating their effectiveness in meeting the needs of career education throughout the United States, and in determining the need for further legislative remedy in order that all citizens may benefit from the purpose of career education as described in section 406 and in the Career Education Incentive Act.

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JOHN LINDIA,
Delegate, National Advisory Council for Career Education.

[FR Doc. 78-20893 Filed 7-27-78; 8:45 am]

[4110-03]

Food and Drug Administration

[DOCKET No. 782-0105]

ASPER FIBER CORP., FIBER FOR, INC.

Petition for Affirmation of Gens Status

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: Aspen Fiber Corp. and Fiber For, Inc., have jointly filed a petition (GRASP MF-3714) proposing affirmation that ground whole aspen and ground aspen parts used as a feedstuff for livestock are generally recognized as safe (GRAS).

DATE: Comments by September 26, 1978.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and
Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

William D. Price, Bureau of Veterinary Medicine (HFV-123), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-3442.

SUPPLEMENTARY INFORMATION:

Under the Federal Food, Drug, and Cosmetic Act (secs. 201(a), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(a), 348, 371(a))), and the regulations for affirmation of GRAS status (§ 570.35 (21 CFR 570.35)), notice is given that Aspen Fiber Corp., Box 14, Marcell, Minn. 56667, and Fiber For, Inc., R.D. No. 4, Box 207, Prior Lake, Minn. 55372, have jointly filed a petition for GRAS affirmation (GRASP MF-3714) which has been placed on public display at the Office of the Hearing Clerk. The petition proposes affirmation that ground whole aspen and ground aspen parts are GRAS as an animal feed.

The petition states that ground whole aspen is composed of the entire tree, including leaves, branches, trunk, and bark, but excluding roots and stump. Aspen parts may likewise include leaves, branches, trunk, and bark, but not in the precise ratio as in the harvested whole tree, whose parts also vary somewhat with tree age and size. Roots and stump are excluded to avoid possible contamination of dirt and rocks in the product. No processing other than that which physically changes the final particle size shall change the product. A mature harvestable aspen tree with a normal ratio of plant parts as occurring in the forest should contain 16 percent crude protein and 2.0 percent fat, and no more than 60.0 percent fiber.

Any petition that meets the format requirements outlined in § 570.35 is filed by the Food and Drug Administration. There is no prefilling review of the adequacy of data to support a GRAS conclusion. Thus the filing of a petition for GRAS affirmation should not be interpreted as a preliminary indication of suitability for affirmation.

Interested persons may, on or before September 28, 1978, review the petition and/or file comments, preferably four copies, with the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857. Comments should be identified with the Hearing Clerk docket number found in brackets in the heading of this document and should include any available information helpful in determining whether the substance is, or is not, generally recognized as safe. A copy of the petition and received comments may be seen in the office of the Hearing Clerk, address given above, from 9 a.m. to 4 p.m., Monday through Friday.


FRED J. KENGEL, Acting Director, Bureau of Veterinary Medicine.

[FR Doc. 78-20714 Filed 7-27-78; 8:45 am] [4110-03]

CIRCULATORY SYSTEM DEVICES PANEL
Meeting
AGENCY: Food and Drug Administration.

Each public advisory committee meeting listed above may have as many as four separable portions: (1) an open public hearing; (2) an open committee discussion; (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. The dates and times reserved for the separate portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairman determines will facilitate the committee’s work.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this Federal Register notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed.
above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairman's discretion.

Persons interested in specific agenda items to be discussed in open session may ascertain from the contact person the approximate time of discussion.

A list of committee members and summary minutes of meetings may be obtained from the Public Records and Documents Center (IPC-18), 5600 Fishers Lane, Rockville, Md. 20857, between the hours of 9 a.m. and 4 p.m., Monday through Friday. The FDA regulations relating to public advisory committees may be found in 21 CFR Part 14.

The Commissioner, with the concurrence of the Chief Counsel, has determined for the reasons stated that those portions of the advisory committee meetings so designated in this notice shall be closed. The Federal Advisory Committee Act (FACA), as amended by the Government In the Sunshine Act (Pub. L. 94-409), permit such closed advisory committee meetings in certain circumstances. Those portions of a meeting designated as closed, however, shall be closed for the shortest possible time, consistent with the intent of the cited statutes.

The FACA, as amended, provides that a portion of a meeting may be closed where the matter for discussion involves a trade secret; commercial or financial information that is privileged or confidential; information of a personal nature, disclosure of which would be a clearly unwarranted invasion of personal privacy.

Examples of portions of FDA advisory committee meetings that ordinarily shall not be closed include the review, discussion, and evaluation of general preclinical and clinical test protocols and procedures for a class of drugs or devices; consideration of labeling requirements for a class of marketed drugs or devices; review of data and information on specific investigational or marketed drugs and devices that have previously been made public; presentation of any other data or information that is not exempt from public disclosure pursuant to the FACA, as amended; and, notably, deliberative sessions to formulate advice and recommendations to the agency on matters that do not independently justify closing.


DONALD KENNEDY, Commissioner of Food and Drugs.

(FD Rs. 78-30652 Filed 7-27-78; 8:45 am)

[4110-03]

(Docket No. 78N-0179)

KAHLE TURKEY FARMS & HATCHERY

Applications For Animal Feeds Bearing or Containing New Animal Drugs; Opportunity For Hearing

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This is a notice of opportunity for hearing on the proposal by the Director of Bureau of Veterinary Medicine to withdraw approval of all applications for animal feeds bearing or containing new animal drugs (form FD-1800) for Kahle Turkey Farms & Hatchery, 1, Fort Jennings, Ohio 45844. The reason for the proposed withdrawal is that new information shows that the firm's methods and controls used for manufacturing and processing such feeds are not adequate to assure and preserve the identity, strength, quality, and purity of the new animal drugs therein nor were they made adequate within a reasonable time after receipt of written notice specifying the deficiencies.

DATE: A written appearance requesting a hearing and data and analysis upon which a request for a hearing relies must be submitted by August 28, 1978.

ADDRESS: Written requests to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-45, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT: Frank Pugliese, Bureau of Veterinary Medicine (HFA-294), Food and Drug Administration, Room 4-717, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-3460.

SUPPLEMENTARY INFORMATION: Kahle Turkey Farms & Hatchery raises turkeys and also manufactures medicated feeds to be fed to the turkeys that it raises. Three approved medicated feed applications (form FD-1800) for the manufacture of medicated feeds bearing or containing a new animal drug as required by section 512(m) of the Federal Drug, Food, and Cosmetic Act (21 U.S.C. 360b(m)) as follows:

1. F 39-529V for animal feeds containing 0.0375 percent carbarsone (not U.S.P.); approved August 1, 1968.

2. F 39-528V for animal feeds containing 0.0375 percent carbarsone (not U.S.P.); 0.01875 percent zoalene; approved March 9, 1970.

3. C 49-338V for animal feeds containing 0.0375 percent carbarsone (not U.S.P.); 0.0011 percent bacitracin (as bacitracin methylene disalicylate); approved March 15, 1972.

For a feed manufacturer to obtain approval of the Food and Drug Administration (FDA) for the manufacture of a medicated feed bearing or containing a new animal drug, it must submit a form FD-1800 for each medicated feed that it wishes to produce. Such application requires, among other things, that certain assays be performed at periodic intervals and that the sponsor comply with the current good manufacturing practice regulations as set forth in part 225 (21 CFR pt. 225).

The current good manufacturing practice regulations in part 225 are criteria for the manufacturing of medicated feeds to assure that such drugs meet the requirements of the act as to safety and that they have the identity and strength, quality and purity characteristics they purport or are represented to possess.

On March 14 through 17, 1977, FDA conducted an inspection of the Kahle Turkey Farm. A copy of the findings of the investigator, which were given to Mr. Kahle, manager of the farm, included the following:

1. No. production records were maintained for the manufacture of feeds containing the drug carbarsone.

2. No. production records were maintained for other medications used as water or feed additives.

3. No assay results of finished carbarsone medicated feeds were available for observation.

4. No. assay results of finished medicated feeds using other medications were performed.

In a regulatory letter, dated May 13, 1977, FDA notified the firm that the...
conditions and practices noted during the March inspection were violations of section 501(a)(2)(B) of the Food, Drug, and Cosmetic Act (21 U.S.C. 351(a)(2)(B)) as follows:

1. Failure to maintain daily inventory records for each drug used, as required by §225.42 (21 CFR 225.42).

2. Failure to perform periodic assays of the drug components in the medicated feeds manufactured, as required by §225.102 (21 CFR 225.102).

The Food and Drug Administration requested that the firm take prompt action to correct the violations.

As a followup to the regulatory letter, FDA inspected Kahle Turkey Farms on August 3 and 4, 1977. A copy of the findings, which were given to Mr. Kahle, included the following:

1. No daily inventory record for each drug used was maintained.

2. No periodic assays were run on medicated feeds for drug components.

3. Neither a master record file nor production records for medicated feeds manufactured were maintained.

4. No receipt record was maintained for incoming lots of drugs received.

The Director of the Bureau of Veterinary Medicine notified the firm by letter, dated October 26, 1977, that because of its continuing violations of the Federal Food, Drug, and Cosmetic Act for continuing to fail to withdraw the firm's medicated feed applications unless the violations were promptly corrected. The Director requested that the firm reply within 10 days with a plan as to what it intended to do to correct the violations noted. The firm responded on or about November 18, 1977 that it was keeping records and was trying to comply with the agency's demands.

On February 9 through 14, 1978, FDA reinspected the firm and the investigators noted the following:

1. Daily inventory record for each drug used was not maintained.

2. Master record files or production records for medicated feeds manufactured were not maintained.

3. No periodic assays were run for medicated feeds for drug components.

The investigators stated that although the firm had started to keep inventory records and production records, such recordkeeping was discontinued on October 15, 1977.

Therefore, notice is given to the above-listed firm and to any other interested persons who may be adversely affected that the Director proposes to issue an order under section 512(m) (4)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(m)(4)(B)(ii)), withdrawing approval of the listed applications and all amendments and supplements thereto.

The investigation shows that the methods used in, and the controls used for, the manufacture and processing of animal feeds bearing or containing new animal drugs are inadequate to assure and preserve the identity, strength, quality, and purity of the new animal drugs contained therein, and were not made adequate within a reasonable time after receipt of written notice specifying such deficiencies.

Therefore, notice is given to the holder of the approvals or any other interested person elects to avail himself or herself of an opportunity for hearing under section 512(m)(4)(B) of the act and §514.200 (21 CFR 514.200), that person must file with the hearing clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, a written appearance requesting such a hearing and giving the reason why the applications should not be withdrawn, i.e., show that the required records were being kept and that the required assays were being done, by August 29, 1978.

The failure of the holder of the approvals to file timely written request and request for hearing as required by §514.200 constitutes an election not to avail himself or herself of the opportunity for a hearing, and the Director of the Bureau of Veterinary Medicine will summarily enter a final order withdrawing the approvals.

A request for hearing may not rest upon mere allegations or denials, but it must set forth specific facts showing that there is a genuine and substantial issue of fact that requires a hearing.

If it conclusively appears from the face of the data, information, and factual analyses in the request for hearing that there is no genuine and substantial issue of fact that precludes the withdrawal of approval of the application, or when a request for hearing is not made in the required format or with the required analyses, the Commissioner of Food and Drugs will enter summary judgment against the person who requests a hearing, making findings and conclusions, denying a hearing.

If review of the data or information submitted by the applicant or any other interested persons warrants the conclusion that there exists substantial evidence demonstrating the firm was in compliance with the requirements of current good manufacturing practice, the Commissioner will rescind this notice of opportunity for hearing for that product. The Commissioner reserves the right to verification of such data and information before reaching a decision to rescind the notice.

If a hearing is requested and is justified by the applicant's response to this notice of opportunity for hearing, the issues will be defined, an administrative law judge will be assigned, and a written notice of the time and place at which the hearing will commence will be issued as soon as practicable.

Four copies of all submissions pursuant to this notice must be filed with the hearing clerk, Food and Drug Administration. Except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, responses to this notice may be seen in the office of the hearing clerk (HFA-305), Food and Drug Administration, between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351(m), 82 Stat. 343-351 (21 U.S.C. 360b(m))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1) and redelegated to the Director of the Bureau of Veterinary Medicine (21 CFR 5.84).


Fred J. Kingma,
Acting Director, Bureau of Veterinary Medicine.

[FR Doc. 78-20712 Filed 7-27-78; 8:45 am]

[41110-03]

Recycled Animal Waste

Request for Data, Information, and Views;
Extension of Time for Submissions

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This notice extends to September 25, 1978 the time for submitting data, information, and views concerning a notice regarding use of animal waste as animal feed.


ADDRESS: Written submissions to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT: Veterinary Drugs: Jack Taylor, Bureau of Veterinary Medicine (HVF-138), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-5247.

Foods: William Horwitz, Bureau of
Supplemental information: In a notice published in the Federal Register of December 27, 1977 (42 FR 64662), the Commissioner of Food and Drugs requested data, information, and views regarding use of animal waste as feed. The notice provided that written submissions be submitted by June 26, 1978.

A joint annual meeting of the American Dairy Science Association and the American Society of Animal Science was held July 9-13, 1978 at Michigan State University, East Lansing, Mich. As part of this meeting, a symposium was held on the management and utilization of animal waste, including use of processed animal waste products as feed. To include the information obtained at the symposium and to enable persons attending the symposium to submit their views on the December 1977 Federal Register notice, the Commissioner concludes that a 90-day extension for submitting data, information, and views is justified. Therefore, the period of time for submitting comments is extended to September 25, 1978.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 512, 82 Stat. 343-351 (21 U.S.C. 360b)) and under authority delegated to the Commissioner (21 CFR 5.1).


William P. Randolph,
Acting Associate Commissioner, Regulatory Affairs.

[FR Doc. 78-20713 Filed 7-27-78; 8:45 am]

[4110-03]

SCHERING CORP.

Utonex (Ethinyl-Estradiol and Nitrofurathiazide) Suspension and Suppositories: Withdrawal of Approval of New Animal Drug Applications

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This notice withdraws approval of new animal drug applications (NADA's) 13-003 and 13-660, that provided for use of Utonex Metritis Suspension and Utonex Metritis Suppositories, respectively. These products are intended for treating metritis in cows. This action is taken in response to a request by Schering Corp., the sponsor.


FOR FURTHER INFORMATION CONTACT:

Frank Pugliese, Bureau of Veterinary Medicine (HPV-234), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-3460.

SUPPLEMENTARY INFORMATION: Schering Corp., Galloping Hill Road, Kenilworth, N.J. 07033, is the sponsor of the NADA that is withdrawn. Utonex Metritis Suspension intended for intruterine use in bovine animals for the treatment of metritis and metritis complicated by retained placenta. Each milliliter of the product contains 0.1 milligram of ethinyl estradiol and 1 mg of nitrofurathiazide. The applications became effective on March 5, 1962. The firm is also the sponsor of NADA 13-660 covering Utonex Metritis Suppositories. Each suppository contains either a sulphanilamide and 30 mg of nitrofurathiazide. The product is used in the same manner as the suspension. This NADA was originally approved on February 1, 1963.

Utonex Metritis Suspension was subject to review by the National Academy of Sciences-National Research Council (NAS/NRC) Drug Efficacy Study Group, and the findings of that review and the Food and Drug Administration's conclusions were published in the Federal Register of August 25, 1970 (35 FR 13544). The NAS/NRC review evaluated the products as probably effective for the treatment of metritis and metritis complicated by retained placenta. The sponsor was also notified that tissue residue data might be needed. On December 17, 1971, the agency informed the firm that because the nitrofurathiazide component was a potential carcinogen, either a analytical method or data showing the drug not to be a carcinogen was necessary. The firm agreed to provide the essential data by their letter of May 10, 1972. The firm subsequently initiated a 2-year study in rats and a 1½-year study in mice to establish safety of the products. The final report of the rat study, submitted on April 15, 1977, was found inadequate, and the firm was so notified on February 8, 1978. The final report of the mouse study was submitted February 9, 1978, and was also found inadequate. On May 25, 1978, the agency informed the firm that to permit the continued marketing of the drug in view of unresolved questions regarding the safety of the drugs was not in the public interest. The firm replied by letter of June 8, 1978, advising that distribution of the products had been discontinued and requesting withdrawal of approval of the applications.

Therefore under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b) and in accordance with §514.115 of the new animal drug regulations (21 CFR 514.115), notice is given that approval of NADA's 13-003 and 13-660 and all supplements for Utonex Metritis Suspension and Utonex Metritis Suppositories is hereby withdrawn, effective July 28, 1978.


Fred J. Kingma,
Acting Director, Bureau of Veterinary Medicine.

[FR Doc. 78-20713 Filed 7-27-78; 8:45 am]

[4110-03]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

Applications for preemption of State and local requirements

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This notice announces an opportunity for interested persons to request an oral hearing on a proposed rule on State applications for exemption from preemption of State and local requirements.

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This notice announces an opportunity for interested persons to request an oral hearing on a proposed rule on State applications for exemption from preemption of State and local requirements.


ADDRESS: Written requests (preferably four copies) to the Hearing Clerk (HFC-20), Food and Drug Administration, room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FURTHER INFORMATION CONTACT:

Joseph M. Sheadan, Bureau of Medical Devices (HFK-70), Food and Drug Administration, 8757 Georgia Avenue, Silver Spring, Md. 20910, 301-427-7114.

SUPPLEMENTARY INFORMATION: The Food and Drug Administration announces an opportunity for oral hearing on its proposal on the State applications for exemption from preemption of State and local require-
ments governing the labeling and conditions of sale of hearing aids. The proposal affects the applications of the following State and local governments: Arizona, California, Connecticut, District of Columbia, Florida, Kentucky, Maine, Minnesota, Mississippi, Nebraska, New Jersey, New Mexico, New York, Ohio, Oregon, Pennsylvania, Texas, Washington, and West Virginia. Interested persons may request an oral hearing on or before August 28, 1978.

Elsewhere in this issue of the FEDERAL REGISTER, the Commissioner of Food and Drugs is proposing to grant or to deny each State application requesting an exemption from Federal preemption for certain State laws and regulations pertaining to hearing aids, allowing 60 days for comment. To enable expeditious review of any request for an oral hearing, the Commissioner has limited the period for requesting an oral hearing to the first 30 days of the comment period. Upon a determination that an oral hearing should be held, the Commissioner shall publish a notice in the FEDERAL REGISTER of the time, date, and place of the hearing. The procedures to govern any such oral hearing are those applicable to a public hearing before the Commissioner under Part 15 (21 CFR Part 15).

Interested persons may on or before August 28, 1978, submit requests for an oral hearing on the subject matter to the Hearing Clerk, address above. All requests should be identified with the Hearing Clerk docket number found in brackets in the heading of this notice.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 521, 90 Stat. 574 (21 U.S.C. 360k)) and under authority delegated to the Commissioner (21 CFR 5.1).


SHERWIN GARDNER,
Acting Commissioner
of Food and Drugs.

[FR Doc. 78-20860 Filed 7-27-78; 8:45 am]

NOTICES

PARENTERAL PROTEIN SUPPLEMENTS CONTAINING PROTEIN HYDROLYSATE

Opportunity For Hearing on Proposal To Withdraw Approval of New Drug Applications

AGENCY: Food and Drug Administration (FDA).

ACTION: Notice.

SUMMARY: This notice proposes to withdraw approval of the new drug applications for all parental protein hydrolysate solutions on the basis that the drugs are not shown to be safe for use as a dietary supplement of protein. Protein hydrolysate solutions are sterile parenteral solutions of amino acids and short-chain peptides, derived from natural protein sources such as fibrin or casein, and are administered intravenously.

DATE: Hearing requests due on or before August 28, 1978.

ADDRESS: Communications forwarded in response to this notice should be identified with the reference number DESI 3590, directed to the attention of the appropriate office named below, and addressed to the Food and Drug Administration, 5600 Fishers Lane, Rockville, Md. 20857.

Requests for Hearings (identify with the appropriate Docket number appearing in the heading of this notice: Hearing Clerk, Food and Drug Administration (HFA-305), room 4365. Requests for opinion of the applicability of this notice to the Drug Efficacy Study Implementation Project Manager (HFD-501), Bureau of Drugs.

FOR FURTHER INFORMATION CONTACT:
Ronald L. Wilson, Bureau of Drugs (HFD-32), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-3650.

SUPPLEMENTARY INFORMATION:
In a notice (DESI 3590; Docket No. 78N-0112) published in the FEDERAL REGISTER of September 21, 1976 (FR 11132), the Director of the Bureau of Drugs announced his conclusion that all combination products containing protein hydrolysates and single-entity products containing other than 5 percent protein hydrolysates lack substantial evidence of effectiveness. In response to the NOH, Travensol Laboratories submitted a hearing request for the products described below. Since no other hearing request was received, approval of the other drug products listed in the September 21, 1976 NOH (Docket No. 76N-0112) was withdrawn in the Federal Register of February 4, 1977 (FR 6908).

The part of NDA 5-419 pertaining to Travamin Injection containing 5 percent protein hydrolysate and 5 percent dextrose; Travensol, Laboratories, Inc.

Travamin Injection containing 10 percent protein hydrolysate (no NDA); Travensol Laboratories, Inc.

Travamin Injection containing 5 percent protein hydrolysate, 12.5 percent fructose, and 2.4 percent alcohol (no NDA); Travensol Laboratories proposed to withdraw approval of the new drug applications on the basis that substantial evidence of effectiveness is lacking for the drugs. The Director is hereby admonished that this notice includes the additional ground of a lack of evidence of safety. This amendment applies only to the two combination products and one single-entity product that are the subject of the hearing request submitted by Travensol Laboratories in response to the NOH. In addition, the Director concludes that all the single-entity products containing 5 percent protein hydrolysate that were the subject of the other September 21, 1976 notice (Docket No. 76N-0112) also lack evidence of safety. The Director therefore proposes to withdraw approval of the new drug applications for all protein hydrolysates on the ground that new evidence, not contained in the applications or not available to the Food and Drug Administration until after the applications were approved, evaluated together with the evidence available when the applications were approved, shows that the drug products are not shown to be safe for use under the conditions for use upon the basis of which the applications were ap-
proved. Specifically, the Director refers to the following adverse effects, which give an unfavorable benefit-to-risk ratio for these drugs, and the fact that a more effective alternative drug product having less potential for risk is readily available.

A. Studies have conclusively demonstrated that protein hydrolysates contain large amounts of ammonia (Refs. 1, 3, 7). Although hyperammonemia is usually clinically asymptomatic, it may nevertheless damage the liver (Ref. 3).

B. Fever (Refs. 5, 9) and elevation of liver enzymes have been observed in patients infused with protein hydrolysates (Refs. 3, 14, 17).

C. Fungi and bacteria proliferate rapidly at room temperature in parenteral mixtures prepared from casein hydrolysates and dextrose, while they fail to multiply or grow very slowly in similar solutions of synthetic amino acids (Ref. 3).

D. Thirty to fifty percent of the content is peptides (Refs. 4, 13), and hypersensitivity has been reported on several occasions (Refs. 4, 9).

E. The titratable acidity of protein hydrolysates is high and this may contribute to the potential to cause metabolic acidosis (Ref. 19).

F. The high levels of acidic amino acids in protein hydrolysates, were associated with hypothalamic lesions in immature mice (Ref. 10).

G. The crystalline amino acid solutions for parenteral use are alternative drug products that have less potential for risk. In addition, studies have shown that about 3 times more of the hydrolysates are necessary to achieve the same level of nitrogen balance as compared to the crystalline solutions (Ref. 11), as 30 to 50 percent of the peptides are excreted in the urine (Refs. 13, 15). The amino acid solutions also have the advantage of increased effectiveness because they can be tailored to the patient's needs.

H. The casein hydrolysates are imbalanced in their composition, being poor in aromatic and S-containing amino acids (Refs. 4, 16) and arginine, and containing excessive amounts of glutamic acid (Ref. 12), which can cause vomiting (Ref. 12) and, in immature mice, brain damage (Ref. 10). Moreover, their composition is not reproducible (Refs. 8, 15), since it is difficult to standardize the hydrolytic process. The poor nutritional effectiveness and the high ammonia content of the hydrolysates may be the reason that studies have shown that there is no increase in the survival rate of infants who received hydrolysates as compared to infants supplemented with the crystalline amino acid solutions (Ref. 2). The fact that protein hydrolysates cost less than the crystalline amino acid solutions is far outweighed by their lesser nutritional effectiveness and high ammonia content.

References


Copies of these references are available for public examination in the Office of the Hear ing Clerk, and may be seen during working hours Monday through Friday.

Therefore, notice is given to the holder(s) of the new drug application(s) and col or the intended persons that the Director of the Bureau of Drugs proposes to issue an order under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)), withdrawing approval of the application(s) and all amendments and supplements thereto on the ground that new evidence of clinical experience, not contained in such application(s) or not available to the Director until after such application(s) was approved, shows that such drug(s) is not shown to be safe for use under the conditions of use upon the basis of which the application(s) was approved.

In addition to the holder(s) of the new drug application(s) specifically named above, this notice of opportunity for hearing applies to all persons who manufacture or distribute a drug product that is identical, related, or similar to a drug product named above, as defined in 21 CFR 310.6. It is the responsibility of every drug manufacturer or distributor to review this notice of opportunity for hearing and determine whether it covers any drug product that the person manufactures or distributes. Such person may request an opinion of the applicability of this notice to a specific drug product by writing to the Director of Drug Labeling Compliance (address given above).

In addition to the ground(s) for the proposed withdrawal of approval stated above, this notice of opportunity for hearing encompasses all issues relating to the legal status of the drug products subject to it (including identical, related, or similar drug products as defined in 21 CFR 310.6) e.g., any person that may have a special interest in the subject matter, in the opinion of the Director, shall have an opportunity to present information to the Director when the application(s) are amended and supplemented thereto.
the act, or pursuant to section 107(c) of the Drug Amendments of 1962, or for any other reason.

In accordance with the provisions of section 505 of the act (21 U.S.C. 355) and the regulations promulgated thereunder (21 CFR Parts 310, 314), the applicant(s) and all other persons subject to this notice pursuant to 21 CFR 310.6 are hereby given an opportunity for a hearing to show why approval of the new drug application(s) should not be withdrawn and an opportunity to raise, for administrative determination, all issues relating to the legal status of a drug product named above and of all identical, related, or similar drug products.

An applicant or any other person subject to this notice pursuant to 21 CFR 310.6 who decides to seek a hearing shall file (1) on or before August 28, 1978, a written notice of appearance and request for hearing, and (2) on or before September 28, 1978, the data, information and analyses on which the person relies to justify a hearing, as specified in 21 CFR 314.200. Any other interested person may also submit comments on this notice. The procedures and requirements governing this notice of opportunity for hearing, a notice of appearance and request for hearing, a submission of data, information, and analyses to justify a hearing, other comments, and a grant or denial of hearing, are contained in 21 CFR 314.200.

The failure of an applicant or any other person subject to this notice pursuant to 21 CFR 310.6 to file timely written appearance and request for hearing as required by 21 CFR 314.200 constitutes an election by the person not to make use of the opportunity for a hearing concerning the action proposed with respect to the product and constitutes a waiver of any contentions concerning the legal status of any such drug product. Any such drug product may not thereafter lawfully be marketed, and the Food and Drug Administration will initiate appropriate regulatory action to remove such drug products from the market. Any new drug product marketed without an approved NDA is subject to regulatory action at any time.

A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the data, information, and factual analyses in the request for the hearing that there is no genuine and substantial issue of fact which precludes the withdrawal of approval of the application, or when a request for hearing is not made in the required format or with the required analyses, the Commissioner will enter summary judgment against the person(s) who requests the hearing, making findings and conclusions, denying a hearing.

All submissions pursuant to this notice shall be filed in quintuplicate. Such submissions, except for data and information prohibited from public disclosure pursuant to 21 U.S.C. 331(j) or 18 U.S.C. 1951, may be seen in the office of the Hearing Clerk between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (Sec. 505, 52 Stat. 1052-1053, as amended (21 U.S.C. 355)), and under authority delegated to the Director of the Bureau of Drugs (21 CFR 5.62).


J. Richard Crout,
Director, Bureau of Drugs.

[6712-01]

FEDERAL COMMUNICATIONS COMMISSION

MEXICAN STANDARD BROADCAST STATIONS

Notification List

List of New Stations, proposed changes in existing stations, deletions, and corrections in assignments of Mexican standard broadcast stations contained in the appendix to the recommendations of the North American Regional Broadcasting Agreement Engineering Meeting, January 30, 1941.

JUNE 1, 1978.

MEXICAN LIST No. 294

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<th>Call letters</th>
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<th>Schedule</th>
<th>Class</th>
<th>Antenna height (feet)</th>
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<td>550 kHz</td>
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<td>XEES</td>
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<td>XEAMO</td>
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<td>Cd Obregan, Son.</td>
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<td>XEAG</td>
<td>Lazaro Cardenas, Mich.</td>
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<td>240</td>
<td>120</td>
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<tr>
<td>Call letters</td>
<td>Location</td>
<td>Power watts</td>
<td>Antenna radiation m/ kw</td>
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<td>XEGEM</td>
<td>Toluca, Mex., N. 19°17'33&quot;, W. 99°39'38&quot;, (PO 12 kW, ND-U-173)</td>
<td>2.000N</td>
<td>930 kHz</td>
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<td>Oaxaca, Oax., N. 17°00'52&quot;, W. 99°30'06&quot;, (PO 12 kW, ND-U-175)</td>
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<td>XEUM</td>
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<td>II</td>
<td>100</td>
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<td>XEEB</td>
<td>Ecatepec, Mts., N. 23°29'29&quot;, W. 105°66'15&quot;, (PO 250 kW, ND-U-170)</td>
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<td>DA-N</td>
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<td>1120 kHz</td>
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<td>1120 kHz</td>
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<td>Zacatecas, Zac., N. 22°46'41&quot;, W. 107°31'31&quot;</td>
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<td>ND-D-175</td>
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<td>XEYJ</td>
<td>Cancun, Q., N. 21°00'58&quot;, W. 86°51'11&quot;</td>
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<td>1340 kHz</td>
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<td>XEOK</td>
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<td>1360 kHz</td>
<td>ND-D-190</td>
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<td>III</td>
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<td>120</td>
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<td>XEJS</td>
<td>Puerto Vallarta, Jal., N. 20°36'06&quot;, W. 105°14'30&quot;</td>
<td>1.000</td>
<td>1360 kHz</td>
<td>ND-D-190</td>
<td>D</td>
<td>III</td>
<td>185</td>
<td>120</td>
</tr>
<tr>
<td>XESA</td>
<td>Culiacan, Sin., N. 24°54'34&quot;, W. 107°24'47&quot;, (see assignment on 620 kHz)</td>
<td>1.000D/ .500N</td>
<td>1360 kHz</td>
<td>ND-U-219</td>
<td>U</td>
<td>III</td>
<td>246</td>
<td>120</td>
</tr>
<tr>
<td>XEXM</td>
<td>Jeron, Zac., N. 22°36'51&quot;, W. 102°39'48&quot;, (PO 1 kW, ND-D-180)</td>
<td>1.000D/ .100N</td>
<td>1360 kHz</td>
<td>ND-U-190</td>
<td>D</td>
<td>III</td>
<td>185</td>
<td>120</td>
</tr>
<tr>
<td>XEXOK</td>
<td>Las Cruces, Gro., N. 18°56'55&quot;, W. 99°49'34&quot;</td>
<td>1.000</td>
<td>1380 kHz</td>
<td>ND-D-190</td>
<td>D</td>
<td>III</td>
<td>200</td>
<td>120</td>
</tr>
<tr>
<td>XEBP</td>
<td>Tecom, Coah., N. 25°32'18&quot;, W. 103°27'55&quot;</td>
<td>1.000D/ .250N</td>
<td>1450 kHz</td>
<td>ND-U-175</td>
<td>U</td>
<td>IV</td>
<td>230</td>
<td>90</td>
</tr>
<tr>
<td>XEUAA</td>
<td>Aguaclancares, Agu., N. 21°54'46&quot;, W. 102°19'01&quot;</td>
<td>.250</td>
<td>1550 kHz</td>
<td>ND-D-190</td>
<td>D</td>
<td>II</td>
<td>161</td>
<td>120</td>
</tr>
<tr>
<td>XEHOS</td>
<td>Hermosillo, Son., N. 20°04'29&quot;, W. 110°57'36&quot;</td>
<td>5.000D/ 5.000N</td>
<td>1540 kHz</td>
<td>ND-U-175</td>
<td>U</td>
<td>II</td>
<td>213</td>
<td>120</td>
</tr>
</tbody>
</table>

**NOTICES**

**MEXICAN LIST No. 284—Continued**
NOTICES

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Office of the Secretary
SOCIAL SECURITY ADMINISTRATION

Statement of Organization, Functions, and Delegations of Authority

Part S (formerly Part 4) of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health, Education, and Welfare contains the Statement of Organization, Functions, and Delegations of Authority for the Social Security Administration (SSA). Notice is hereby given that the organization of the Office of Family Assistance published in the FEDERAL REGISTER (p. 32846-7) of June 28, 1977, is amended to reflect organizational changes necessary to permit the Associate Commissioner, OFA to devote more of his time and energy to interfaces with other components of SSA, to active leadership in program direction and program development in the regions, and to working with other Federal agencies as well as non-governmental bodies toward more effective and efficient income maintenance programs in the States and other jurisdictions.

The changes made establish a second Deputy Associate Commissioner and eliminate the two positions of Office Director. These changes affect section SF-10 and section SF-20 as indicated below.

Section SF-10 Office of Family Assistance (Organization) The Office of Family Assistance, under the leadership of the Associate Commissioner for Family Assistance consists of the:

A. Associate Commissioner for Family Assistance
B. Deputy Associate Commissioner for Family Assistance
C. Deputy Associate Commissioner for Family Assistance
D. Immediate Office of the Associate Commissioner for Family Assistance which includes the:
   I. Regional Liaison Staff
   E. The Special Programs Staff
F. The Division of Policy
G. The Division of Procedures
H. The Division of Financial Management
I. The Division of Management Support
J. The Division of Planning, Evaluation and Statistical Analysis

Section SF-20 Office of Family Assistance (Functions)

A. 1. The Associate Commissioner for Family Assistance is directly responsible to the Commissioner of Social Security (the Commissioner) for performance of OFA's mission and provides general supervision to the principal components of OFA.
   2. During the absence or disability of the Associate Commissioner for Family Assistance (the Associate Commissioner) the Deputy Associate Commissioner designated by the Associate Commissioner shall act as Associate Commissioner. In the event of a vacancy in the position of Associate Commissioner, the Deputy Associate Commissioner designated by the Commissioner shall act as Associate Commissioner.
   3. In the event of the absence or disability of the Associate Commissioner and both Deputy Associate Commissioners an OFA executive designated by the Associate Commissioner shall serve as acting head of OFA.
   4. Should the positions of Associate Commissioner and both Deputy Associate Commissioners become vacant, an SSA official designated by the Commissioner shall serve as acting head of OFA.

B. The Deputy Associate Commissioner for Family Assistance assists the Associate Commissioner in carrying out his responsibilities and performs such other duties as the Associate Commissioner may prescribe. In addition, has specialized duties in day-to-day program policy activities. Such specialized duties would not lessen the deputy's OFA-wide responsibility.

C. The Deputy Associate Commissioner for Family Assistance
   Assists the Associate Commissioner in carrying out his responsibilities and performs such other duties as the Associate Commissioner may prescribe. In addition, has specialized duties in day-to-day program implementation activities. Such specialized duties would not lessen the deputy's OFA-wide responsibility.

D. The Immediate Office of the Associate Commissioner for Family Assistance:

I. The Regional Liaison Staff
   a. Assures continuous and effective communications between central and regional offices on program and management concerns.
   b. Assures that regional concerns and needs are given attention for resolution by central office components and/or the regional offices.

E. The Special Program Staff (SF-

1): 1. Administers the Cuban and Indochinese Refugee Programs including the development of regulations, policies and procedures and making arrangements for: financial assistance, resettlement services, emergency health services, assistance to public schools in impacted areas, loans to refugee students and protective care of minors. These regulations and guidelines pertaining to these programs.
   2. Directs Federal program activities relating to the repatriation of U.S. citizens from foreign countries. Coordinates the return of repatriates with Department of State. Coordinates the provision of services to repatriates with regional offices. Approves claims by State agencies for reimbursement, and makes determinations whether repayment by the repatriate is appropriate. Develops regulations and guidelines pertaining to the program.

F. The Division of Policy (SF-2):

1. Develops regulations and policies to implement laws governing family assistance programs and coordinates with the SSA Office of Policy and Regulations (OPR) on the issuance of regulations governing Federal/State income maintenance programs including policies to safeguard the rights of individuals and families; i.e., dependent and needy children in their own homes, in protective care in AFDC family foster homes, in child care institutions, and for emergency assistance to needy families with children.
   2. Develops, analyzes, and recommends concepts for new legislation concerning family assistance programs and coordinates these activities with the SSA Office of Program Evaluation and Planning.
   3. Evaluates State plan materials for consistency with Federal policies and recommends revisions to assure consistency with Federal law and regulations. Reviews and evaluates program management and quality control reports to determine program policy effectiveness and develops proposals for policy changes, proposed regulatory and/or legislative changes.
   4. Supports office of general counsel and other legal authorities in litigation involving family assistance programs.
   5. Conducts review of identified compliance and reconsideration issues; recommends and manages appropriate action.
6. Provides technical assistance and consultation to regions and States concerning Federal policies.

G. The Division of Procedures (SF/F-3):
1. Develops, issues and interprets operational procedures, relative to income maintenance regulations and which are designed to provide States with leadership and guidance in the most efficient and effective techniques of administering OFA programs.
2. Reviews proposed income maintenance legislation and regulations for procedural implementation impacts and feasibility.
3. Reviews and approves applications from States for Federal financial participation in the acquisition of ADP equipment or the design of automated information systems in support of OFA programs.
4. Reviews and evaluates the utilization of State and local agency manpower devoted to OFA program administration.
5. Provides technical assistance and consultation to the States concerning such matters as operational procedures, systems analysis, program training and establishing models and guides for States regarding income maintenance methods.

H. The Division of Financial Management (SF/F-1):
1. Reviews State budget forecasts and expenditure reports and related financial management activities and analyzes the consequences of these reports for the Federal budget.
2. Exercises financial control over grants to States for public assistance provided under OFA programs.
3. Provides training, technical assistance, and guidance to OFA regional components on matters pertaining to Federal/State financial management activities.
4. Establishes and issues program fiscal and accounting policies and procedures.
5. Prepares, presents, and executes the total OFA budget.
6. Analyzes and presents cost data for activities funded under OFA programs.

I. The Division of Management Support (SF/F-2):
1. Plans, organizes, and directs OFA's internal manpower utilization, organization, and training programs, in accordance with Federal, HEW, and SSA personnel management regulations, policies, and procedures.
2. Analyzes the organizational effectiveness of OFA components and insures uniform and effective manpower utilization and position management.
3. Manages the OFA repository of State plans for AFDC programs and periodic program appraisals and publishes "Characteristics of State AFDC Plans" and related analyses and reports.
4. Prepares the program budget for the U.S. repatriate program and performs related financial management activities.
5. Prepares and executes the salaries and expenses budget for the OFA.
6. Analyzes OFA facilities, space, and equipment needs and initiates necessary actions to provide same. Provides management services in the areas of forms; issuances; mail; reports; travel; safety; records; and property management.
7. Coordinates the review, preparation, and publication of OFA operational instructions to insure consistency, lack of duplication, receipt, and access to such material by OFA audiences. Coordinates the issuance process of the OFA regulations and program policies with the SSA Office of Policy and Regulations.

J. The Division of Planning, Evaluation, and Statistical Analysis (SF/F-3):
1. Develops OFA emergency, long-range, and short-range plans to assure effective continuity of OFA activities. Prepares trend analyses and reports, and energy and environmental impact statements.
2. Specifies program information needs and provides program input to SSA research efforts. Assesses the practical application of research findings to OFA program administration.
3. Develops statistical information relative to State, regional, and national program administration. Based upon such information, data developed by the Office of Research and Statistics, and other reports, evaluates program effectiveness, identifies potential program abuse, reports findings and recommends actions aimed at improving program administration and integrity.
4. Develops projects concerning client populations and program activities to meet the needs of OFA components and State agencies.
5. Develops a coordinated and comprehensive program for identifying major OFA operational planning objectives and monitors the implementation of such goals.
6. Coordinates external audits and audit reporting requirements with the SSA Office of Management and Administration.
7. Provides technical assistance and consultation to regions and States concerning planning, evaluation, statistical analyses, and related matters.


Leonard D. Schaeffer,
Assistant Secretary for Management and Budget.

[FRR Doc. 78-20638 Filed 7-21-78; 8:45 am]

[4110-88]

Alcohol, Drug Abuse, and Mental Health Administration

MINORITY ADVISORY COMMITTEE, ADAMHA

Meeting Cancellation

In FR Doc. 78-19146 appearing on page 29989 in the issue of Wednesday, July 12, 1978, the August 2-4, 1978 meeting of the Minority Advisory Committee, ADAMHA was announced. This meeting has been postponed and will be rescheduled at a later date.


Carolyn T. Evans,
Committee Management Officer, Alcohol, Drug Abuse, and Mental Health Administration.

(FRR Doc. 78-21143 Filed 7-27-78; 10:03 am)

[4310-84]

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

OUTER CONTINENTAL SHELF, GULF OF MEXICO

Proposed Oil and Gas Lease Sale No. 65

In connection with oil and gas leasing on the Outer Continental Shelf, the Secretary of the Interior has established a new policy relating to sale notices to further and enhance consultation with the affected coastal States. That policy includes providing the affected States with the opportunity to review the draft proposed sale notice prior to its final publication in the Federal Register. The following is a draft sale notice for proposed sale No. 65 in the offshore waters of the eastern Gulf of Mexico area. This notice is hereby published as a matter of information to the public.

Arnold E. Petty,
Acting Director,
Bureau of Land Management.

Approved: July 24, 1978.

Cecil D. Andrus,
Secretary of the Interior.

PROPOSED SALE NOTICE

1. Authority. This notice is published pursuant to the Outer Continental Shelf Lands Act (43 U.S.C. 1331-1343) and the regulations issued thereunder (43 CFR 3300).

2. Filing of Bids. Sealed bids will be received by the Manager, New Orleans Outer Continental Shelf (OCS) Office, Bureau of Land Management, Hale Boggs Federal Building, 500 Camp Street, Suite 841, New Orleans, La. 70130. Bids may be delivered, either by mail or in person, to the above address until 4:15 p.m. C.S.T., October 5, 1978; or by personal delivery to the Tulane...
NOTICES
32875

3. Method of Bidding. A separate bid in a sealed envelope labeled ’Sealed Bid for Oil and Gas Lease (insert number of tract), oil or gas, not to be opened until 10 a.m., c.s.t., October 17, 1978.” must be submitted for each tract. A suggested form appears in paragraph 11 of this notice. Bidders are advised that tract numbers are assigned solely for administrative purposes and are not the same as block numbers found on official protraction diagrams. All bids received shall be deemed submitted in accordance with applicable regulation, including 43 CFR 3300. The list of restricted joint bidders which applies to this sale was published in 43 FR 15560, April 13, 1978, as corrected in 43 FR 16427, April 18, 1978.

4. Bonus Bidding With a Fixed Sliding Scale Royalty. Bids on tracts 65-25, 65-26, 65-27, 65-28, 65-30, 65-31, 65-79, 65-80, 65-81, 65-82, 65-83, 65-84, 65-90, 65-91, 65-92, 65-93, 65-94, 65-95, 65-96, 65-97, 65-107, 65-109, and 65-110 must be submitted on a cash bonus bid basis with the percent royalty due in amount or value of production saved, removed or sold fixed according to the sliding scale formula described below. This formula fixes the percent royalty at a level determined by the value of lease production during each calendar quarter. For purposes of determining the royalty percent due on production during a quarter, the value of production during the quarter will be adjusted for inflation as described below. The determination of the value of the production on which royalty is due will be made pursuant to 30 CFR 250.54.

The fixed sliding scale formula operates in the following way: when the quarterly value of production, adjusted for inflation, is less than or equal to $13,235,259 million, a royalty of 18.66667 percent in amount or value of production saved, removed, or sold will be due on the unadjusted value or amount of production. When the adjusted quarterly value of production is equal to or greater than $13,235,259 million, but less than or equal to $16,654,082 million, the royalty percent due on the unadjusted value or amount of production is given by

\[
R_p = b \log_2 (V_s / S)
\]

where

- \( R_p \) = the percent royalty that is due and payable on the unadjusted amount or value of all production saved, removed, or sold in quarter \( q \).
- \( b = 10.0 \).
- \( \log_2 \) = natural logarithm.
- \( V_s \) = the value of production in quarter \( q \), adjusted for inflation, in millions of dollars.
- \( S = 25 \).

When the adjusted quarterly value of production is equal to or greater than $16,654,082 million, the royalty percent due on the unadjusted value or amount of production is given by

\[
R_p = b \log_2 (V_s / S)
\]

where

- \( R_p \) = the percent royalty that is due and payable on the unadjusted amount or value of all production saved, removed, or sold in quarter \( q \).
- \( b = 20.17329 \).
- \( \log_2 \) = natural logarithm.
- \( V_s \) = the value of production in quarter \( q \), adjusted for inflation, in millions of dollars.
- \( S = 32.875 \).

In determining the quarterly percent royalty due, \( R_p \), the calculation will be carried to five decimal places (for example, 20.17329 percent). This calculation will incorporate the adjusted quarterly value of production, \( V_s \), in millions of dollars, rounded to the sixth digit; i.e., to the nearest dollar (for example, 15.392847 millions of dollars).

The form of the sliding scale royalty schedule is illustrated in Figure 1. Note that the effective quarterly royalty rate depends upon the inflation adjusted quarterly value of production. However, this rate is applied to the unadjusted quarterly value of production to determine the royalty payments due.

In adjusting the quarterly value of production for use in calculating the percent royalty due on production during the quarter, the actual value of production will be adjusted to account for the effects of inflation by dividing the actual value of production by the following inflation adjustment factor. The inflation adjustment factor used will be the ratio of the GNP fixed weighted price index for the calendar quarter preceding the quarter of production to the value of that index for the quarter preceding the issuance of the lease. The GNP fixed weighted price index is published monthly in the Survey of Current Business by the Bureau of Economic Analysis, U.S. Department of Commerce. The percent royalty will be due and payable on the actual amount or value of production saved, removed, or sold as determined pursuant to 30 CFR 250.54. The timing of procedures for inflation adjustments and determinations of the royalty due will be specified at a later date. Table 1 provides hypothetical examples of quarterly royalty calculations using the sliding scale formula just described under two different values for the quarterly price index.

Leases awarded on the basis of a cash bonus bid with fixed sliding scale royalty will provide for a yearly rental or minimum royalty payment of $3 per acre or fraction thereof.

Bidders for these tracts should recognize that the Department of Energy is authorized, under section 302 (b) and (c) of the Department of Energy Organization Act, to establish production rates for all Federal oil and gas leases.
NOTICES

Quarterly Royalty Rate
(Percent of unadjusted quarterly value of production)

Quarterly Royalty Rate
(Percent of unadjusted quarterly value of production)

65.00000

16.66667

$10$ $100$ $1000$ $10000$

Adjusted Quarterly Value of Production (mil. $)

Table 1. Hypothetical Quarterly Royalty Calculations

<table>
<thead>
<tr>
<th>Actual Value of Quarterly Production (millions of dollars)</th>
<th>GNP Fixed Weighted Price Index</th>
<th>Inflation Factor</th>
<th>Adjusted Value of Quarterly Production</th>
<th>Percent Royalty Rate</th>
<th>Royalty Payment (millions of dollars)</th>
</tr>
</thead>
<tbody>
<tr>
<td>10.000000</td>
<td>200.0</td>
<td>4/3</td>
<td>7.500000</td>
<td>16.66667</td>
<td>1.666667</td>
</tr>
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<td>200.0</td>
<td>4/3</td>
<td>22.500000</td>
<td>21.97225</td>
<td>6.591675</td>
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<tr>
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<td>200.0</td>
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<td>67.500000</td>
<td>32.95837</td>
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<td>43.94449</td>
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<tr>
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<td>607.500000</td>
<td>54.93061</td>
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<tr>
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<td>6.000000</td>
<td>16.66667</td>
<td>1.666667</td>
</tr>
<tr>
<td>30.000000</td>
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<tr>
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<td>250.0</td>
<td>5/3</td>
<td>496.000000</td>
<td>52.69918</td>
<td>426.863358</td>
</tr>
</tbody>
</table>

1 Column (2) divided by 150.0 (assumed value of GNP fixed weighted price index at time leases are issued).
2 Column (1) divided by Inflation Factor.
3 Column (1) times Column (5); All values are rounded for display purposes only.

FEDERAL REGISTER, VOL 43, NO. 146—FRIDAY, JULY 28, 1978
NOTICES

5. Bonus bidding with a fixed constant royalty. Bids on the remaining tracts to be offered at this sale must be on a cash bonus basis with a fixed royalty of 16% percent. Leases which may be issued will provide for a yearly rental payment or minimum royalty payment of $3 per acre or fraction thereof. A suggested cash bonus bid form is shown in paragraph 17.

6. Equal opportunity. Each bidder must have submitted by 9:30 a.m., c.s.t., October —, 1978, the certification required by 41 CFR 60-1.7(b) and Executive Order No. 11246 of September 24, 1965, and any bid must be a cash bonus bid; and

(a) The bidder has complied with the requirements of this notice and applicable regulations;

(b) The bid is the highest valid cash bonus bid accepted; and

(c) The amount of the cash bonus bid together with the first year’s annual rental, and satisfy the bonding requirements of 43 CFR 3304.1 within the time provided in 43 CFR 3302.5.

12. Protraction diagrams. Tracts offered for lease may be located on the following official protraction diagrams which are available from the manager, New Orleans Outer Continental Shelf Office, at the address stated in paragraph 2. They sell for $2 each.

<table>
<thead>
<tr>
<th>Tract No.</th>
<th>Block</th>
<th>Description</th>
<th>Acreage</th>
</tr>
</thead>
<tbody>
<tr>
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<td>038</td>
<td>All</td>
<td>$750</td>
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<td>6S-42</td>
<td>039</td>
<td>All</td>
<td>$750</td>
</tr>
<tr>
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<td>042</td>
<td>All</td>
<td>$750</td>
</tr>
<tr>
<td>6S-49</td>
<td>043</td>
<td>All</td>
<td>$750</td>
</tr>
<tr>
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<td>$750</td>
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<td>045</td>
<td>All</td>
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</tr>
<tr>
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<td>$750</td>
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<tr>
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<td>447</td>
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<td>$750</td>
</tr>
<tr>
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<td>$750</td>
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<td>$750</td>
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<tr>
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</table>

OCS OFFICIAL PROTRACt DIAGRAM, PENSACOLA NH 16-5


<table>
<thead>
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<th>Block</th>
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<td>6S-3</td>
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<td>All</td>
<td>$750</td>
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<td>6S-4</td>
<td>825</td>
<td>All</td>
<td>$750</td>
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<td>6S-5</td>
<td>826</td>
<td>All</td>
<td>$750</td>
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<tr>
<td>6S-6</td>
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<td>$750</td>
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<tr>
<td>6S-7</td>
<td>927</td>
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<td>$750</td>
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<tr>
<td>6S-8</td>
<td>928</td>
<td>All</td>
<td>$750</td>
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<tr>
<td>6S-9</td>
<td>929</td>
<td>All</td>
<td>$750</td>
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<tr>
<td>6S-10</td>
<td>930</td>
<td>All</td>
<td>$750</td>
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<tr>
<td>6S-11</td>
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<td>All</td>
<td>$750</td>
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<tr>
<td>6S-12</td>
<td>971</td>
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<tr>
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OCS OFFICIAL PROTRACt DIAGRAM, DESTIN DOME NH 10-8


<table>
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<th>Tract No.</th>
<th>Block</th>
<th>Description</th>
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<tr>
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OCS OFFICIAL PROTRACt DIAGRAM, TARPON SPRINGS NH 17-10


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<td>6S-43</td>
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<td>$750</td>
</tr>
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</table>
NOTICES

When the adjusted quarterly value of production is equal to or greater than $1662.854083 million, a royalty of 65.00000 percent in amount or value of production saved, removed or sold will be due on the unadjusted quarterly value of production. Thus, in no instance will the quarterly royalty due exceed 65.00000 percent in amount or value of production saved, removed or sold.

In determining the quarterly percent royalty due, R, the calculation will be carried to five decimal places (for example, 20.17269 million). This calculation will incorporate the adjusted quarterly value of production, $V$, in millions of dollars, rounded to the sixth digit, i.e., to the nearest dollar (for example, 15.332847 million of dollars).

Lease Terms and Stipulations.

For these lease tracts, falling within the Zones 1 and 2 in which there is reason to believe a cultural resource exists, the Supervisor will conduct remote sensing surveys to determine if indications are present suggesting the existence of a cultural resource that may be adversely affected by any lease operation. A report of this survey and assessment prepared by the marine survey archaeologist or underwater archaeologist using survey equipment and techniques as deemed necessary by the Supervisor, either that such operations will not adversely affect the location identified or that the potential cultural resource suggested by the occurrence of the indicators does not exist.

Prior to any drilling activity or placement of any structure or pipelines or any other exploration or production activity, the lessee will submit to the Supervisor as part of his exploration and/or development plan a qualified survey archaeologist's report of this survey and assessment. This map will include interpretations for the presence of live bottom areas within a minimum one mile radius of the proposed exploration or production activity site.

If it is determined that remote sensing data indicate the possibility of live bottom areas, the lessee shall submit to the Supervisor a qualified survey archaeologist's report of this survey and assessment. This map will include interpretations for the presence of live bottom areas within a minimum one mile radius of the proposed exploratory drilling sites or proposed platform locations or points as determined by the Supervisor.

If it is determined that live bottom areas might be adversely impacted by the proposed activities, then the Supervisor will require the lessee to undertake any measures deemed economically, environmentally, and technologically feasible to protect live bottom areas. These measures may include, but are not limited to, the following:

14. Lease Terms and Stipulations. Leases issued as a result of this sale will be on Form 3300-1 (December 1976), available from the Manager, New Orleans Outer Continental Shelf Office, at the address stated in paragraph 2. For leases resulting from this sale for tracts offered on a cash bonus basis with fixed sliding scale royalty listed in paragraph 4 of this Notice of Sale, Form 3300-1, will be amended as follows:

Scc. 3(b)(3) Royalty on Production. To pay the lessor a royalty of that percent in amount or value of production saved, removed or sold from the leased area as determined by the sliding scale royalty formula as follows. When the quarterly value of production, adjusted for inflation, is less than or equal to $13,263,229 million, a royalty of 16.5667 percent in amount or production saved, removed or sold will be due on the unadjusted value or amount of production. When the adjusted quarterly value of production is equal to or greater than $16,808,020 million, the royalty percent due on the unadjusted value or amount of production given is by

\[ R = 10 \ln \left( \frac{V}{50} \right) \]

where

- \( R \) = the percent royalty that is due and payable on the unadjusted amount or value of all production saved, removed or sold in quarter.
- \( V \) = the value of production in quarter, adjusted for inflation, in millions of dollars.
- \( \ln \) = natural logarithm.
- \( \times 10 \) = 10.00000

Stipulation No. 1

a. The lessee agrees that if any site, structure, or object of historical or archaeological significance is discovered during the conduct of operations on any leased area, he shall report immediately such findings to the Supervisor, and make every reasonable effort to preserve and protect the cultural resource until the Supervisors has given directions as to its preservation.

b. (To apply only to the leases resulting from this proposed sale for tracts 65-1 through 65-20.)

For these lease tracts, falling within Cultural Resource Zones 1 and 3 as defined and plotted in the final report Cultural Resource Survey Evaluation of the Northern Gulf of Mexico Continental Shelf (Coastal Environments, Inc., 1977), and tracts falling outside the Zones 1 and 2 in which there is reason to believe a cultural resource exists, the Supervisor shall require the lessee to comply with the following:

Prior to any drilling activity or the construction or placement of any structure or pipelines or any other exploration or production activity, the lessee will submit to the Supervisor a qualified survey archaeologist's report of this survey and assessment. This map will include interpretations for the presence of live bottom areas within a minimum one mile radius of the proposed exploration or production activity site.

b. (To apply to all leases resulting from this proposed sale.)

If it is determined that remote sensing data indicate the possibility of live bottom areas, the lessee shall submit to the Supervisor a qualified survey archaeologist's report of this survey and assessment. This map will include interpretations for the presence of live bottom areas within a minimum one mile radius of the proposed exploratory drilling sites or proposed platform locations or points as determined by the Supervisor.

If it is determined that live bottom areas might be adversely impacted by the proposed activities, then the Supervisor will require the lessee to undertake any measures deemed economically, environmentally, and technologically feasible to protect live bottom areas. These measures may include, but are not limited to, the following:

FEDERAL REGISTER, VOL. 43, NO. 146—FRIDAY, JULY 28, 1978
1. The relocation of operations to avoid live bottom areas.

2. The shunting of all drilling fluids and cuttings is to be conducted in a manner to avoid live bottom areas.

3. The transportation of drilling fluids and cuttings is to be conducted in a manner to avoid live bottom areas.

4. The monitoring of live bottom areas to assess the adequacy of any mitigating measures taken and the impact of lessee-initiated activities.

**STIPULATION No. 3**


   Whether or not compensation for such damage or injury might be due under a theory of strict or absolute liability or otherwise, the lessee assumes all risks of damage or injury to persons or property, which occur in, on, or above the Outer Continental Shelf, to any persons or to any property of any person or persons who are agents, employees or invitees of the lessee, its agents, independent contractors or subcontractors doing business with the lessee in connection with any activities being performed by the lessee in, on, or above the Outer Continental Shelf, if such injury or damage to such person or property occurs by reason of the activities of any agency of the U.S. Government, its contractors or subcontractors, or any of their agents, officers or employees, being conducted as a part of, or in connection with the programs and activities of the Air Force Base, Tyndall Air Force Base, Eglin Air Force Base, MacDill Air Force Base, Tyndall Air Force Base, the Army Command, Naval Air Station, Corpus Christi, Tex. The lessee assumes this risk whether such injury or damage is caused in whole or in part by any act or omission, regardless of negligence or fault, of the United States, its contractors or subcontractors, or of any of their agents, officers, or employees, or the lessee agrees to control his own electromagnetic emissions and those of his employees and whether such claims might be sustained under theories of strict or absolute liability or otherwise.

   The lessee agrees to control his own electromagnetic emissions and those of his employees, invitees, independent contractors or subcontractors emanating from individual designated defense warning areas in a manner to avoid live bottom areas, as determined by the commander of the appropriate onshore military installation, i.e., Pensacola Naval Air Station, Eglin Air Force Base, MacDill Air Force Base, Tyndall Air Force Base, to the degree necessary to prevent damage to, or unacceptable interference with, Department of Defense flight, testing or operational activities, conducted within individual designated warning areas.

   The lessee agrees to control his own electromagnetic emissions and those of the appropriate onshore military installation conducting operations in the particular warning area: Provided, however, that control of such emissions shall in no instance prohibit all manner of electromagnetic communication during any period of time between a lessee, its agents, employees, invitees, independent contractors or subcontractors or onshore facilities.

   The lessee, when operating or causing to be operated on its behalf boats or aircraft traffic into the individual designated warning areas shall enter into an agreement with the commander of the appropriate onshore military installation, i.e., Pensacola Naval Air Station, Eglin Air Force Base, MacDill Air Force Base, Tyndall Air Force Base, utilizing an individual designated warning area prior to commencing such traffic. Such agreement will provide for positive control of boats and aircraft operating into the warning areas at all times.

b. (To apply only to the leases resulting from this proposed sale for tracts 65-25 through 65-28, 65-30, and 65-31.)

   When the activities of the Armament Development and Test Center at Eglin Air Force Base may endanger personnel or property, the lessee agrees, upon receipt of a directive from the Secretary, to evacuate personnel from all structures on the lease and to shut-in and secure all wells and other equipment, including pipelines on the lease, within forty-eight (48) hours or within a period of time greater than seventy-two (72) hours; however, such period of time may be extended by subsequent directive from the Secretary. Equipment and structures may remain in place on the lease during such time as the directive remains in effect.

**STIPULATION No. 4**

Pipelines will be required: (1) If pipeline rights-of-way can be determined and obtained; (2) If pipeline use is technologically feasible and environmentally preferable, and (3) If, in the opinion of the lessor, pipelines can be laid without net social loss, taking into account any incremental costs of pipelines over alternative methods of transportation and any incremental benefits in the form of increased environmental protection and reduced multiple use conflicts. The lessor specifically reserves the right to require that any pipeline used for transporting production to shore be placed in certain designated management areas. In selecting the means of transportation, consideration will be given to any recommendation of the Intergovernmental Planning Program for Leasing and Management of Transportation of Outer Continental Shelf Oil and Gas with the participation of Federal, State, and local government, and the industry. Where feasible, all DOI regulated pipelines, including both flow lines and gathering lines for oil and gas, shall be buried to a depth suitable for adequate protection from water currents, sand waves, storm scouring, fisheries treading gear, and other uses as determined on a case-by-case basis.

Following the completion of pipeline installations, no crude oil production will be transported by surface vessel from offshore production sites, except in the case of emergency determinations as to emergency conditions and appropriate responses to these conditions will be made by the Supervisor. Where the three criteria set forth in the firstfullname of this stipulation are not met and surface transportation must be employed.

All vessels used for carrying hydrocarbons to shore from the lease area will conform with all standards established for such vessels, pursuant to the Ports and Waterways Safety Act of 1972 (46 U.S.C. 391a).

**STIPULATION No. 5**

Lessee shall comply with regulations which affect activities under this lease and which are promulgated under applicable statutes by other Federal agencies, including the Department of Energy, the Department of Transportation, and the Environmental Protection Agency.

**STIPULATION No. 6**

To be included in any leases resulting from this proposed sale for the following royalty tracts listed in paragraph 4 of this notice.

(a) The royalty rate on production saved, removed only and not sold from the lease is subject to consideration for reduction under the same authority that applies to all other oil and gas leases on the Outer Continental Shelf (30 CFR, 46). The Director of the Interior Department's Current Survey, may grant a reduction for only 1 year at a time. Reduction of royalty rates will not be approved unless production has been underway for 1 year or more.

(b) Although the royalty rate specified in section 30(11) of this lease or as subsequently modified in accordance with applicable regulations and stipulations is applicable to all production under this lease, not more than 16 percent of the production saved, removed and not sold from this lease area may be taken as royalty in amount, except as provided in section 66C; the royalty on any portion of the production saved, removed or not sold, in excess of 16 percent may only be taken in value of the production saved, removed or sold from the lease area.

**STIPULATION No. 7**

Unless the lessee can demonstrate to the satisfaction of the Supervisor that it would not be in the interest of conservation, all reservoirs underlying this lease which extend into one or more other leases with either a different royalty rate or a royalty rate based on a sliding scale, as indicated by drilling and other information, shall be operated and produced only under a unit agreement including the other leases and approved by the Supervisor. Such a unit agreement shall provide for the fair and equitable allocation of production and costs. The Supervisor shall prescribe the method of allocating production and costs if event operators are unable to agree on a method acceptable to him.

**STIPULATION No. 8**

(To be included in any lease resulting from this proposed sale for the following tracts: 65-72 through 65-73, 65-77, 65-78, 32079...

Portions of these tracts may contain karst sinkholes. Exploratory drilling operations, emplacement of structures (platforms) or seafloor wellheads for the production of storage of oil or gas will not be allowed on those portions of the tract which contain karst sinkholes until the lessee has demonstrated to the Supervisor's satisfaction that exploratory drilling operations can be safely conducted or structures (platforms), casing, and wellheads can be safely designed and installed at the proposed location.

15. Information to Lessees. The Department of the Interior will seek the advice of the States of Mississippi, Louisiana, Alabama, and Florida and other Federal agencies to identify areas of special concern which might require appropriate protective measures for live bottom areas and areas which might contain cultural resources.

If it is determined that live bottom areas might be adversely impacted by the proposed activities, then the Supervisor, in consultation with the Regional Director, Fish and Wildlife Service (FWS), the Manager, BLM and the States, will require the lessee to undertake any measures deemed economically, environmentally, and technically feasible to protect live bottom areas.

Some of the tracts offered for lease may fall in areas which may be included in fairways, precautionary zones, or traffic separation schemes. Corps of Engineers permits are required for construction of any fixed structures or artificial islands located on the Outer Continental Shelf in accordance with section 4(f) of the Outer Continental Shelf Lands Act of 1953 (67 Stat. 463; 43 U.S.C. 1333(f)).

In applying safety, environmental and conservation laws and regulations, the Supervisor will require the use of the best available and safest technology which is determined to be economically achievable. To the extent practicable, the Supervisor will consult with the relevant Federal agencies and the affected State(s) in the execution of these responsibilities.

Bidders are advised that the Departments of the Interior and Transportation have entered into a memorandum of understanding dated May 6, 1976, concerning the design, installation, operation and maintenance of offshore pipelines. Bidders should consult both Departments for regulations applicable to offshore pipelines.

The U.S. Congress is considering OCS Lands Act Amendments which would institute many new provisions in the leasing and administration of the resources on the OCS. Two of these provisions: (1) The Fishermen's Gear Compensation Fund; and (2) the Oil Spill Liability Fund will, if enacted, establish programs to repay damages and the costs of oil spills resulting from OCS activities. These funds may be supported by assessments levied on lessees and operators.

Bidders are hereby notified that these and other provisions of the OCS Lands Act Amendments may apply to leases resulting from sale 65.

The Department's regulations found in 30 CFR and 43 CFR, as amended, are applicable to this lease sale. Recent amendments to these regulations are found in 42 FR 53956, October 4, 1977 (suspension of leases); 43 FR 3860, January 27, 1978 (oil and gas operations and oil and gas information program); and 43 FR 3892, January 27, 1978 (environmental assessment and oil and gas information program).

16. OCS Orders. Operations on all leases resulting from this sale will be conducted in accordance with the provisions of all Gulf of Mexico OCS Orders, as of their effective date, and any other applicable OCS Order as it becomes effective.

17. Suggested Bid Form. It is suggested that bidders submit their bids to the Manager, New Orleans Outer Continental Shelf Office, in the following form:

Oil and Gas Bid

The following bid is submitted for an oil and gas lease on the tract of the Outer Continental Shelf specified below:

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Proportionate Interest of Company(s) Submitting Bid

Qualification No. ____________________________

Percent Interest ____________________________

Address ____________________________

Signature ____________________________

(Please type signer's name under signature)

18. Required Joint Bidders Statement. In the case of joint bids, each joint bidder is required to execute a joint bidder’s statement before a notary public and submit it with his bid. A suggested form for this statement is shown below.

Joint Bidder’s Statement

I hereby certify that ____________________________ (entity submitting bid) is eligible under 43 CFR 3302 to bid jointly with the other parties submitting this bid.

Signature ____________________________

(Please type signer's name under signature)

Sworn to and subscribed before me this ______ day of ________ 19 ______

NOTARY PUBLIC

State of ____________________________

County of ____________________________

[FR Doc 78-20717 Filed 7-27-78; 8:45 am]
NOTICES

32881

[4310–84]

{W-64624} WYOMING

Notice of Application


Notice is hereby given that pursuant to section 28 of the Mineral Leasing Act of 1920, as amended (30 U.S.C. 183), the Northern Utilities, Inc. of Casper, Wyo., filed an application for a right-of-way to construct a dehydration station for the purpose of reducing water vapor content of natural gas being transported and will affect the following described public lands:

SIXTH PRINCIPAL MERIDIAN, WYOMING

T. 39 N., R. 78 W., Sec. 19, SW4SE4.

The proposed dehydration station site will consist of 0.086 acres and will be located adjacent to an existing measuring station and 6 inch pipeline, all located in Natrona County, Wyo.

The purpose of this notice is to inform the public that the Bureau will be proceeding with consideration of whether the application should be approved, and if so, under what terms and conditions.

Interested persons desiring to express their views should do so promptly. Persons submitting comments should include their name and address and send them to the District Manager, Bureau of Land Management, 951 Union Boulevard, Casper, Wyo. 82601.

WILLIAM S. GILMER,
Acting Chief, Branch of Lands and Minerals Operations.

[FR Doc. 78-20913 Filed 7-27-78; 8:45 am]

[4310–55]

ENDANGERED SPECIES PERMIT

Notice of Receipt of Application

Applicant: Ila Loetscher, P.O. Box 2049, South Padre Island, Texas 78597.

The applicant requests a permit to salvage endangered and threatened species of sea turtles for rehabilitation at her facilities and release to the wild to enhance the survival of the species. Humane care and treatment during transport has been indicated by the applicant.

Documents and other information submitted with this application are available to the public during normal business hours in room 534, 1717 H Street NW., Washington, D.C., or by writing to the Director, U.S. Fish and Wildlife Service (WPS), Washington, D.C. 20240.

This application has been assigned file number PRT 2-2158. Interested persons may comment on this application by submitting written data, views, or arguments to the Director at the above address on or before August 28, 1978. Please refer to the file number when submitting comments.


DONALD G. DONAHOO,

[FR Doc. 78-20905 Filed 7-27-78; 8:45 am]
ENDANGERED SPECIES PERMIT

NOTICE OF RECEIPT OF APPLICATION

Applicant: Verxes Regional Primate Research Center, Emory University, Atlanta, Georgia 30322.

The applicant wishes to export refrigerated or frozen blood and tissue samples collected from laboratory gorillas (Gorilla gorilla) and orangutans (Pongo pygmaeus) for biomedical research.

Documents and other information submitted with this application are available to the public during normal business hours in Room 534, 1717 H Street NW., Washington, D.C., or by writing to the Director, U.S. Fish and Wildlife Service (WPS), Washington, D.C. 20240.

This application has been assigned file number PRT 2-2390. Interested persons may comment on this application by submitting written data, views, or arguments to the Director at the above address on or before August 28, 1978. Please refer to the file number when submitting comments.


DONALD G. DONAHOO,

ENDANGERED SPECIES PERMIT

NOTICE OF RECEIPT OF APPLICATION

Applicant: Otis Edward Trosper, 8649 Southaven Circle East, Southaven, Miss. 38671.

The applicant requests a permit to purchase in interstate commerce, two pairs of captive-bred masked bobwhite quail (Colinus virginianus ridgwayi) from Maresa Co., Inc., Vista, Calif., for enhancement of propagation. Humane care and treatment during transport has been indicated by the applicant.

Documents and other information submitted with this application are available to the public during normal business hours in Room 534, 1717 H Street, NW., Washington, D.C., or by writing to the Director, U.S. Fish and Wildlife Service (WPS), Washington, D.C. 20240.

This application has been assigned file number PRT 2-2746. Interested persons may comment on this application by submitting written data, views, or arguments to the Director at the above address on or before August 28, 1978. Please refer to the file number when submitting comments.


DONALD G. DONAHOO,

NOTICES


DONALD G. DONAHOO,

[FR Doc. 78-20907 Filed 7-27-78; 8:45 am]

ENDANGERED SPECIES PERMIT

NOTICE OF RECEIPT OF APPLICATION

Applicant: Dr. Lawrence J. Poerdor, 9000 Beach Ave., Arleta, Calif. 91701.

The applicant requests a permit to import from Canada a pair of captive-born leopards (Panthera pardus) for propagation and exhibition. Humane care and treatment during transport has been indicated by the applicant.

Documents and other information submitted with this application are available to the public during normal business hours in Room 534, 1717 H Street NW., Washington, D.C., or by writing to the Director, U.S. Fish and wildlife Service (WPO), Washington, D.C. 20240.

This application has been assigned file number PRT 2-2873. Interested persons may comment on this application by submitting written data, views, or arguments to the Director at the above address on or before August 28, 1978. Please refer to the file number when submitting comments.


DONALD O. DONAHOO,

[FR Doc. 78-20910 Filed 7-27-78; 8:45 am]

NOTICES


DONALD O. DONAHOO,

[FR Doc. 78-20911 Filed 7-27-78; 8:45 am]

ASIAN ELEPHANT

Waiver of 30 Day Public Comment Period Prior To Issuance of an Endangered Species Permit

On July 13, 1978, a letter waiving the 30 day public comment period required prior to issuance of an endangered species permit was issued to the Central Florida Zoological Society, Sanford, Fla., as well as a permit PRT 2-2900 authorizing interstate commerce in the course of a commercial activity for the sale of one male Asian elephant (Elephas maximus) to the International Animal Exchange facilities at Grand Prairie, Tex.

It was determined by the U.S. Fish and Wildlife Service that an emergency did in fact exist and that the elephant might have to be destroyed since it posed a threat to human life in that its housing facility was inadequate for its temperament during breeding cycles. It had in fact recently seriously injured three attendants and should be moved to the facilities of the International Animal Exchange which are thought to be adequate.

This emergency waiver was issued in accordance with the Endangered Species Act of 1973, as amended by Pub. L. 94-359 (90 Stat. 911).

Documents and other information submitted with this application are available to the public during normal business hours in Room 534, 1717 H Street NW., Washington, D.C., or by writing to the Director, U.S. Fish and Wildlife Service (WPO), Washington, D.C. 20240.

This permit has been assigned file No. PRT 2-2900. Interested persons may comment on this application by submitting written data, views, or arguments to the Director at the above address on or before August 28, 1978. Please refer to file No. PRT 2-2900 when submitting comments.


DONALD O. DONAHOO,

ENDANGERED SPECIES PERMIT

NOTICE OF RECEIPT OF APPLICATION

Applicant: Dr. Lawrence J. Poerdor, 9000 Beach Ave., Arleta, Calif. 91711.

The applicant requests a permit to import from Canada a pair of captive-born leopards (Panthera pardus) for propagation and exhibition. Humane care and treatment during transport has been indicated by the applicant.

Documents and other information submitted with this application are available to the public during normal business hours in Room 534, 1717 H Street NW., Washington, D.C., or by writing to the Director, U.S. Fish and Wildlife Service (WPO), Washington, D.C. 20240.

This application has been assigned file number PRT 2-2873. Interested persons may comment on this application by submitting written data, views, or arguments to the Director at the above address on or before August 28, 1978. Please refer to the file number when submitting comments.


DONALD G. DONAHOO,

[FR Doc. 78-20911 Filed 7-27-78; 8:45 am]
SNAIL DARTER
Waiver of 30 Day Public Comment Period Prior To Issuance of an Endangered Species Permit

On July 12, 1978, a notice of receipt of an application (PRT 2-2873) received by the Service July 7, 1978, from the Tennessee Valley Authority for a permit to capture, mark and release snail darters (Percina tanasi) in order to maintain population estimates appeared in the Federal Register. Comments were invited for submission on or before August 11, 1978.

On July 13, 1978, based on a recommendation resulting from a unanimous vote by the Snail Darter Recovery Team, the applicant requested a waiver of the 30 day comment period and immediate issuance of a permit contending that there was a real and present danger of losing the snail darter population in the Little Tennessee River and that the activities proposed in their application must immediately commence in order to secure financial assistance to scientifically support recovery plans.

On July 14, 1978, in accordance with the Endangered Species Act of 1973, as amended by Pub. L. 94-359 (90 Stat. 911), the Service concurred with the applicant's contention and issued a letter waiving the 30 day comment period and permit PRT 2-2873 to the applicant authorizing the requested activities.

Documents and other information submitted with this application are available to the public during normal business hours in Room 534, 1717 H Street NW., Washington, D.C., or by writing to the Director, U.S. Fish and Wildlife Service (WPSO), Washington, D.C. 20240.

This application has been assigned file number PRT 2-2873. Interested persons may comment on this application by submitting written data, views, or arguments to the Director at the above address by August 18, 1978. Please refer to the file number when submitting comments.

DONALD G. DONAHOO

[FR Doc. 78-20999 Filed 7-27-78; 8:45 am]

DEPARTMENT OF LABOR
Employment and Training Administration

EMPLOYMENT TRANSFER AND BUSINESS COMPETITION DETERMINATIONS UNDER THE RURAL DEVELOPMENT ACT

Notice of Applications

The organizations listed in the attachment have applied to the Secretary of Agriculture for financial assistance. In the form of grants, loans, or loan guarantees in order to establish or improve facilities at the locations listed for the purposes given in the attached list. The financial assistance would be authorized by the Consolidated Farm and Rural Development Act, as amended, 7 U.S.C. 1924(b), 1932, or 1942(b).

The act requires the Secretary of Labor to determine whether such Federal assistance is calculated to or is likely to result in the transfer from one area to another of any employment or business activity provided by operations of the applicant. It is permissible to assist the establishment of a new branch, affiliate or subsidiary, only if this will not result in increased unemployment in the place of present operations and there is no reason to believe the new facility is being established with the intention of closing down an operating facility.

The act also prohibits such assistance if the Secretary of Labor determines that it is calculated to or is likely to result in an increase in the production of goods, materials, or commodities, or the availability of services or facilities in the area, when there is not sufficient demand for such goods, materials, commodities, services, or facilities to employ the efficient capacity of existing competitive commercial or industrial enterprises, unless such financial or other assistance will not have an adverse effect upon existing employment and contributing factors.

The Secretary of Labor's review and certification procedures are set forth at 29 CFR Part 75. In determining whether the applications should be approved or denied, the Secretary will take into consideration the following factors:

1. The overall employment and unemployment situation in the local area in which the proposed facility will be located.
2. Employment trends in the same industry in the local area.
3. The potential effect of the new facility upon the local labor market, with particular emphasis upon its potential impact upon competitive enterprises in the same area.
4. The competitive effect upon other facilities in the same industry located in other areas (where such competition is a factor).
5. In the case of applications involving the establishment of branch plants or facilities, the potential effect of such new facilities on other existing plants or facilities operated by the applicant.

All persons wishing to bring to the attention of the Secretary of Labor any information pertinent to the determinations which must be made regarding these applications are invited to submit such information in writing within 2 weeks of publication of this notice to:

Deputy Assistant Secretary for Employment and Training, 601 D Street NW., Washington, D.C. 20213.

Signed at Washington, D.C. this 24th day of July 1978. ERENS G. GREEN, Assistant Secretary for Employment and Training.

APPLICATIONS RECEIVED DURING THE WEEK ENDING JULY 21, 1978

<table>
<thead>
<tr>
<th>Name of applicant and location of enterprise</th>
<th>Principal product or activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marion Rohr Corp.</td>
<td>(tenant Manufacturing of city of Hornell, NY: ladies' underwear)</td>
</tr>
<tr>
<td>The Eastern Idea, Inc.</td>
<td>(Manufacture of Richlands and Grundy, VA: women's robes and children's nightwear)</td>
</tr>
<tr>
<td>J.R. Clark Co.</td>
<td>(Manufacture of Mountville, Va: stainless steel cookware and barbecue grills)</td>
</tr>
<tr>
<td>Brennan Group, Ltd., Hilton Convention hotel</td>
<td>(Hired Hand for the Domestic care of aged, Reidsville, N.C.)</td>
</tr>
<tr>
<td>Brasswood Home for the Domestic care</td>
<td>(Aged, Reidsville, N.C.)</td>
</tr>
<tr>
<td>Weiss Dealeman Inc., Processor of pressure</td>
<td>(pressure sensitive film)</td>
</tr>
<tr>
<td>Braskin Investment Corp., Retail discount</td>
<td>(repair of machinery)</td>
</tr>
<tr>
<td>Dothan, Ala.</td>
<td>(repair of machinery)</td>
</tr>
<tr>
<td>Cascade Machine &amp; Eng. Manufacture and</td>
<td>(repair of machinery)</td>
</tr>
<tr>
<td>necessities Corp., Inc., Sylaca, Ala.</td>
<td>(machinery)</td>
</tr>
<tr>
<td>Perklick Hall, Division of Alcoholism Health Institutes, Inc.</td>
<td>(treatment services)</td>
</tr>
<tr>
<td>Johns Island, S.C.</td>
<td>(treatment services)</td>
</tr>
<tr>
<td>Michie Colbert Co.</td>
<td>(Manufacture of crocked steel pipe)</td>
</tr>
<tr>
<td>TC&amp;G Corp., Gallipolis, Restaurant, Ohio.</td>
<td>(Gallipolis Restaurant)</td>
</tr>
<tr>
<td>Guaranty Fuels, Inc., Bay.</td>
<td>(Production wood of pet pens)</td>
</tr>
<tr>
<td>Internation Industries, Inc., Engineering</td>
<td>(development and manufacture of transistors of OMA-electronic components)</td>
</tr>
<tr>
<td>Rowell, N.Mex.</td>
<td>(development and manufacture of transistors of OMA-electronic components)</td>
</tr>
<tr>
<td>Bay Equipment Co., Hitchcock, Tex.</td>
<td>(Manufacture of structural clay products)</td>
</tr>
<tr>
<td>Scheduled Skyways, Inc., Air passenger, air</td>
<td>(Manufacture of structural clay products)</td>
</tr>
<tr>
<td>Fayetteville, Ark.</td>
<td>(Manufacture of structural clay products)</td>
</tr>
<tr>
<td>Dan Wallace, Michael Kahn, Motel.</td>
<td>(Manufacture of structural clay products)</td>
</tr>
<tr>
<td>and Fred Gipson, Seminar, Okla.</td>
<td>(Manufacture of structural clay products)</td>
</tr>
<tr>
<td>Central Gulf Ice, Inc., Ber. Ice plant.</td>
<td>(Manufacture of structural clay products)</td>
</tr>
<tr>
<td>Davis Funeral Home, Henrietta, Tex.</td>
<td>(Manufacture of structural clay products)</td>
</tr>
<tr>
<td>Christian Retirement Corp., Nursing care and</td>
<td>(Manufacture of structural clay products)</td>
</tr>
<tr>
<td>Santa Fe, N.Mex.</td>
<td>(Manufacture of structural clay products)</td>
</tr>
<tr>
<td>O'Blay Brothers Construction Co., Maryville, Mo.</td>
<td>(Manufacture of structural clay products)</td>
</tr>
<tr>
<td>Woodmoor Country Club, Country club.</td>
<td>(Manufacture of structural clay products)</td>
</tr>
<tr>
<td>The I-25 Partnership Monument, Colorado.</td>
<td>(Manufacture of structural clay products)</td>
</tr>
</tbody>
</table>

(FRD Doc. 78-20914 Filed 7-27-78; 8:45 am)
32884

NOTICES

[4510-30]
EMPLOYMENT TRANSFER AND BUSINESS COMPETITION DETERMINATIONS UNDER THE
RURAL DEVELOPMENT ACT
Applications

5. In the case of applications involving the establishment of branch plants
or facilities, the potential effect of
such new facilities on other existing
plants or facilities operated by the applicant.
All persons wishing to bring to the
attention of the Secretary of Labor
any information pertinent to the determinations which must be made regarding these applications are invited
to submit such information in writing
within 2 weeks of publication of this
notice to: Deputy Assistant Secretary
for Employment and Training, 601 D
Street NW., Washington, D.C. 20213.

The organizations listed in the attachment have applied to the Secretary of Agriculture for financial assistance in the form of grants, loans, or
loan guarantees in order to establish
or improve facilities at the locations
listed for the purposes given in the attached list. The financial assistance
would be authorized by the Consolidated Farm and Rural Development
Act, as amended, 7 U.S.C. 1924(b),
Signed at Washington, D.C., this
1932, or 1942(b).
17th day of July 1978.
The act requires the Secretary of
ERNEST G. GREENr,
Labor to determine whether such FedAssistant Secretaryfor
eral assistance Is calculated to or is
Employment and Training.
likely to result in the transfer from
one area to another of any employAPPLICATIONS RECEIVED DURING THE WEE
ment or business activity provided by
ENDni JULY 14, 1978
It
is
peroperations of the applicpnt.
LOCATION OF ENTERPRISE,
NAME
OF
APPLICANT,
missible to assist the establishment of
AND PRINCIPAL PRODUCT OR ACTIVITY
a new branch, affiliate or subsidiary,
MirrorLake resort
In, tr.,
PI.id, N.Y., hote4
only if this will not result in increased
andLake
restaurant
unemployment in the place of present
Nursing Home, Inc., Athens, Pa.,
operations and there is no reason to Heritage
nursing care.
believe the new facility is being estab- Avtex
Fibers-Front Royal Inc., Front Royal,
lished with the intention of closing
Va., specialty rayon fibers.
down an operating facility.
Covington Inn, Clarksville, Tenn., motel.
The act also prohibits such assist- Key Petroleum, Inc., Mango, 'la., distribution and retail sales of petroleum prodance If the Secretary of Labor deteructs.*
I
I
mines that It is calculated to or is
likely to result in an increase in the John F. Wolcott, Sr., Bossier City, La., complete hotel services.
production of goods, materials, or com- Muskogee
Aluminum, Inc., Muskogee, Okla.,
modities, or the availability of services
manufacture of aluminum sheet and foil
or facilities in the area, when there is Allied Fabricators, Inc., Mexia, Tex., masts
not sufficient demand for such goods,
and substructures for oil well drilling rig.
materials, commodities, services, or fa- Speed-A-Way, Inc., Cushing, Okla.. wholesale gasoline.
cilities to employ the efficient capacity
of existing Competitive commercial or 'North Platte Venture, Douglas, Wyo.,
motel.
industrial enterprises, unless such fiA. Sawyer, Sheridan, Wyo., motel,
nancial or other assistance will not Thomas
office building, mini mart, self serve and
upon
existing
have an adverse effect
rural gas.
competitive enterprises in the area.
United Budget Luxury Inns, Inc., BrunsThe Secretary of Labor's review and
wick, Ga., motel, restaurant, gift shop,
and gas station.
certification procedures are set forth
at 29 CFR Part 75. In determining Sasse Corp. T/A Rivertree Inn, Clarkston,
Wash., transient accommodations.
whether the applications should be apLumber Co., Cleveland and Alto,
proved or denied, the Secretary will Blalock
Ga., manufacture of softwood and hardtake into consideration the following
wood lumber, hardwood flooring and byfactors:
products.
1. The overall employment and un- Southeast Manufacturing Co., Inc., Joplin,
Mo., manufacture of farm equipment and
employment situation in the local area
fireplace grates and accessories.
in which the proposed facility will be
Somerset Group, Inc., Youngstown, N.Y.,
located.
operation of foreign trade zone.
2. Employment trends in the same Alternate
Growing Environment, Inc., Las
industry in the local area.
Cruces, N. Mex., Intermediate nursing
3. The potential effect of the new facare.
cility upon the local labor market, Rex Monroe -Kennedy, Jacksonville, N.C.,
sale and repair of automobiles.
with particular emphasis upon its potential impact upon competitive enter- Prosser-Agrinetics Charcoal Interests, Doniphan, Mo., manufacture, packaging and
prises in the same area.
sales of wood charcoal briquettes.
4. The competitive effect upon other
Donald E.Stephens, Leadvile, Colo., motel.
facilities in the same industry located
(FR Doc. 78-20923 Filed 7-27-78; 8:45 am]
in other areas (where such competition is a factor).

[4510-26]
Occupational Safety and Health Admlnlstrallon
ADVISORY COMMITTEE ON CONSTRUCTION
SAFETY AND HEALTH
Meeting

Notice is hereby given that the Advisory Committee on Construction
Safety and Health, established under
section 107(e)(1) of the Contract Work
Hours and Safety Standards Act (40
U.S.C. 333) and section 7(b) of the Occupational Safety and Health Act of
1970 (29 U.S.C. 656) will meet on Tuesday, August 15; Wednesday, August 16,
and Thursday, August 17, 1978, in
Room W5437, Department of Labor
Building, Third Street and Constitution Avenue NW., Washington, D.C.
20210. The meeting is open to the
public and will begin at 9 a.m.
Pursuant to the decision of the U.S.
Court of Appeals for the District of
Columbia Circuit (National Construc.
tors Association v. Ray Marshlall, ,Sec.
retary of Labor,et aL, C.A.D.C. No. 771197) regarding OSHA's Ground-Fault
Circuit Protection Standard (29 CFR
1910.309(c) for general industry and 20
CFR 1926.400(h)), the Advisory Committe will review said standard, and
make such recommendations as appropriate.
To assist the Advisory Committee In
Its review, the agency has provided
each member with copies of the following documents:
1. A copy of the Court decision.
2. An index of the Record on Ground.
Fault protection.
67-April 7, 1975-Ground-F-ult Circuit
Protection-Revocation of Standard.
170-September 2,1975-Notice of Hearing
on Ground-Fault Circuit Protection.
These and other related documents
may also be obtained by members of
the public by contacting OSHA's
Technical Data Center, telephone 202523-7894.
A technical presentation will be
made on behalf of the agency by Dr,
Jerry Purswell, Director of OSHA
Safety Standards Programs, and will
include a discussion of both the "assured equipment grounding conductor
program" alternative and GroundFault Circuit Interrupters. In accordance with the above court decision,
the standard will continue to remain
full n effect during this period of reconsideration.
In addition, the Advisory Committee
will discuss residual matters relating
to the Identification of 29 CFR Part
1910 standards (general industry) specifically applicable to the construction
industry (29 CFR Part 1926).

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Written data, views, or arguments may be submitted, preferably with 20 copies to the Division of Consumer Affairs. Any such submissions received prior to the meeting will be provided to the members of the committee and will be included in the record of the meeting.

Anyone wishing to make an oral presentation should notify the Division of Consumer Affairs before the meeting. The request should state the amount of time desired, the capacity in which the person will appear, and a brief outline of the content of the presentation.

Oral presentations will be scheduled at the discretion of the chairman, depending on the extent to which time permits. Communications may be mailed to: Ken Hunt, Office of Information and Consumer Affairs, Occupational Safety and Health Administration, Third Street and Constitution Avenue NW., Washington, D.C. 20210, telephone 202-523-3024.

Materials provided to members of the Committee are available for inspection and copying at the above address.


EULA BINGHAM, Assistant Secretary of Labor

Office of the Secretary,

INVESTIGATIONS REGARDING CERTIFICATIONS OF ELIGIBILITY TO APPLY FOR WORKER ADJUSTMENT ASSISTANCE

Petitions have been filed with the Secretary of Labor under section 221(a) of the Trade Act of 1974 ("the Act") and are identified in the appendix to this notice. Upon receipt of these petitions, the Director of the Office of Trade Adjustment Assistance, Bureau of International Labor Affairs, has instituted investigations pursuant to section 221(a) of the Act and 29 CFR 90.12.

The purpose of each of the investigations is to determine whether absolute or relative increases of imports of articles like or directly competitive with articles produced by the workers' firm or an appropriate subdivision thereof have contributed importantly to an absolute decline in sales or production, or both, of such firm or subdivision and to the actual or threatened total or partial separation of a significant number or proportion of the workers of such firm or subdivision.

Petitioners meeting these eligibility requirements will be certified as eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act in accordance with the provisions of Subpart B of 29 CFR Part 90. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

Pursuant to 29 CFR 90.13, the petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than —?

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than —?

The petitions filed in this case are available for inspection at the Office of the Director, Office of Trade Adjustment Assistance, Bureau of International Labor Affairs, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, D.C. 20210.


MARTYN M. FOOKE, Director, Office of Trade Adjustment Assistance.

APPENDIX

<table>
<thead>
<tr>
<th>Petitioner: Union/workers or former worker of:</th>
<th>Location</th>
<th>Date received</th>
<th>Date of petition</th>
<th>Petition No.</th>
<th>Articles produced</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Balance scales, pharmaceutical and student balances.</td>
</tr>
</tbody>
</table>

[FEDERAL REGISTER, VOL. 43, NO. 146—FRIDAY, JULY 28, 1978]
total or partial separation of a significant number or proportion of the workers of such firm or subdivision.

Petitioners meeting these eligibility requirements will be certified as eligible to apply for adjustment assistance under title II, chapter 2, of the Act in accordance with the provisions of subpart B of 29 CFR 90. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

Pursuant to 29 CFR 90.13, the petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than August 7, 1978.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than August 7, 1978.

The petitions filed in this case are available for inspection at the Office of the Director, Office of Trade Adjustment Assistance, Bureau of International Labor Affairs, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, D.C. 20210.

Signet at Washington, D.C., this 13th day of July 1978.

MARTIN M. FUKES,
Director, Office of Trade Adjustment Assistance.

**NOTICES**

**Appendix**

<table>
<thead>
<tr>
<th>Petitioner: Union/workers or Location</th>
<th>Date received</th>
<th>Date of petition</th>
<th>Petition No.</th>
<th>Articles produced</th>
</tr>
</thead>
</table>

(FR Doc. 78-20960 Filed 7-27-78; 8:45 am)

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**[4510-26]**

**[TA-W-2948]**

A & F LEATHERS, INC., BOSTON, MASS.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-2948: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on January 25, 1978, in response to a worker petition received on January 9, 1978, which was filed on behalf of workers and former workers producing leather coats, and jackets at A & F Leathers, Inc., Boston, Mass.

The notice of investigation was published in the Federal Register on February 17, 1978 (43 FR 7068). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of A & F Leathers, Inc., the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of section 222 of the act must be met. Without regard to whether any of the other criteria have been met the following criterion has not been met:

That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

Employment of production workers at A & F Leathers, Inc., increased 2.5 percent in 1977 compared to 1976 and increased 21.4 percent in the first 2 months of 1978 compared to the same period in 1977. Average weekly hours worked by production workers declined 2.8 percent from 1976 to 1977 and then increased 10.2 percent in the first 2 months of the 1978 compared to the same period in 1977. Section 223 of the Trade Act of 1974 states that a certification shall not apply to any worker last separated from employment more than 1 year before the date of the petition, which in this case is January 6, 1978.

From January 6, 1977, to the present, the only significant separations took place in the last week of 1977, a seasonal layoff which also took place in 1976 and 1975, and in the second week of February 1978 when the plant shut down due to a blizzard that affected Boston.

**Conclusion**

After careful review, I determine that all workers at A & F Leathers, Inc., are denied eligibility to apply for trade adjustment assistance under title II, chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 21st day of July 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-20964 Filed 7-27-78; 8:45 am]
NOTICES

32887

Signed at Washington, D.C., this 18th day of July 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FED Doc. 78-20965 Filed 7-27-78; 8:45 am]

[TA-W-3160; TA-W-3162; TA-W-3358]

ARROW CLOTHES, INC., NEW YORK, N.Y., ET AL

Certifications Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-3160, 3162, 3358: Investigations regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

Investigations TA-W-3160 and TA-W-3162 were initiated on February 21, 1978, in response to a worker petition received on February 6, 1978, which was filed by the Amalgamated Clothing and Textile Workers Union on behalf of workers and former workers producing men's tailored suits, sport jackets and trousers at Arrow Clothes, Inc., New York, N.Y. (TA-W-3358). All three companies operate in an integrated fashion.

Notices of investigation were published in the Federal Register on March 3, 1978 (43 FR 8864) for TA-W-3160 and TA-W-3162 and on April 7, 1978 (43 FR 14776) for TA-W-3358. No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from Andrew Pallack & Co., Inc., Arrow Clothes, Inc., Bruce Ramsey, Ltd., their customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination of certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the act must be met. It is concluded that all of the requirements have been met.

NOTICES

32887

Signed at Washington, D.C., this 18th day of July 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FED Doc. 78-20965 Filed 7-27-78; 8:45 am]

[TA-W-3160; TA-W-3162; TA-W-3358]

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Notices of investigation were published in the Federal Register on March 3, 1978 (43 FR 8864) for TA-W-3160 and TA-W-3162 and on April 7, 1978 (43 FR 14776) for TA-W-3358. No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from Andrew Pallack & Co., Inc., Arrow Clothes, Inc., Bruce Ramsey, Ltd., their customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the act must be met. It is concluded that all of the requirements have been met.

U.S. imports of men's tailored suits increased from 3,106 thousand units in 1975 to 3,562 thousand units in 1976 and to 4,091 thousand units in 1977. Imports of men's suits relative to domestic production increased from 18.3 percent in 1975 to 20.0 percent in 1976.
NOTICES

[4510-28]

(BA-1-2512)

BELL & HOWELL COMMUNICATIONS CO. AND COMPOSITE MICROCIRCUITS, INC. BURLINGTON, MASS.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-2512: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 223 of the act.

The investigation was initiated on October 27, 1977, in response to a worker petition received on October 25, 1977, which was filed on behalf of workers and former workers producing communications equipment, surveillance equipment, and decoders at Bell & Howell Communications Co. (BHCC), Burlington, Mass.

The investigation was expanded to include Composite Microcircuits, Inc. (CMI), a wholly owned subsidiary of BHCC that is located at the Burlington facilities and supplies BHCC with component parts.

The notice of investigation was published in the Federal Register on November 15, 1977 (42 FR 59132). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Bell & Howell, BHCC, CMI, their customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the act must be met. With regard to whether any of the other criteria have been met, the following criterion has not been met:

That increases of imports of articles like or directly competitive with articles produced by the firm or subdivision have contributed importantly to the total or partial separation, or threat thereof, and to the absolute decline in sales or production.

BHCC produced one-way paging receivers, portable transceivers, alarm systems, and special surveillance equipment. Pagers were sold to commercial customers and represented the majority of sales. Transceivers, alarms, and surveillance equipment were sold to State and local police departments and Federal agencies. CMI supplied BHCC with microcircuit assemblies used in the manufacture of communications equipment.

Microcircuits produced at CMI were used almost entirely in the production of communications equipment at BHCC.

U.S. imports of radio paging equipment increased from 2.0 million dollars in 1975 to 6.6 million dollars in 1976 and to 14.3 million dollars in 1977. The ratio of imports to domestic production increased from 12.8 percent in 1976 to 24.6 percent in 1977.

A sample of customers of BHCC was surveyed regarding their purchases of communications equipment. None of the customers surveyed, who reduced purchases from BHCC, purchased any imports.

CONCLUSION

After careful review, I determined that all workers at Bell & Howell Communications Co., Inc., Burlington, Mass., and Composite Microcircuits, Burlington Mass. are denied eligibility to apply for adjustment assistance under title II, chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 24th day of July 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-20967 Filed 7-27-78; 8:45 am]

[4510-28]

(BA-W-2649)

BUCYRUS-ERIE CO., GLASSPORT, PA.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-2649: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 223 of the act.

The investigation was initiated on November 23, 1977, in response to a worker petition received on November 14, 1977, which was filed by the United Steelworkers of America on behalf of all workers producing steel castings at the Glassport, Pa., plant of Bucyrus-Erie Co.

The notice of investigation was published in the Federal Register on December 6, 1977 (42 FR 61695). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Bucyrus-Erie Co., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment ass-
The information upon which the determination was made was obtained principally from officials of Bethlehem Steel Corp., the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met:

That increases of imports of articles like or directly competitive with articles produced by the firm or subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

The investigation revealed that U.S. imports of metal tanks and vessels decreased from $14,500,000 in 1976 to $8,600,000 in 1977. The ratio of imports to domestic shipments decreased from 0.67 percent in 1976 to 0.29 percent in 1977. During the 5-year period from 1973 through 1977, market penetration of imports was less than 0.7 percent annually.

The Hallendale Beach, Fla. plant of the Buffalo Tank Division of Bethlehem Steel Corp. produced standard industrial tanks for gasoline and water storage. The plant closed on March 31, 1978, primarily due to the lack of business. There are no prospects for reopening.

CONCLUSION

After careful review I determine that all workers of the Buffalo Tank Division of Bethlehem Steel Corp., Hallendale Beach, Fla., are denied eligibility to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.


HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-20969 Filed 7-27-78; 8:45 am]

[4510-28]

ITA-W-37161
BUFFALO TANK DIVISION, Bethlehem Steel Corp., Hallendale Beach, Fla.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 222 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3716: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the Act.

The investigation was initiated on May 16, 1978, in response to a worker petition received on May 5, 1978, which was filed by the United Steelworkers of America on behalf of all workers producing standard industrial tanks at the Buffalo Tank Division of Bethlehem Steel Corp., Hallendale Beach, Fla.

The Notice of investigation was published in the Federal Register on June 27, 1978 (43 FR 27923). No public hearing was requested and none was held.

The investigation revealed that U.S. imports of metal tanks and vessels decreased from $14,500,000 in 1976 to $8,600,000 in 1977. The ratio of imports to domestic shipments also decreased from 0.67 percent in 1976 to 0.29 percent in 1977. During the 5-year period from 1973 through 1977, market penetration of imports was less than 0.7 percent annually.

The Dunellen, N.J., plant of the Buffalo Tank Division of Bethlehem Steel Corp. produces standard and some specialized tanks for storage purposes.

CONCLUSION

After careful review I determine that all workers of the Buffalo Tank Division of Bethlehem Steel Corp., Dunellen, N.J., are denied eligibility to apply for adjustment assistance under Title II, Chapter 2, of the Trade Act of 1974.

Signed at Washington, D.C., this 21st day of July 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-20970 Filed 7-27-78; 8:45 am]
NOTICES

[TA-W-3728]
FREDERICK H. BURNHAM CO., MICHIGAN CITY, IND.

Pursuant to section 221 of the Trade Act of 1974, an investigation was initiated on May 18, 1978, in response to a petition received on that date which was filed by the Amalgamated Clothing & Textile Workers Union on behalf of workers and former workers producing work gloves at the Frederick H. Burnham Co., Michigan City, Ind.

Notice of the investigation was published in the Federal Register on June 13, 1978 (43 FR 25498). No public hearing was requested and none was held.

The petitioner in this case requested withdrawal of the petition on June 12, 1978. The investigation is therefore terminated.

Signed at Washington, D.C. this 17th day of July 1978.

MARVIN M. FOOKS,
Director, Office of Trade Adjustment Assistance.

[FEDERAL REGISTER, VOL 43, NO. 146—FRIDAY, JULY 28, 1978]

[TA-W-3273]
CRESTLANE CLOTHES, INC., NEW YORK, N.Y.
Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3273: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on March 1, 1978, in response to a worker petition received on February 21, 1978, which was filed by the Amalgamated Clothing & Textile Workers' Union on behalf of workers and former workers producing men's suits at Crestlane Clothes, Inc., New York, N.Y.

The notice of investigation was published in the Federal Register on March 14, 1978 (43 FR 10649). No public hearing was requested and none was held.

The petitioners in this case requested withdrawal of the petition on March 13, 1978, which was filed on behalf of workers and former workers producing men's suits from Crestlane and increased purchases of imports in 1977 compared to 1976.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with men's suits produced by Crestlane Clothes, Inc., New York, N.Y., contributed importantly to the decline in sales and production and to the total or partial separation of workers at that firm. In accordance with the provisions of the act, I make the following certification:

All workers at Crestlane Clothes, Inc., of New York, N.Y., who became totally or partially separated from employment on or after March 25, 1977, are eligible to apply for adjustment assistance under Title II, Chapter 2, of the Trade Act of 1974.

Signed at Washington, D.C., this 24th day of July 1978.

HARRY J. GILSAN,
Acting Director, Office of Foreign Economic Research.

[FEDERAL REGISTER, VOL 43, NO. 146—FRIDAY, JULY 28, 1978]

[TA-W-3430]
ETHEL MANUFACTURING, LINDENHURST, N.Y.
Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-3430: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on March 28, 1978 in response to a worker petition received on March 13, 1978, which was filed on behalf of workers and former workers producing ladies' coats at Ethel Manufacturing, Lindenhurst, N.Y. The investigation revealed that ladies' raincoats are also produced.

The notice of investigation was published in the Federal Register on April 11, 1978 (43 FR 15205). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Ethel Manufacturing, its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the act must be met. It is concluded that all of the requirements have been met.

Imports of men's and boys' tailored suits increased from 3,106 thousand units in 1975 to 3,562 thousand units in 1976 and to 4,091 thousand units in 1977. The ratio of imported raincoats relative to imports of men's suits from Crestlane and increased purchases of imports in 1977 compared to 1976.

For adjustment assistance under Title II, Chapter 2, of the Trade Act of 1974.

Signed at Washington, D.C., this 24th day of July 1978.

HARRY J. GILSAN,
Acting Director, Office of Foreign Economic Research.

[FEDERAL REGISTER, VOL 43, NO. 146—FRIDAY, JULY 28, 1978]
raincoats for one manufacturer. A survey of the customers of that manufacturer revealed that many customers increased purchases of imported ladies' coats and raincoats while decreasing purchasers from the manufacturer from 1976 to 1977. The manufacturer also began to import ladies raincoats in 1977, decreasing its utilization of Ethel Manufacturing.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with the ladies' coats and raincoats produced at Ethel Manufacturing, Lindenhurst, N.Y. contributed importantly to the decline in sales or production and to the total or partial separation of workers at that firm. In accordance with the provisions of the act, I make the following certification:

All workers at Ethel Manufacturing, Lindenhurst, N.Y. who became totally or partially separated from employment on or after March 11, 1977 are eligible to apply for adjustment assistance under title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 24th day of July 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-20974 Filed 7-27-78; 8:45 am]

[4510-28]

[TA-W-2974]

GIRL TOWN CORP., BOSTON, MASS.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-2974: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on January 30, 1978, in response to a worker petition received on January 12, 1978, which was filed on behalf of Workers and former workers producing girls' sportswear at Girltown Corp., Boston, Mass.

The notice of investigation was published in the Federal Register on February 17, 1978 (43 FR 7069). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Girltown Corp., its customers, the U.S. Department of Commerce, the National Cotton Council of America, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the act must be met. It is concluded that all of the requirements have been met.

The Department's investigation revealed that imports of electronic receiving tubes (including finished tubes, unfinished tubes, and mounts) increased in each year, from 54.2 percent in 1975 to 68.4 percent in 1977, increasing from 55.8 percent in the first quarter of 1977 to 63.4 percent in the first quarter of 1978.

The Department of Commerce, the U.S. Department of Commerce, the National Cotton Council of America, the U.S. International Trade Commission, industry analysts, and Department files. In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the act must be met. It is concluded that all of the requirements have been met.

U.S. imports of women's, misses', and children's slacks, shorts, blouses, and skirts increased absolutely and relative to domestic production in 1976 over 1975 and increased absolutely in 1977 over 1976.

U.S. imports of women's, misses', and children's skirts increased absolutely and relative to domestic production in 1976 over 1975 and decreased absolutely from 1976 to 1977.

Girltown imports of products competitive with those produced at the Girltown facility have increased in 1977 over 1976 and in January 1978 over January 1977. Girltown contracts approximately one third of its work overseas.

Some customers of Girltown who were surveyed indicated they have decreased purchases from Girltown and increased imports of girls' sportswear in 1976 over 1975 and in 1977 over 1976.

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Signed at Washington, D.C., this 24th day of July 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-20975 Filed 7-27-78; 8:45 am]
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CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports like or directly competitive with girls' sportswear manufactured at Girltown Corp., Boston, Mass., contributed importantly to the decline in sales or production and to the total or partial separation of the workers of that plant. In accordance with the provisions of the act, I make the following certification:

All workers of Girltown Corp., Boston, Mass., who became totally or partially separated from employment on or after January 9, 1977, and on or after December 4, 1976, are eligible to apply for worker adjustment assistance under Title II, Chapter 2, of the Trade Act of 1974.

Signed at Washington, D.C., this 21st day of July 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.
[FR Doc. 78-20976 Filed 7-27-78; 8:45 am]

[4510-28]

GOLDBERG & SUSSELES, INC., NEW YORK, N.Y.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-3326: Certification regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on March 9, 1978. In response to a worker petition received on February 28, 1978, which was filed on behalf of former workers producing men's and boys' belts at Goldberg & Susseles, Inc., New York, N.Y., the following criterion has been met:

The information upon which the determination was made was obtained principally from officials of Goldberg & Susseles, Inc., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the act must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met:

That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-3119: Certification regarding eligibility to apply for adjustment assistance as prescribed in section 222 of the act.

Signed at Washington, D.C., this 24th day of July 1978.

JAMES F. TAYLOR,
Director, Office of Management, Administration, and Planning.
[FR Doc. 78-20977 Filed 7-27-78; 8:45 am]

[4510-28]

IMPALA TEXTILE, INC., NEW YORK, N.Y.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-3119: Certification regarding eligibility to apply for adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on February 13, 1978, in response to a worker petition received on January 31, 1978, which was filed on behalf of workers and former workers engaged in textile converting at Impala Textile, New York, N.Y.

The notice of investigation was published in the Federal Register on February 28, 1978 (43 FR 8207). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Impala Textile, Inc., its customers, the U.S. International Trade Commission, U.S. Department of Commerce, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the act must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met:

That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-2902: Certification regarding eligibility to apply for adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on January 11, 1978, in response to a worker petition received on December 19, 1977, which was filed on behalf of workers and former workers producing...
shoe patterns at Jeans & Gauvin Pattern Co., Inc., Haverhill, Mass.

The notice of investigation was published in the Federal Register on January 27, 1978 (43 FR 3776). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Jeans & Gauvin Pattern Co., Inc., its customers, the U.S. Department of Commerce, the American Footwear Industries Association, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the act must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met:

That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

U.S. imports of shoe patterns are not separately identifiable in the official trade statistics. A Department survey of shoe pattern manufacturers, purchasers, and commodity analysts has shown imports of these products to be negligible.

Imports of finished shoes are not “like or directly competitive” with shoe patterns within the meaning of section 222 of the Trade Act of 1974. A survey of customers of Jeans & Gauvin Pattern Co., Inc., indicated that none of the customers purchased imported shoe patterns from foreign sources during 1976 or 1977.

CONCLUSION

After careful review, I determine that all workers at Jeans & Gauvin Pattern Co., Inc., Haverhill, Mass., are denied eligibility to apply for trade adjustment assistance under Title II, Chapter 2, of the Trade Act of 1974.

Signed at Washington, D.C., this 18th day of July 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-20979 Filed 7-27-78; 8:45 am]

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[4510-28]

(TA-W-3205)

JOIET-WAUKEGAN WORKS, UNITED STATES STEEL CORP., JOIET, ILL.

Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3205: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on February 22, 1978, in response to a worker petition received on January 18, 1978, which was filed by the United Steelworkers of America on behalf of all workers engaged in employment related to the production of carbon steel wire rods and merchant wire (wire and wire products) at the Joliet, III., plant of the Joliet-Waukegan Works of the United States Steel Corp.

The Notice of Investigation was published in the Federal Register on March 3, 1978 (43 FR 8883). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of the United States Steel Corp. and its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met:

That sales or production, or both of such firm or subdivision have decreased absolutely;

That sales of wire and wire products increased in quantity in 1977 compared to 1976 and continued to increase in the first 2 months of 1978 compared to the 1977 period. Plant sales approximate plant production.

With respect to workers engaged in employment related to the production of wire rod, all of the criteria have been met.

A significant percentage of the Joliet plant’s 1977 production of wire rod was shipped to the Waukegan, Ill., plant of the United States Steel Corp. where it was used in the production of carbon steel wire. All workers of the Waukegan, Ill., plant of the United States Steel Corp. who became totally or partially separated from employment on or after November 15, 1976, have previously been certified eligible to apply for adjustment assistance benefits. See Department case file TA-W-2836.

CONCLUSION

After careful review, I determined that all workers of the Joliet, Ill., plant of the Joliet-Waukegan Works of the United States Steel Corp. engaged in employment related to the production of wire and wire products are not eligible to apply for adjustment assistance benefits.

I further conclude that increased imports of articles like or directly competitive with the carbon steel wire produced at the Waukegan, Ill., plant of the United States Steel Corp. have contributed importantly to the total or partial separation of workers engaged in the production of wire rod, and to the decline in sales or production of wire rod, at the Joliet, Ill., plant of the Joliet-Waukegan Works of the United States Steel Corp. as required for certification under the Trade Act of 1974. In accordance with the provisions of the act, I make the following certification:

All workers of the Joliet, Ill., plant of the Joliet-Waukegan Works of the United States Steel Corp. engaged in employment related to the production of wire rod who became totally or partially separated from employment on or after January 12, 1977, are eligible to apply for adjustment assistance benefits under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 20th day of July 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

(FR Doc. 78-20980 Filed 7-21-78; 8:45 am)

[4510-28]

(TA-W-2833)

JONES & LAUGHLIN STEEL CORP., PITTSBURGH WORKS, PITTSBURGH, PA.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-2833: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on January 3, 1978 in response to a worker petition received on December 8, 1977, which was filed by the United Steelworkers of America on behalf of workers producing cold finished bars, hot rolled bars and shapes, cold rolled...
sheet and galvanized sheet at the Pittsburgh Works and Hazelwood Works of Jones & Laughlin Steel Corp., Pittsburgh, Pa. During the course of the investigation it was found that workers at Hazelwood Works, producing hot rolled sheet and plate were certified on August 12, 1977 (TA-W-1479).

The Notice of Investigation was published in the Federal Register on January 17, 1978 (43 FR 2459). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Jones & Laughlin Steel Corp., its customers, the U.S. International Trade Commission, the U.S. Department of Commerce, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the act must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met: that sales of production, or both, of the firm or subdivision have decreased absolutely.

On August 12, 1977 the Department issued a certification of eligibility to apply for adjustment assistance applicable to workers engaged in employment related to the production of hot rolled plate and hot rolled sheet at the Pittsburgh Works. Total shipments of the remaining products of the Pittsburgh Works—cold rolled sheets, galvanized sheets, hot rolled bars and shapes, and cold finished bars—and shipments of each of the four products increased in 1976 compared to 1975 and in 1977 compared to 1976. Shipments equal production.

CONCLUSION

After careful review, I determine that workers engaged in employment related to the production of cold rolled sheets, galvanized sheets, hot rolled bars and shapes and cold finished bars at the Pittsburgh Works of Jones & Laughlin Steel Corp., Pittsburgh, Pa., are denied eligibility to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 18th day of July 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-20981 Filed 7-27-78; 8:45 am]

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[4510-28]

TA-W-3086

JONES & LAUGHLIN STEEL CORP., MCKINLEY MINE, MCKINLEY, MINN.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3086: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on February 7, 1978 in response to a worker petition received on January 26, 1978 which was filed by the United Steelworkers of America on behalf of workers and former workers engaged in the production of iron ore at the Minnesota Ore Division of Jones & Laughlin Steel Corp., McKinley, Minn. The McKinley Mine is part of Jones & Laughlin's Northwest Ore Division.

Another facility of the Northwest Ore Division, the Hill Annex Mine and Plant, Calumet, Minn. is currently under investigation (TA-W-3087).

The Notice of Investigation was published in the Federal Register on February 24, 1978 (43 FR 7744). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Jones & Laughlin Steel Corp., the U.S. International Trade Commission, the U.S. Department of Commerce, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met:

That sales or production, or both, of the firm or subdivision have decreased absolutely.

The McKinley Mine ships iron ore during the period from May through October. Shipments equal production. The McKinley Mine ships iron ore to the basic steelmaking facilities of Jones & Laughlin Steel Corp., and to manufacturing facilities not affiliated with Jones & Laughlin. Total shipments of iron ore are less than the McKinley Mine increased from 1976 to 1977. Shipments to Jones & Laughlin's steelmaking facilities as well as shipments to the other manufacturing facilities increased from 1976 to 1977.

CONCLUSION

After careful review, I determine that all workers of the Northwest Ore Division of Jones & Laughlin Steel Corp., McKinley Mine and Plant, McKinley, Minn. are denied eligibility to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 24th day of July 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-20982 Filed 7-27-78; 8:45 am]

[4510-28]

TA-W-3087

JONES AND LAUGHLIN STEEL CORP., HILL ANNEX MINE, CALUMET, MINN.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3087: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on February 7, 1978, in response to a worker petition received on January 26, 1978, which was filed by the United Steelworkers of America on behalf of workers and former workers engaged in the production of iron ore at the Hill Annex Mine and Plant of Jones and Laughlin Steel Corp., Calumet, Minn. The Hill Annex Mine and Plant are part of Jones and Laughlin's Northwest Ore Division. Another facility of the Northwest Ore Division, the McKinley Mine and Plant, McKinley, Minn., is currently under investigation (TA-W-3086).

The Notice of Investigation was published in the Federal Register on February 24, 1978 (43 FR 7744). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Jones and Laughlin Steel Corp., the U.S. International Trade Commission, the U.S. Department of Commerce, the U.S. Department of the Interior, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met:

That sales or production, or both, of the firm or subdivision have decreased absolutely.

To

The Hill Annex Mine ships iron ore during the period from May through

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October. Shipments equal production. The Hill Annex Mine ships iron ore to the basic steelmaking facilities of Jones and Laughlin Steel Corp. and to manufacturing facilities not affiliated with Jones and Laughlin. Total shipments of iron ore pellets by the Hill Annex Mine increased from 1976 to 1977. Shipments to Jones and Laughlin's steelmaking facilities as well as shipments to the other manufacturing facilities increased from 1976 to 1977.

**CONCLUSION**

After careful review, I determine that all workers of the Northwest Ore Division of Jones and Laughlin Steel Corp., Hill Annex Mine and Plant, Calumet, Mmm., are denied eligibility to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 24th day of July 1978.

JAMES F. TAYLOR,
Director, Office of Management, Administration and Planning.

[FDR Doc. 78-20983 Filed 7-27-78; 8:45 am]

[4510-28]

**TA-W-3233**

**LAND MANUFACTURING CO., NEWARK, N.J.**

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of **TA-W-3233**: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 223 of the act.

The investigation was initiated on February 21, 1978 in response to a worker petition received on February 7, 1978, which was filed by the International Ladies' Garment Workers' Union on behalf of workers and former workers producing ladies' raincoats and raincoats at Land Manufacturing Co., Newark, N.J. During the course of the investigation it was determined that only ladies raincoats were produced at the company.

The notice of investigation was published in the **FEDERAL REGISTER** on March 14, 1978 (43 FR 10650). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Land Manufacturing Co., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the act must be met. It is concluded that all of the requirements have been met.

U.S. imports women's, misses' and children's raincoats have increased in 1975 to 191 thousand dozens, increased in 1976 to 261 thousand dozen, and decreased in 1977 to 222 thousand dozens.

Imports of all-weather coats are included in import figures for women's and misses' coats and jackets. U.S. imports in this category increased from 1,517 thousand in 1975 to 2,282 thousand in 1977. The ratio of imports to domestic production increased from 38.9 percent in 1975 to 57.5 percent in 1976.

Lanson Industries, the sole manufacturer for whom Land Manufacturing Co. produced ladies raincoats increased purchases of imported ladies raincoats in 1977 over 1976 while decreasing purchases with Land Manufacturing during the same period.

**Conclusion**

After careful review of the facts obtained in the investigation, I conclude that increases of imports like or directly competitive with ladies' raincoats produced at Land Manufacturing Co., Newark, N.J., contributed importantly to the decline in sales or production and the total or partial separation of the workers of that plant. In accordance with the provisions of the act, I make the following certification:

All workers of Land Manufacturing Co., Newark, N.Y. who became totally or partially separated from employment on or after February 21, 1977, are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 24th day of July 1978.

JAMES F. TAYLOR,
Director, Office of Management, Administration and Planning.

[FDR Doc. 78-20984 Filed 7-27-78; 8:45 am]

[4510-28]

**TA-W-3468**

**MCCURIE STEEL MANUFACTURING, BLAIRSVILLE, GA.**

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of **TA-W-3468**: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 223 of the act.

The investigation was initiated on April 4, 1978, in response to a worker petition received on March 27, 1978, which was filed on behalf of four individuals producing wrought iron items at McClure Steel Manufacturing, Blairsville, Ga.

The notice of investigation was published in the **FEDERAL REGISTER** on April 28, 1978 (43 FR 18360). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from the partners in McClure Steel Manufacturing and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the act must be met. Without regard to whether any of the other criteria have been met the following criterion has not been met:

That a significant number of proportion of the workers in the workers' firm, or an appropriate subdivision thereof, have become totally or partially separated, or are threatened to become totally or partially separated.

The basic question in this case is whether the four individuals are "workers," employed by an employer for wages, within the meaning of the Trade Act of 1974. The four individuals are partners in McClure Steel Manufacturing and are also the only workers at the firm. The partners pay themselves by making periodic withdrawals from the profits of McClure Steel Manufacturing. Rather than "wages," defined at 29 CFR 91.3 as "all compensation for employment with an employer," the partners' withdrawals from the profits of McClure Steel Manufacturing Co. serve as "remuneration"—defined in section 247 of the act as "wages and net earnings derived from services performed as a self-employed individual."

Section 232(a) of the Trade Act of 1974 draws a clear distinction between "remuneration" for services performed as a self-employed individual, and "wages." An individual whose weekly earnings are derived solely from remuneration as opposed to wages would not be eligible to receive trade readjustment allowances.

Although the Trade Act does not contain a definition of the term "workers" for purposes of section 222(1), it is clear that the intent of the act is to cover individuals earning compensation, in the form of wages, in return for employment with an employer.

After careful review of the issues, I have determined that as self-employed individuals the four partners of McClure Steel Manufacturing Co., Blairsville, Ga., are not workers employed by an employer for wages within the meaning of section 222(1) and section
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232(a) of the Trade Act of 1974, and therefore are denied eligibility to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 18th day of July 1978.

HARRY J. GILMAN, Acting Director, Office of Foreign Economic Research.

(FR Doc. 78-20986 Filed 7-27-78; 8:45 am)

[4510-28]

TA-W-3235

MICKEY BLUMFIELD INC., COMMACK, N.Y., NEW YORK, N.Y.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-3235: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 223 of the act.

The investigation was initiated on February 23, 1978, in response to a worker petition received on February 8, 1978, which was filed on behalf of all workers producing ladies' coats and raincoats at Mickey Blumfield, Inc., Commack, N.Y. The investigation revealed the company produces ladies' cloth, wool, leather, and suede coats. No raincoats are produced.

The notice of investigation was published in the FEDERAL REGISTER on March 14, 1978 (43 FR 10650). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Mickey Blumfield Inc., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 223 of the act must be met. Regardless of whether any of the other criteria have been met, the following criterion has not been met:

That increases of imports of articles like or directly competitive with the articles produced by such workers' firm or an appropriate subdivision thereof contributed importantly to such total or partial separation, or threat thereof, and to such decline in sales or production.

The Department conducted separate surveys of some of the manufacturers for which New B Garment Co., New Bethlehem, Pa., are denominated as a contractor and of some of the customers that purchase garments directly from New B Garment. None of the manufacturers who responded to the survey purchased imported ladies' or boys' knit tops or shirts in 1976 or 1977. Most of the respondents purchasing knit tops under the private label reported increased purchases from New B Garment in 1977 compared to 1976.

CONCLUSION

After careful review, I determine that all workers of the New B Garment Co., New Bethlehem, Pa., are denied eligibility to apply for adjustment assistance under Title II, Chapter 2, of the Trade Act of 1974.

Signed at Washington, D.C., this 24th day of July 1978.

JAMES F. TAYLOR,
Director, Office of Management, Administration, and Planning.

(FR Doc. 78-20986 Filed 7-27-78; 8:45 am)

[4510-28]

TA-W-3283

NEW B GARMENT CO., NEW BETHLEHEM, PA.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-3283: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 223 of the act.

The investigation was initiated on March 1, 1978, in response to a worker petition received on February 22, 1978, which was filed by the Amalgamated Clothing & Textile Workers' Union on behalf of all workers producing ladies' and boys' knit tops and shirts at the New Bethlehem, Pa., plant of New B Garment Co.

The notice of investigation was published in the FEDERAL REGISTER on March 1, 1978 (43 FR 10649). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of New B Garment Co., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 223 of the act must be met. Regardless of whether any of the other criteria have been met, the following criterion has not been met:

That increases of imports of articles like or directly competitive with the articles produced by such workers' firm or an appropriate subdivision thereof contributed importantly to such total or partial separation, or threat thereof, and to such decline in sales or production.

The Department conducted separate surveys of some of the manufacturers for which New B Garment Co., New Bethlehem, Pa., are denominated as a contractor and of some of the customers that purchase garments directly from New B Garment. None of the manufacturers who responded to the survey purchased imported ladies' or boys' knit tops or shirts in 1976 or 1977. Most of the respondents purchasing knit tops under the private label reported increased purchases from New B Garment in 1977 compared to 1976.

CONCLUSION

After careful review, I determine that all workers of the New B Garment Co., New Bethlehem, Pa., are denied eligibility to apply for adjustment assistance under Title II, Chapter 2, of the Trade Act of 1974.

Signed at Washington, D.C., this 24th day of July 1978.

JAMES F. TAYLOR,
Director, Office of Management, Administration, and Planning.

(FR Doc. 78-20987 Filed 7-27-78; 8:45 am)

[4510-28]

TA-W-3289


Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-3289: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 223 of the act.

The investigation was initiated on February 23, 1978, in response to a worker petition received on February
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7, 1978, which was filed by the United Automobile, Aerospace & Agricultural Implement Workers of America (UAW) on behalf of workers and former workers producing basic oxygen furnaces, ladles, and cylinder-railroad cars at the New Castle, Pa., plant of Pennsylvania Engineering Corp.

The Department's investigation revealed that the New Castle plant of Pennsylvania Engineering Corp. also produces fume gas hoods and other equipment used in the steel industry.

The notice of investigation was published in the Federal Register on March 14, 1978 (43 FR 10550). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Pennsylvania Engineering Corp., its customers, the U.S. Department of Commerce, the International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the act must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met:

That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threats thereof, and to the absolute decline in sales or production.

The Department's investigation revealed that imports of basic oxygen furnaces, ladles, cylinder railroad cars, and fume gas hoods by customers of Pennsylvania Engineering Corp. were small and declining during the period from 1976 through 1977. None of the customers responding to the Department's survey reported any purchases of imports of these items in 1977.

Similarly, imported steel cannot be considered to have contributed importantly to the separations, or threats thereof, and to the absolute decline in sales or production.

U.S. imports of finished fabric increased from 408 million square yards in 1975 to 464 million square yards in 1976 before decreasing to 453 million square yards in 1977.

The ratio of imported finished fabric to domestic production was 6.6 percent in 1975 and increased to 8.0 percent in 1976.

The petitioners allege that increased imports of apparel contributed importantly to the declines in sales and production of finished fabric and resulting unemployment at Prints-N-Things. However, apparel is not 'like or directly competitive' with finished fabric within the meaning of section 222 of the Trade Act. Import injury must be considered in determining import injury to workers producing finished fabric.


CONCLUSION

After careful review, I determine that all workers at Prints-N-Things, Inc., New York, N.Y., are denied eligibility to apply for trade adjustment assistance under Title II, Chapter 2, of the Trade Act of 1974.

Signed at Washington, D.C., this 24th day of July 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-20989 Filed 7-27-78; 8:45 am]

PRINTS-N-THINGS, INC., NEW YORK, N.Y.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-3200: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on February 22, 1978, in response to a worker petition received on November 15, 1977, which was filed on behalf of workers formerly producing printed fabric at Prints-N-Things, Inc., New York, N.Y.

The notice of investigation was published in the Federal Register on March 3, 1978 (43 FR 8863). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from Prints-N-Things, Inc., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the act must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met:

That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threats thereof, and to the absolute decline in sales or production.

The Department's investigation revealed that imports of basic oxygen furnaces, ladles, cylinder railroad cars, and fume gas hoods by customers of Pennsylvania Engineering Corp. were small and declining during the period from 1976 through 1977. None of the customers responding to the Department's survey reported any purchases of imports of these items in 1977.

Similarly, imported steel cannot be considered to have contributed importantly to the separations, or threats thereof, and to the absolute decline in sales or production.

U.S. imports of finished fabric increased from 408 million square yards in 1975 to 464 million square yards in 1976 before decreasing to 453 million square yards in 1977.

The ratio of imported finished fabric to domestic production was 6.6 percent in 1975 and increased to 8.0 percent in 1976.

The petitioners allege that increased imports of apparel contributed importantly to the declines in sales and production of finished fabric and resulting unemployment at Prints-N-Things. However, apparel is not 'like or directly competitive' with finished fabric within the meaning of section 222 of the Trade Act. Import injury must be considered in determining import injury to workers producing finished fabric.


CONCLUSION

After careful review, I determine that all workers at Prints-N-Things, Inc., New York, N.Y., are denied eligibility to apply for trade adjustment assistance under Title II, Chapter 2, of the Trade Act of 1974.

Signed at Washington, D.C., this 24th day of July 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-20989 Filed 7-27-78; 8:45 am]

FEDERAL REGISTER, VOL 43, NO. 146—FRIDAY, JULY 28, 1978
The investigation was initiated on February 15, 1978, in response to a worker petition received on January 2, 1978, which was filed on behalf of workers and former workers producing athletic footwear at Rani-Merona of New Hampshire, Inc., Portsmouth, N.H.

The notice of investigation was published in the Federal Register on February 26, 1978 (43 FR 3209). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Rani-Merona of New Hampshire, Inc., its customer, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met. Without regard to whether any of the criteria have been met, the following criterion has not been met:

That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threats thereof, and to the absolute decline in sales or production.

The Department’s investigation revealed that Rani-Merona of New Hampshire, Inc., started producing athletic footwear in November 1977, and production was less than one percent from 1972 through the first half of 1977. Imports of shoe uppers which incorporate uppers are not “like or directly competitive” with uppers within the meaning of section 223(3) of the Trade Act of 1974.

The only customer that purchased shoe uppers from the Lowell and Haverhill, Mass. plants of Rani-Merona Corp. indicated that it did not purchase imported shoe uppers.

From November 1977 through January 1978, the Lowell and Haverhill plants supplied uppers to the Portsmouth, New Hampshire plant of Rani-Merona which produced finished footwear. The Rani-Merona Corp. terminated all footwear production after 2 months in operation.

CONCLUSION

After careful review I determine that all workers at the Lowell and Haverhill, Mass. plants of Rani-Merona Corp. are denied eligibility to apply for trade adjustment assistance under title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 20th day of July 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

(FR Doc. 78-20990 Filed 7-27-78; 8:45 am)
for adjustment assistance under title II, chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 21st day of July 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-20992 Filed 7-27-78; 8:45 am]

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports like or directly competitive with women’s suede coats assembled from sheepskin tanned at the Shawmut Tanning Co., Peabody, Mass., contributed importantly to the total or partial separation of the workers of that plant. In accordance with the provisions of the act, I make the following certification:

All workers at the Shawmut Tanning Co., Peabody, Mass., who became totally or partially separated from employment on or after November 18, 1976 are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 20th day of July 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-20993 Filed 7-27-78; 8:45 am]

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports like or directly competitive with women’s leather and suede coats from New England Sports Wear in 1977 compared to 1975 increased their purchases of imported leather coats and jackets or increased their purchases from domestic sources which utilized foreign manufacturers of leather coats.

A Department survey of New England Sports Wear’s customers revealed that many customers who had decreased their purchases of women’s leather and suede coats from New England Sports Wear in 1977 compared to 1975 increased their purchases of imported leather coats and jackets or increased their purchases from domestic sources which utilized foreign manufacturers of leather coats.

The Clarksburg plant produces primarily graphite electrodes. Some graphite anodes and specialty items such as graphite pipes and flexing tubes are also produced.

Customers of Union Carbide were surveyed regarding their purchases from the Clarksburg plant. Of the responding customers, most of those who reduced purchases from Clarksburg also reduced purchases of imports. The ratio of imports to domestic production increased from 13.4 percent in 1976 to 14.7 percent in 1977.

Signed at Washington, D.C., this 20th day of July 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-20994 Filed 7-27-78; 8:45 am]

CONCLUSION

After careful review, I determine that all workers at the Clarksburg, W. Va. plant of Union Carbide Corp., Carbon Products Division are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 24th day of July 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-20994 Filed 7-27-78; 8:45 am]

CONCLUSION

After careful review, I determine that all workers at the Clarksburg, W. Va. plant of Union Carbide Corp., Carbon Products Division are denied eligibility to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 24th day of July 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-20994 Filed 7-27-78; 8:45 am]

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CONCLUSION

After careful review I determine that all workers at the Marietta, Ohio Chemicals & Plastics Division plant of Union Carbide Corp. are denied eligibility to apply for adjustment assistance under title II, chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 24th day of July 1978.

HARRY J. GILLMAN
Acting Director, Office of Foreign Economic Research.

[FEDERAL REGISTER, Vol. 43, No. 146-Friday, July 28, 1978]

[4510-28]

ITA-W-3345

UNIVERSAL SPORTSWEAR, ELIZABETH, N.J.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-3345: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on March 9, 1978, in response to a worker petition received on February 28, 1978, which was filed on behalf of workers and former workers producing outerwear at Universal Sportswear. The investigation revealed that men's and boys' outer jackets and coats are produced at Universal Sportswear.

The notice of investigation was published in the FEDERAL REGISTER on March 24, 1978 (43 FR 12401). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Universal Sportswear, its customers, the Steelworkers of America on behalf of all workers producing cast iron cookware at Wagner Manufacturing Division, J. R. Clark Co., Sidney, Ohio.

The notice of investigation was published in the FEDERAL REGISTER on March 24, 1978 (43 FR 12401). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Universal Sportswear, its customers, the Steelworkers of America on behalf of all workers producing cast iron cookware at Wagner Manufacturing Division, J. R. Clark Co., Sidney, Ohio.

The notice of investigation was published in the FEDERAL REGISTER on March 24, 1978 (43 FR 12401). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Universal Sportswear, its customers, the Steelworkers of America on behalf of all workers producing cast iron cookware at Wagner Manufacturing Division, J. R. Clark Co., Sidney, Ohio.

The notice of investigation was published in the FEDERAL REGISTER on March 24, 1978 (43 FR 12401). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Universal Sportswear, its customers, the Steelworkers of America on behalf of all workers producing cast iron cookware at Wagner Manufacturing Division, J. R. Clark Co., Sidney, Ohio.

The notice of investigation was published in the FEDERAL REGISTER on March 24, 1978 (43 FR 12401). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Universal Sportswear, its customers, the Steelworkers of America on behalf of all workers producing cast iron cookware at Wagner Manufacturing Division, J. R. Clark Co., Sidney, Ohio.

The notice of investigation was published in the FEDERAL REGISTER on March 24, 1978 (43 FR 12401). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Universal Sportswear, its customers, the Steelworkers of America on behalf of all workers producing cast iron cookware at Wagner Manufacturing Division, J. R. Clark Co., Sidney, Ohio.

The notice of investigation was published in the FEDERAL REGISTER on March 24, 1978 (43 FR 12401). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Universal Sportswear, its customers, the Steelworkers of America on behalf of all workers producing cast iron cookware at Wagner Manufacturing Division, J. R. Clark Co., Sidney, Ohio.

The notice of investigation was published in the FEDERAL REGISTER on March 24, 1978 (43 FR 12401). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Universal Sportswear, its customers, the Steelworkers of America on behalf of all workers producing cast iron cookware at Wagner Manufacturing Division, J. R. Clark Co., Sidney, Ohio.

The notice of investigation was published in the FEDERAL REGISTER on March 24, 1978 (43 FR 12401). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Universal Sportswear, its customers, the Steelworkers of America on behalf of all workers producing cast iron cookware at Wagner Manufacturing Division, J. R. Clark Co., Sidney, Ohio.

The notice of investigation was published in the FEDERAL REGISTER on March 24, 1978 (43 FR 12401). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Universal Sportswear, its customers, the Steelworkers of America on behalf of all workers producing cast iron cookware at Wagner Manufacturing Division, J. R. Clark Co., Sidney, Ohio.

The notice of investigation was published in the FEDERAL REGISTER on March 24, 1978 (43 FR 12401). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Universal Sportswear, its customers, the Steelworkers of America on behalf of all workers producing cast iron cookware at Wagner Manufacturing Division, J. R. Clark Co., Sidney, Ohio.

The notice of investigation was published in the FEDERAL REGISTER on March 24, 1978 (43 FR 12401). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Universal Sportswear, its customers, the Steelworkers of America on behalf of all workers producing cast iron cookware at Wagner Manufacturing Division, J. R. Clark Co., Sidney, Ohio.
concluded that all of the requirements have been met.

Imports of cast iron cookware increased absolutely in 1977 compared to 1976 and in the first quarter of 1978 compared to the first quarter of 1977.

A survey of some of the customers which purchased cast iron cookware from Wagner Manufacturing Division in 1976 and 1977 indicated that some customers reduced purchases from Wagner and increased purchases of imported cast iron cookware.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with the cast iron cookware produced by the Wagner Manufacturing Division of the J. R. Clark Co., Sidney, Ohio, contributed importantly to the sales and production declines and to the total or partial separations of the workers of that plant. In accordance with the provisions of the act, I make the following certification:

All workers at the Wagner Manufacturing Division of the J. R. Clark Co., Sidney, Ohio, engaged in employment related to the production of cast iron cookware who became totally or partially separated from employment on or after February 20, 1971, are eligible to apply for adjustment assistance under Title II, Chapter 2, of the Trade Act of 1974.

Signed at Washington, D.C., this 24th day of July 1978.

HARRY J. GITMAN
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-20998 Filed 7-27-78; 8:45 am]

[7501-01]

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

Notice (78-33)

APPLICATIONS STEERING COMMITTEE (ASC)
SUPPORTING RESEARCH AND TECHNOLOGY (S.R. & T.) AD HOC ADVISORY SUBCOMMITTEE

Meeting

The Non-Renewable/Renewable Resources Panel of the ASC, S.R. & T. Ad Hoc Advisory Subcommittee will meet at the Goddard Space Flight Center, Greenbelt, Md. 20771, on August 7-11, 1978. The meeting will be held in the auditorium of building 8 from 8:30 a.m. to 4:30 p.m. each day. The subcommittee will conduct a comprehensive evaluation of the proposals submitted to NASA in response to the applications notice for the supporting research and technology phase of the space and terrestrial applications program. Public discussion of the professional qualifications of the proposers and their potential scientific contributions to the S.R. & T. program would invoke the privacy of the proposers and the other individuals involved. Since the subcommittee sessions will be concerned throughout with matters listed in 5 U.S.C. 552(b)(6), as described above, it has been determined that the sessions should be closed to the public.


ARNOLD W. FRUTFIN
Acting Associate Administrator for External Relations.

[FR Doc. 78-20995 Filed 7-27-78; 8:45 am]

[7510-01]

NASA ADVISORY COUNCIL (NAC)

Meeting

The Ad Hoc Informal Subcommittee on Handling of Alternative Aircraft

FEDERAL REGISTER, VOL. 43, NO. 146—FRIDAY, JULY 28, 1978
This meeting is for the purpose of Panel review, discussion, evaluation, and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including discussion of information given in confidence to the agency by grant applicants. In accordance with the determination of the Chairman published in the Federal Register of March 17, 1977, these sessions will be closed to the public pursuant to subsection (c) (4), (6), and (9)(B) of section 5 of title 5, U.S.C.

Further information with reference to this meeting can be obtained from Mr. John H. Clark, Advisory Committee Management Officer, National Endowment for the Arts, Washington, D.C. 20506, or call (202) 634-6070.


John H. Clark,
Director, Office of Council and Panel Operations, National Endowment for the Arts.

[FED Reg Doc 78-20914 Filed 7-27-78; 8:45 am]

NOTICES

[7537-01]

NATIONAL COUNCIL ON THE ARTS

Notice of Meeting

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given that a meeting of the National Council on the Arts will be held on August 11, 1978, from 9 a.m. to 5:30 p.m., and August 12, 1978, from 9 a.m. to 5:30 p.m., in the 14th floor conference rooms of the Columbia Plaza Office Building, 2401 E Street NW., Washington, D.C. 20546.

A portion of this meeting will be open to the public on Friday, August 11, 1978, from 9 a.m. to 5:30 p.m., and Saturday, August 12, 1978, from 10 a.m. to 12:45 p.m. Topics of discussion will be program policy and guidelines for the challenge, dance, Federal-State partnership, and theater programs; reports of the fashion design task force and from regional representatives; the annual evaluation plan; and other general reports.

The remaining sessions of this meeting will be closed to the public: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), as amended, notice is hereby given that a meeting of the Media Arts Advisory Panel (Aid to Film/Video Exhibition) to the National Council on the Arts will take place August 21, 1978, from 9:30 a.m. to 5:30 p.m., and August 22, 1978, from 9:30 a.m. to 5:30 p.m., in room 1422 of the Columbia Plaza Office Building, 2401 E Street NW., Washington, D.C. 20506.

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[7555-01]
NATIONAL SCIENCE FOUNDATION

AD HOC SUBCOMMITTEE FOR THE CEPEX SITE REVIEW

Meeting

In accordance with the Federal Advisory Committee Act, as amended, Pub. L. 92-463, the National Science Foundation announces the following meeting:

Name: Ad Hoc Subcommittee for the Site Review of the Controlled Ecosystem Population Experiments (CEPEX) of the Advisory Committee for Ocean Sciences.

Date and time: August 13-15, 1978; 10 a.m. to 5:30 p.m. daily.

Place: CEPEX Site, Institute of Ocean Sciences, Sidney, British Columbia, Canada.

Type of meeting: Closed.

Contact person: Dr. Lauriston R. King, Acting Head, International Decade of Ocean Exploration Section, room 605, National Science Foundation, Washington, D.C. 20550, telephone 202-632-7256.

Purpose of subcommittee: To provide advice and recommendations concerning support for research on CEPEX.

Agenda: To review and evaluate the past research and the 1978 field season of the CEPEX project as part of the recommendation process for future support.

Reason for closing: The review process includes information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are within exemptions (4) and (6) of 5 U.S.C. 552(b)(c), Government in the Sunshine Act.

Authority to close meeting: This determination was made by the Committee Management Officer pursuant to provisions of section 16(b) of Pub. L. 92-463. The Committee Management Officer was delegated the authority to make such determinations by the Acting Director, NSF, on February 18, 1977.

M. REBECCA WINKLER,
Committee Management Coordinator.


[FR Doc. 78-20878 Filed 7-27-78; 8:45 am]

[7555-01]

ADVISORY GROUPS

Availability of Reports

The National Science Foundation has filed with the Library of Congress some reports which were prepared by various advisory committees of the National Science Foundation:

- Report of the Ad Hoc Advisory Group for Future Scientific Ocean Drilling
- Report of the Science Applications Task Force

The reports were filed in accordance with the Federal Advisory Committee Act, Pub. L. 92-463, and are available for public inspection and use at the Library of Congress, Rare Book Division, Room 256, Washington, D.C. A copy of each report is also available for public inspection and use at the National Science Foundation, Committee Management Office, Room 248, Washington, D.C.

M. REBECCA WINKLER,
Committee Management Coordinator.


[FR Doc. 78-20878 Filed 7-27-78; 8:45 am]

[7590-01]

NUCLEAR REGULATORY COMMISSION

(Docket Nos. 50-416 and 50-417)

MISSISSIPPI POWER & LIGHT CO. AND MIDDLE SOUTH ENERGY, INC. (GRAND GULF NUCLEAR STATION, UNITS 1 & 2)

Receipt of Application for Facility Operating License; Availability of Applicants' Environmental Report; Consideration of Issuance of Facility Operating Licenses and Opportunity for Hearing

Notice is hereby given that the Nuclear Regulatory Commission (the Commission) has received an application for facility operating licenses from Mississippi Power & Light Co. and Middle South Energy, Inc. (the applicants) to possess, use, and operate Grand Gulf Nuclear Station, Units 1 and 2 (the facilities), located on the applicants' site in Calhoun County, Miss., at a core power level of 3,833 megawatts thermal, with an equivalent net electrical output of approximately 1,250 megawatts.

The applicants have also filed, pursuant to the National Environmental Policy Act of 1969 and the regulations of the Commission in 10 CFR Part 51, an environmental report. The report, which discusses environmental considerations related to the proposed operation of the facilities is being made available at the Southwest Mississippi Planning and Development District, P.O. Box 636, Mindville, Miss. 38653.

After the environmental report has been analyzed by the Commission's staff, a draft environmental statement will be prepared. Upon preparation of the draft environmental statement, the Commission will, among other things, cause to be published in the Federal Register a notice of availability of the draft statement, requesting comments from interested persons on the draft statement. The summary notice will also contain a statement to the effect that any comments of Federal agencies and State and local officials will be made available when received. The draft environmental statement will focus only on any matters which differ from those previously discussed in the final environmental statement prepared in connection with the issuance of the construction permits. Upon consideration of comments submitted with respect to the draft environmental statement, the Commission's staff will prepare a final environmental statement, the availability of which will be published in the Federal Register.

The Commission will consider the issuance of facility operating licenses to Mississippi Power & Light Co. and Middle South Energy, Inc., which would authorize the applicants to possess, use, and operate the Grand Gulf Nuclear Station, Units 1 and 2, in accordance with the provisions of the licenses and the technical specifications appended thereto, upon (1) the completion of a favorable safety evaluation of the application by the Commission's staff; (2) the completion of the environmental review required by the Commission's regulations in 10 CFR Part 51; (3) the receipt of a report on the applicants' application for facility operating licenses by the Advisory Committee on Reactor Safeguards; and (4) a finding by the Commission that the application for the facility licenses, as amended, complies with the requirements of the Atomic Energy Act of 1954, as amended (the act), and the Commission's regulations in 10 CFR Chapter I. Construction of the facilities was authorized by Construction Permit Nos. CPFR-118 and CPFR-119, issued by the Commission on September 4, 1974.

Prior to issuance of any operating licenses, the Commission will inspect...
the facilities to determine whether they have been constructed in accordance with the application, as amended, the provisions of the construction permits. In addition, the licenses will not be issued until the Commission has made the findings reflecting its review of the application under the act, which will be set forth in the proposed licensing action and concluded that the issuance of the licenses will not be inimical to the common defense and security or to the health and safety of the public. Upon issuance of the licenses, the applicants will be required to execute an indemnity agreement as security or to the health and safety of the public.

Copies of the proposed operating licenses and the ACRS report, when available, may be obtained by request to the Director, Division of Project Management, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Copies of the Commission’s staff safety evaluation report and final environmental statement, when available, may be purchased at current rates, from the National Technical Information Service, Department of Commerce, 5285 Port Royal Road, Springfield, Va. 22161.

For the Nuclear Regulatory Commission.

Dated at Bethesda, Md., this 28th day of July 1978.

JOHN F. STROZ,
Chief, Light Water Reactors Branch 1, Division of Project Management.

[FR Doc. 78-20752 Filed 7-27-78; 8:45 am]

NEW YORK STATE ELECTRIC & GAS CORP.
AND LONG ISLAND LIGHTING CO.

Receipt of Attorney General’s Advice and Time for Filing of Petitions to Intervene on Antitrust Matters

The Commission has received, pursuant to section 105c of the Atomic Energy Act of 1954, as amended, the following advice from the Attorney General of the United States, dated July 14, 1978 with respect to a construction permit application for Nuclear Power Station/New Haven—Stuyvesant Sites, Units 1 and 2:

You have requested our advice pursuant to section 105 of the Atomic Energy Act, as amended, in regard to the above cited application by New York State Electric & Gas Corp. on behalf of itself and Long Island Lighting Co. (LICEA). Both of the applicants have been the subject of prior antitrust advice letters written by the Department. On January 7, 1975, we rendered antitrust advice on an application by LICEA to construct the Jamesport Nuclear Power Station, Units 1 and 2. Most recently, on January 27, 1974, we rendered antitrust advice concerning New York State with respect to its application to participate in the Jamesport Nuclear Power Station, Units 1 and 2. We also rendered antitrust advice on December 27, 1974, regarding New York State’s application to construct the Somerset Nuclear Station, Units 1 and 2.

In each of the above-referenced letters we advised our conclusions that the applicants under the licenses applied for would not create or maintain a situation inconsistent with the antitrust laws.
Since the last antitrust advice letters were written Lilio has had a change in its operations that may affect the status of its application for a change in the Nuclear Material License No. SNM-1773, which was amended to License No. SNM-1773 issued pursuant to 10 CFR Part 70 to authorize the receipt and storage of Oconee Nuclear Station spent fuel at the McGuire facility.

The proposed amendment would authorize the receipt and storage of Oconee Nuclear Station spent fuel at the McGuire facility in accordance with the licensee's request made in Docket No. 50-369 and 50-370. Activities for which additional authorization is sought involve receipt, possession, inspection and storage of spent nuclear fuel at the licensee's Oconee Nuclear Facility in Oconee County, S.C., at the licensee's McGuire facility located in Mecklenburg County, N.C., including transport of the Oconee spent fuel by truck between the two sites. The activities are reviewed also local storage of Oconee irradiated fuel with the spent fuel to be generated by the operation of the McGuire facility. In its license amendment Duke Power Co. also requested certain special arrangements with respect to the Act Indemnification. This request is under consideration by the Commission as a separate matter, and it will be the subject of a separate action, including any public notice required. Issuance of an operating license for the McGuire Nuclear Facility is presently under consideration in a separate proceeding pursuant to 10 CFR Part 50 in Docket Nos. 50-369 and 50-370.

The NRC will not issue the license amendment for storage of Oconee spent fuel at the McGuire Nuclear Station spent fuel pool until the completion of a safety evaluation on the licensee's request and the completion of environmental evaluations made pursuant to 10 CFR Part 51; and (2) unless favorable findings required by the Atomic Energy Act of 1954, as amended (the act), and the NRC's rules and regulations have been made.

The McGuire Nuclear Facility is presently under consideration in a separate proceeding pursuant to 10 CFR Part 50 in Docket Nos. 50-369 and 50-370.

The NRC will not issue the license amendment for storage of Oconee spent fuel at the McGuire Nuclear Station spent fuel pool until the completion of a safety evaluation on the licensee's request and the completion of environmental evaluations made pursuant to 10 CFR Part 51; and (2) unless favorable findings required by the Atomic Energy Act of 1954, as amended (the act), and the NRC's rules and regulations have been made.

The McGuire Nuclear Facility is presently under consideration in a separate proceeding pursuant to 10 CFR Part 50 in Docket Nos. 50-369 and 50-370.

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shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter, and the bases for each. All petitions will be acted upon by the Commission or the Licensing Board, designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel. Timely petitions will be considered to determine whether a hearing should be noticed or another appropriate order issued regarding the disposition of the petitions.

In the event that a hearing is held and a person is permitted to intervene, that person becomes a party to the proceeding and has a right to participate fully in the conduct of the hearing. For example, that person may present evidence and cross-examine witnesses.

A copy of the Federal Register Notice is available for public inspection at the Federal Register Public Document Room, 1717 H Street NW, Washington, D.C., and at the local Public Document Rooms at the Public Library of Charlotte and Mecklenburg County, 310 North Tryon Street, Charlotte, N.C. 28202, between the hours of 9 a.m. and 9 p.m. weekdays, 9 a.m. and 6 p.m. on Saturday and 2 p.m. and 6 p.m. on Sunday, and at the Occonee County Library, 201 South Spring Street, Walhalla, S.C. 29691, between the hours of 10 a.m. and 9 p.m. on Monday, 9 a.m. and 5 p.m. Tuesday through Friday, 9 a.m. and 12 noon on Saturday. The Commission has arranged for other documents and correspondence relating to the proposed amendment to the Special Nuclear Material License No. SNM-1773 to be kept at the same locations.

Dated at Silver Spring, Md., this 14th day of July, 1978.

For the Nuclear Regulatory Commission.

RICHARD W. STAROSTEKI, Chief, Fuel Reprocessing and Recycle Branch Division of Fuel Cycle and Material Safety.

[FR Doc. 78-20753 Filed 7-27-78; 8:45 am]

NOTICES

The petitioner requests the Commission to amend section 31.11, general license for use of byproduct material for certain in vitro clinical or laboratory testing, to include veterinarians as general licensees. The petitioner states that:

It has been brought to my attention that licensed veterinarians are unable to register on Form AEC-483 for in vitro testing under the terms of the general license provided for in section 31.11 of 10 CFR Part 31. Rather, veterinarians must request a specific byproduct material license on Form AEC-313. It is also my understanding that the fee for the specific byproduct license will be $190. I believe the fee for use of veterinary equipment is considerably, I believe it is a hindrance to progress to require a different license than that extended to physicians. The small quantity used and similarity of use to that of a physician (specifically, RIA use (Radioimmunoassay) would imply a similar type license for veterinarians. Would you please consider this type of license for veterinarians also?


All persons who desire to submit written comments or suggestions concerning the petition for rulemaking should send their comments to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch, By September 26, 1978.


For the Nuclear Regulatory Commission.

SAMUEL J. CHILK, Secretary of the Commission.

[FR Doc. 78-20868 Filed 7-27-78; 8:45 am]

[7590-01]

ADVISORY COMMITTEE ON REACTOR SAFEGUARDS, SUBCOMMITTEE ON EMERGENCY COOLING SYSTEMS (ECCS) MEETING

The ACRS Subcommittee on Emergency Core Cooling will hold an open meeting on August 14, 1978 at the Westbank Motel Coffee Shop, 475 River Parkway, Idaho Falls, Idaho 83401, to review the status of research projects related to LOFT, SEMISCALE, thermal-hydraulic aspects of the Power Burst Facility (PBF), and 2-phase flow instrumentation. Notice of this meeting was published at 43 FR 32162 and 30631, June 16 and July 17, 1978, respectively.

In accordance with the procedures outlined in the Federal Register on October 31, 1977 (42 FR 56972), oral or written statements may be presented by members of the public, recordings will be permitted only during those portions of the meeting when a transcript is being kept, and questions may be asked only by members of the subcommittee, its consultants, and staff.

Persons desiring to make oral statements should notify the designated Federal employee as far in advance as practicable so that appropriate arrangements can be made to allow the necessary time during the meeting for such statements.

The agenda for subject meeting shall be as follows:

Monday, August 14, 1978; 8:30 a.m. until the conclusion of business.

The subcommittee may meet in executive session, with any of its consultants who may be present to explore and exchange their preliminary opinions regarding matters which should be considered during the meeting and to formulate a report and recommendations to the full committee.

At the conclusion of the executive session, the subcommittee will hear presentations by and hold discussions with representatives of the NRC Staff, the Idaho National Engineering Laboratory (INEL), and their consultants, pertinent to the above topics. The subcommittee may then consider whether the matters identified in the initial session have been adequately covered and whether the project is ready for review by the full committee.

Further information regarding topics to be discussed, whether the meeting has been cancelled or rescheduled, the chairman's ruling on requests for the opportunity to present oral statements and the time allotted therefore can be obtained by a prepaid telephone call to the designated Federal employee for this meeting, Dr. Andrew L. Bates, telephone 202-334-3267, between 8:15 a.m. and 5 p.m., e.t.


JOHN C. HOYLE, Advisory Committee Management Officer.

[FR Doc. 78-21132 Filed 7-27-78; 9:09 am]

[3110-01]

OFFICE OF MANAGEMENT AND BUDGET

CLEARANCE OF REPORTS

List of requests

The following is a list of requests for clearance of reports intended for use in collecting information from the public received by the Office of Management and Budget on July 24, 1978 (44 U.S.C. 3509). The purpose of pub-
lishing this list in the Federal Register is to inform the public.

The list includes the title of each request received; the name of the agency sponsoring the proposed collection of information; the agency form number(s), if applicable; the frequency with which the information is proposed to be collected; an indication of who will be the respondents to the proposed collection; the estimated number of responses; the estimated burden in reporting hours; and the name of the reviewer or reviewing division or office.

Requests for extension which appear to raise no significant issues are to be approved after brief notice through this release.

Further information about the items on this daily list may be obtained from the Clearance Office, Office of Management and Budget, Washington, D.C. 20503, 202-395-4529, or from the reviewer listed.

NEW FORMS

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Government National Mortgage Association
Schedule of Pooled Mortgages—Mobile Home, HUD-1725, on occasion, 2,000 mortgage bankers, Caywood, D. P., 395-3443.
Schedule of Pooled Project Mortgages, HUD-1721, on occasion, 90 mortgage bankers, Caywood, D. P., 395-3443.

REVISED

DEPARTMENT OF COMMERCE

Bureau of Census, Survey of Local Government Finances (school system) 7-53A and 33B, annually, State and local public officials, 6,600 responses, 6,600 hours, Office of Federal Statistical Policy and Standard, Laverne V. Collins, 672-7956.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE


EXTENSIONS

GENERAL SERVICES ADMINISTRATION

Contractor's Statement of Contingent or Other Fees, 119, on occasion, contract pricing, 3,700 responses, 3,700 hours, Office of Federal Statistical Policy and Standard, 672-7956.
Contract Pricing Proposal (research and development), OF-60, on occasion contract pricing, 5,000 responses, 15,000 hours, Office of Federal Statistical Policy and Standard, 672-7956.

PENSION BENEFIT GUARANTEE CORPORATION

Survey Form for Multiemployer Termination Insurance Program, single time, multiemployer pension plans, 28 responses, 104 hours, Office of Federal Statistical Policy and Standard, Strasser, A., 672-7956.

DEPARTMENT OF COMMERCE


DAVID R. LEUTHOLD, Budget and Management Officer.

[FR Doc. 78-21029 Filed 7-27-78; 8:45 am]
[3110-01]

CLEARANCE OF REPORTS

List of Requests

The following is a list of requests for clearance of reports intended for use in collecting information from the public received by the Office of Management and Budget on July 25, 1978 (44 U.S.C. 3509). The purpose of publishing this list in the Federal Register is to inform the public.

The list includes the title of each request received; the name of the agency sponsoring the proposed collection of information; the agency form number(s), if applicable; the frequency with which the information is proposed to be collected; an indication of who will be the respondents to the proposed collection; the estimated number of responses; the estimated burden in reporting hours; and the name of the reviewer or reviewing division or office.

Requests for extension which appear to raise no significant issues are to be approved after brief notice through this release.

Further information about the items on this daily list may be obtained from the Clearance Office, Office of Management and Budget, Washington, D.C. 20503, 202-395-4529, or from the reviewer listed.

NEW FORMS

DEPARTMENT OF COMMERCE

Application Form—Professions Program—Law Teacher, seminars annually, 200 individuals, Warren Topelius, 395-6132.
Application Form—Centers for Advanced Study, annually, 40 research centers, Warren Topelius, 395-6132.

DEPARTMENT OF LABOR

Occupational Safety and Health Administration, designation of competent person and log of inspection and tests by competent person, OSHA-73 and 74, on occasion, 625 shipyards, Strasser, A., 395-6132.

REVISED

NATIONAL ENDOWMENT FOR THE HUMANITIES

Application Instructions, NEH-2, on occasion, scholars at all kinds of institutions, 700 responses, 175 hours, Warren Topelius, 395-6132.

DEPARTMENT OF LABOR

Employment Standards Administration:
Medicaid History and Examination for Coal Mine Workers’ Pneumoconiosis, CM-988, on occasion, examining physicians, 8,000 responses, 4,000 hours, Richard Etlinger, 395-3214.
Roentgenographic Interpretation, CM-833, on occasion, hospitals, physicians, 40,000 responses, 20,000 hours, Clearances Office, 395-3772.
Miner’s Claim for Benefits and Employment History, CM-911 and 911A, on occasion, current and former coal miners, 40,000 responses, 40,000 hours, Strasser, A., 395-6132.

EXTENSIONS

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service, report of child nutrition operations, FNS-10, monthly, educational agencies, 672 responses, 672 hours, Ellett, C.A., 395-6132.

FEDERAL REGISTER, VOL. 43, NO. 145—FRIDAY, JULY 28, 1978
NOTICES

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration, report of fish and shellfish caught or purchased from fishermen, NOAA 88-12, monthly, wholesale dealers of fishery products and fishermen dealers, 4,599 responses, 1,170 hours, Clearance Office, 395-3772.

DAVID R. LEUTHOLD,
Budget and Management Officer.
[FR Doc. 78-21089 Filed 7-27-78; 8:45 am]

[8025-01]
SMALL BUSINESS ADMINISTRATION
(Proposal No. 05/05-0130)

FEDERATED CAPITAL CORPORATION

Application for a License as a Small Business Investment Company

Notice is hereby given of the filing of an application with the Small Business Administration (SBA) pursuant to § 107.102 of the SBA regulations (13 CFR 107.102 (1977)) by Federated Capital Corp., 20000 West 12 Mile Road, Southfield, Mich. 48076 for a license to operate as a small business investment company (SBIC) under the provisions of the Small Business Investment Act of 1958 (the act), as amended (15 U.S.C. 661 et seq.).

The proposed officers, directors, and shareholders are:

Name and Address, Title and Relationship

Louis P. Ferris, Jr., president, treasurer, and director, percent of ownership, none, 7031 Warren Road, Ann Arbor, Mich. 48105.

Peter P. McNeil, Deputy Associate Administrator for Investment.

[FR Doc. 78-20875 Filed 7-27-78; 8:45 am]

[8025-01]

ILLINOIS
Declaradion of Disaster Loan Area

St. Clair County and adjacent counties within the State of Illinois constitute a disaster area as a result of damage caused by flooding which occurred on March 25, 1978, through April 30, 1978. Eligible persons, firms, and organizations may file applications for loans for physical damage until the close of business on September 18, 1978, and for economic injury until the close of business on April 19, 1979, at:

Small Business Administration, Branch Office, Illinois National Bank Building, One North Old State Capitol Plaza, Springfield, Ill. 62701.


PATTY M. CLOHERTY,
Acting Administrator.

[FR Doc. 78-20873 Filed 7-27-78; 8:45 am]

[Declaration of Disaster Loan Area No. 16941]

MISSOURI
Declaradion of Disaster Loan Area

St. Louis County and adjacent counties within the State of Missouri constitute a disaster area as a result of damage caused by heavy rains and flooding which occurred on July 14 and 15, 1978. Eligible persons, firms, and organizations may file applications for loans for physical damage until the close of business on September 21, 1978, and for economic injury until the close of business on April 23, 1979, at:

Small Business Administration, District Office, Suite 5500, Mercantile Tower, Mercantile Center, St. Louis, Mo. 63101.

or other locally announced locations.


A. VERNON WEAVER,
Administrator.

[FR Doc. 78-20874 Filed 7-27-78; 8:45 am]

[4710-07]
DEPARTMENT OF STATE

SHIPPING COORDINATING COMMITTEE

SUBCOMMITTEE ON SAFETY OF LIFE AT SEA
Notice of Meeting

The Working Group on Radiocommunications of the Shipping Coordinating Committee’s Subcommittee on Safety of Life at Sea (SOLAS) will conduct an open meeting at 1:30 p.m. on Thursday, August 17, 1978 in room 8442 of the Department of Transportation, 400 Seventh Street SW., Washington, D.C.

The purpose of the meeting is to prepare position documents for the nineteenth session of the Subcommittee on Radiocommunications of the Intergovernmental Maritime Consultative Organization (IMCO), to be held in London September 4-8, 1978. In particular, the SOLAS Working Group will discuss the following topics:

- Code of safety requirements for mobile offshore drilling units;
- Operational standards for shipboard radio equipment;
- Revision of Resolution A.283 (VIII Maritime Distress System).

Requests for further information should be directed to Lt. R. F. Carlson, U.S. Coast Guard (G/OTM/74), Washington, D.C. 20590, telephone 202-426-1345.

The Chairman will entertain comments from the public as time permits.

CARL TAYLOR, Jr.
Acting Director, Shipping Coordinating Committee.

[FR Doc. 78-20916 Filed 7-27-78; 8:45 am]
NOTICES

[4710-07]

[CM-8/81]

STUDY GROUP 5 OF THE U.S. ORGANIZATION FOR THE INTERNATIONAL RADIO CONSULTATIVE COMMITTEE (CCIR)

Notice of Meeting

The Department of State announces that Study Group 5 of the U.S. Organization for the International Radio Consultative Committee (CCIR) will meet on August 22, 1978, from 9:30 a.m. until 12 noon in Conference Room 3 of the Automation Industries Inc.-VITRO Labs, 2361 South Jefferson Davis Highway, Arlington, Va.

Study Group 5 deals with propagation of radio waves (including radio-noise) at the surface of the Earth, through the nonionized regions of the Earth's atmosphere, and in space where the effect of ionization is negligible. The purpose of the meeting is preparation for the Special Preparatory Meeting for the 1979 World Administrative Radio Conference.

Members of the general public may attend the meeting and join in the discussions subject to instructions of the Chairman.

Requests for further information should be directed to G. Huffcutt, State Department, Washington, D.C. 20520, telephone 202-632-2592.


RICHARD E. SHROM,
Acting Director, Office of International Communications Policy.

[FR Doc. 78-20917 Filed 7-27-78; 8:45 am]

[4710-07]

[CM-8/82]

SHIPPING COORDINATING COMMITTEE

SUBCOMMITTEE ON SAFETY AT SEA

Notice of Meeting

The Working Group on Fire Protection of the Shipping Coordinating Committee's Subcommittee on Safety of Life at Sea (SOLAS) will conduct an open meeting at 9:30 a.m. on Wednesday, September 13, 1978, in Room 8236 of the Department of Transportation, 400 Seventh Street SW., Washington, D.C.

The purpose of the meeting is to: Review the outcome of the 21st session (January 23-27, 1978); prepare documents for submittal to the 22nd session of IMCO Subcommittee on Fire Protection; review recently submitted documents by other delegations to determine if a response is appropriate or required; discuss Ro/Re fire safety; discuss future concepts for fire protection of machinery spaces; discuss improvements to Chapter II-2 of SOLAS 1974.

Requests for further information should be directed to Mr. Daniel F. Sheehan, U.S. Coast Guard (B-NMT-4/62), Washington, D.C. 20590, telephone (202) 425-2197.

The chairman will entertain comments from the public as time permits.

CARL TAYLOR, Jr.,
Acting Director,
Shipping Coordinating Committee.

[FR Doc. 78-20918 Filed 7-27-78; 8:45 am]

DEPARTMENT OF THE TREASURY

Internal Revenue Service

DEPARTMENT OF LABOR

Pension and Welfare Benefit Programs

[Prohibited Transaction Exemption 78-11]

LEO F. QUINN, P.A. PROFIT SHARING TRUST

Grant of Individual Exemption

AGENCIES: Department of the Treasury/Internal Revenue Service, Department of Labor.

ACTION: Grant of individual exemption.

SUMMARY: This exemption enables the Leo F. Quinn, P.A. Profit Sharing Trust (the Trust) to sell certain trust assets to Drs. Jacob L. Raney, Charles G. Dalbey and Leo F. Quinn, who are officers, directors, 10 percent or more shareholders and highly compensated employees of Leo F. Quinn, P.A. (the Employer).

FOR FURTHER INFORMATION CONTACT:

Timothy Smith of the Prohibited Transactions Staff of the Employee Plans Division, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, D.C. 20224 (Attention: EEP-P1-1) (202-566-6761). This is not a toll free number.

SUPPLEMENTARY INFORMATION:

On April 25, 1978, notice was published in the Federal Register (43 FR 17561) of the pendency before the Internal Revenue Service and the Department of Labor (the Agencies) of an exemption from the taxes imposed by section 4975 (a) and (b) of the Internal Revenue Code of 1954 (the Code), by reason of section 4975(c)(1) (A), (D) and (E) of the Code and from the provisions of sections 406(a)(1) (A) and (D), 406(b)(1) and 406(b)(2) of the Employee Retirement Income Security Act of 1974 (the Act), for a transaction described in an application submitted by the Employer and the trustees of the Trust. The notice set forth a summary of the facts and representations contained in the application for exemption and referred interested persons to the application for a complete statement of the facts and representations. The application has been available for public inspection at the Agencies in Washington, D.C. The notice also invited interested persons to submit comments on the requested exemption to the Internal Revenue Service (the Service). In addition, the notice stated that any interested person might submit a written request that a hearing be held relating to this exemption. No public comments and no requests for a hearing were received by the Service.

FEDERAL REGISTER, VOL. 43, NO. 146—FRIDAY, JULY 28, 1978
NOTICES

GENERAL INFORMATION

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption granted under section 4975(c)(2) of the Code and section 408(a) of the act does not relieve a fiduciary or party in interest or disqualified person with respect to a plan to which the exemption is applicable from certain other provisions of the Code and the act. These provisions include any prohibited transaction provisions to which the exemption does not apply and the general fiduciary responsibility provisions of section 404 of the act, which among other things require a fiduciary to discharge his duties respecting the plan solely in the interests of the participants and beneficiaries of the plan and in a prudent fashion in accordance with subsection (a)(1)(B) of section 404 of the act, nor are they designed to provide a safe harbor for transactions which are not prohibited transactions. Accordingly, the following exemption is subject to the express conditions that the material facts and representations contained in the application are true and complete and that the application accurately describes all material terms of the transaction consummated pursuant to the exemption.

Signed at Washington, D.C., this 24th day of July 1978.

IAN D. LANOFF,
Administrator for Pension and Welfare Benefit Programs,
Labor-Management Services Administration,
U.S. Department of Labor.

FRED J. OCHS,
Director, Employee Plans Division,
Internal Revenue Service.

1978-20924 Filed 7-27-78; 8:45 am

DEPARTMENT OF THE TREASURY
Customs Service

BICYCLE TIRES AND TUBES FROM THE REPUBLIC OF KOREA

Preliminary Countervailing Duty Determination

AGENCY: U.S. Customs Service, Treasury Department.

ACTION: Preliminary Countervailing Duty Determination.

SUMMARY: This notice is to inform the public that a countervailing duty investigation has resulted in a preliminary determination that the Government of the Republic of Korea has given benefits which are considered to be bounties or grants on the manufacture, production, or sale of bicycle tires and tubes constituting the payment or bestowal of a bounty or grant within the meaning of section 303, Tariff Act of 1930 as amended (19 U.S.C. 1592).

For purposes of this notice the term "bicycle tires and tubes" means pneumatic bicycle tires, and tubes, of rubber or plastic, whether such tires and tubes are sold together as units or separately. Bicycle tires and tubes are covered under items 718.45 and 772.57, respectively, of the Tariff Schedules of the United States (TSUS).

Based upon the information received thus far, pursuant to an investigation conducted under § 159.47(c) of the Customs Regulations (19 CFR 159.47(c)), there appear to be three programs that are utilized by Korean firms exporting bicycle tires and tubes to the United States which constitute bounties or grants within the meaning of the law. However, only one of the three firms exporting to the United States, Korea Inoue Kasel, receives benefits from these programs that in the aggregate exceed what we have in the past regarded as a de minimis amount. The aggregate benefits received by Inoue were 0.50 percent ad valorem. Whether this is to be treated as de minimis in relation to the size of the regular duty or other criteria will be considered in connection with the final determination. The aggregate benefits received by the other two companies exporting to the United States, Dae Young Tire & Rubber Co., Ltd., and Hung-A Industrial Co., Ltd., were 0.31 and 0.34 percent, respectively, which are de minimis by our existing standards.

The three countervailable programs which are taken advantage of by one or all of the companies are as follows:

1. FOREIGN CAPITAL INDUCEMENT LAW

The Foreign Capital Inducement Law (FCIL), which was promulgated on August 3, 1966, has as its purpose the "inducement and protection of foreign capital conducive to the sound economy and the improvement of the international balance of payments." The program provides benefits to companies which are wholly or
Export Financing  Korean exporters  the benefits received were related to dislocation costs. Only submitted to indicate that the benefits relate to dislocation costs. Only one of the three Korean firms exporting to the United States, Inoue, qualified for and took advantage of this program. The benefits received amounted to 0.24 percent ad valoreum. Therefore, this program, in the case of Inoue, has the effect of a subsidy on production that is subject to countervailing because the entirety of Inoue's production is exported.

2. ACCELERATED DEPRECIATION

Article 51 of the Enforcement Decree to the Corporation Tax Law permits a firm earning more than 50 percent of its total proceeds from foreign exchange to increase its normal depreciation by 30 percent. Although two firms in this program, only one, Hung-A, could take advantage of it since the other received benefits under the Foreign Capital Inducement Law. The benefits received by Hung-A, in this instance were equivalent to 0.06 percent ad valoreum on the merchandise imported into the United States.

3. SHORT-TERM PREFERENCE

Pursuant to the “Regulation for Export Financing” Korean exporters are entitled to short-term loans (up to 180 days) at a rate of interest which is normally 8 percent for the purpose of acquiring imported raw materials used in production for export. However, such short-term loans are commercially available only at rates that range from 15 percent to 18 percent. All three firms exporting to the United States took advantage of this program. In no case did the individual company benefit exceed 0.31 percent ad valoreum.

![](image)

There are certain practices of the Korean Government alleged to be beneficial in this case, which do not on their face constitute bounties or grants. They are the following:

1. EXEMPTION FOR EXPORT-ORIENTED BUSINESSES FROM BUSINESS TAX

This tax has been viewed in previous investigations as an indirect tax which is directly related to the product and therefore, pursuant to consistent policy, as upheld in the Zenith case, not a bounty or grant under the law. (Preliminary Countervailing Duty Determination in Footwear from the Republic of Korea, July 3, 1975 (40 FR 21053)).

2. EXEMPTION FROM COMMODITY TAX AND CUSTOMS DUTIES ON IMPORTED MATERIAL

Just as with the Business Tax, both the Commodity Tax and drawback provisions have been viewed as not constituting bounties or grants. (Preliminary Countervailing Duty Determination in Handbags from the Republic of Korea, December 1, 1976 (41 FR 52377)). Furthermore, both the Business Tax and the Commodity Tax were replaced by a Value Added Tax on July 1, 1977, so that the issue is now moot.

3. WASTAGE ALLOWANCE FOR IMPORTED RAW MATERIALS

This program provides what amounts to a drawback on imported raw materials that are used in the production of exported products but which are, in fact, “waste” because they are not actually incorporated in the product. The concept of “wastage allowance” has been determined in previous cases involving Korea to be in conformance with accepted international principles governing drawback. Petitioner has alleged that the wastage allowance is excessive and therefore constitutes a bounty. Although the available information indicates that no excessive wastage allowance was granted to this industry, more information is required before this issue can be resolved definitively. However, in light of past practices this is preliminarily not regarded as a bounty or grant.

There were numerous other programs alleged which conceptually are bounties or grants but which were either not utilized or not available to manufacturers or exporters of bicycle tires and tubes.

These programs are described briefly below:

1. ACCELERATED DEPRECIATION FOR FIRMS LOCATED IN “INDUSTRIAL DEVELOPMENT DISTRICTS”

There is no such “district” in the Republic of Korea, although there are “rural development districts”. However, none of the manufacturers exporting to the United States is located in these districts.

2. MISCELLANEOUS TAX BENEFITS

Publicly-held or government-owned corporations are entitled to certain tax benefits, such as tax-exemption from interest on holdings of stocks and debentures. However, none of the firms exporting to the United States is publicly-held or government-owned. Therefore, none of the companies investigated was eligible to benefit from these miscellaneous tax provisions.

3. INDUSTRIAL ESTATES

The Industrial Estate Management Law, which superseded a similar law December 31, 1977, has as its purpose the encouragement of investment outside of the heavily populated areas of the country. The Government develops the necessary infrastructure on these estates. However, the Korean Government claims that the benefits which flow from being located on these estates, such as low land costs, adequate power and water supplies and good road networks, do not arise from government subsidization but instead from the fact that land values and the cost of basic services in the areas where these industrial estates are located, are lower than in other geographic areas of the country. Only one of the three manufacturers investigated is located on one of these industrial estates and no evidence was received indicating that it received any benefits at non-commercial terms not available to any company locating in that region. Furthermore, the present law, in contrast to the old law, does not require that a company be an exporter to be located on such an estate so that there is no direct export relationship to the provision of infrastructure to companies locating on these estates.

4. FREE EXPORT ZONES

Only one of the companies is located in a Free Export Zone. However, that company utilizes only the drawback provision on imported raw material. It receives no preferential financing as a result of being located in such a zone, nor any other benefits.

5. GOVERNMENT ASSUMPTION OF QUALITY CONTROL ON EXPORTS

Petitioner alleged that the Government assumes the cost of quality control inspections on exported merchandise. The response to the Customs' questionnaire, however, indicates that the bicycle tire and tube manufacturers are fully responsible for the costs of such quality control measures.

6. RAILWAY FREIGHT AND ELECTRIC POWER DISCOUNTS

No manufacturer exporting to the United States utilized rail transportation and all the companies pay standard utility rates. However, more information is needed to determine if utility rates in general might be subsidized by the Government so to confer a bounty or grant on the manufacture of this merchan-
In this preliminary determination, it is concluded that bounties or grants, within the meaning of section 303, are being paid or bestowed, directly or indirectly, upon the manufacture, production, or exportation of bicycle tires and tubes from the Republic of China.

This preliminary determination is published pursuant to section 303(a) of the Tariff Act of 1930, as amended (19 U.S.C. 1303(a)).

Pursuant to Reorganization Plan No. 25 of 1950 and Treasury Department Order 190 Revision 15, March 16, 1978, the provisions of Treasury Department Order No. 165, Revised, November 2, 1954 and §159.47 of the Customs Regulations (19 CFR 159.47), to the extent that they pertain to the issuance of a preliminary countervailing duty determination by the Commissioner of Customs are hereby waived.


Henry C. Stockell, Jr.,
Acting General Counsel of the Treasury.

[FR Doc. 78-20899 Filed 7-27-78; 8:45 am]
NOTICES

32913

Determination in Bicycles from the Republic of China, October 27, 1976
(41 FR 47089.)

2. EXEMPTION FROM COMMODITY TAX AND CUSTOMS DUTIES ON IMPORTED MATERIAL

Consistent with Treasury's long-established practice, drawback of duties on imports incorporated into exports are not regarded as bounties or grants.

3. EXEMPTION OF HARBOR DUES ON IMPORTED RAW MATERIAL

The exemption of harbor dues on imported raw material used in production for export has been determined in prior cases not to be countervailable because the Government's decision to finance harbor facilities by means other than user charges is a legitimate state function that does not confer a bounty to industries which benefit from such facilities. Further, there is no information to show that given sectors of the Taiwanese economy benefit from harbor facilities more than others. This is in contrast to the case of Canadian fish wherein the Government of Canada provided grants for the improvement of wharves and docksides. Thus, it was determined that the harbor facilities were utilized almost exclusively by the fishing industry.

There were numerous other programs alleged which conceptually are bounties or grants but which were either not utilized by or not available to manufacturers or exporters of bicycle tires and tubes. These programs are described briefly below:

1. INCOME TAX HOLIDAYS OR ACCELERATED DEPRECIATION

This provision under the Statute for the Encouragement of Investment provides income-tax holidays or accelerated depreciation for approved firms. However, no manufacturer in the bicycle tire and tube industry utilized this provision during the period investigated and none has received any tax concession under this provision since January of 1974.

2. TAX INCENTIVES FOR SALES PROMOTION ABROAD

This provision allows qualified firms to deduct overseas sales promotion expenses in excess of those permitted by the income tax law. The actual expenses incurred by bicycle tire and tube manufacturers on travel abroad did not exceed the limitation specified by law and therefore no benefit was realized.

3. TAX CEILING FOR HIGH TECHNOLOGY FIRMS

A tax ceiling of 22 percent of taxable income is established for "high technology" firms. However, no manufacturer in this industry qualified as a "high technology" firm.

4. DEFERRED PAYMENT OF LAND INCREMENT TAXES

Bicycle tire and tube manufacturers qualified for installment payments on land increment taxes. However, no benefits were received by any of the companies during the period investigated.

5. MISCELLANEOUS TAX BENEFITS FOR PUBLICLY-LISTED ENTERPRISES

Although bicycle tire and tube manufacturers qualified for various tax benefits related to publicly-held companies, none of the manufacturers received benefits under any of these provisions.

6. TAX BENEFITS FOR FIRMS IN INDUSTRIAL DISTRICTS

For firms located in such districts, an exemption from the deed tax or house tax is granted. Although manufacturers in this industry qualified for benefits, none received any.

EXPORT PROCESSING ZONES

No bicycle tire or tube manufacturers are located in Export Processing Zones. Consequently, no benefits were received.

9. RAILWAY FREIGHT RATES

Although there was no reduction in railway freight rates granted to bicycle tires and tubes for export, no definitive decision can be made on this practice until it is known whether the Government assumes operating costs or provides other subsidies to the railways which would result in a general reduction in railway freight rates.

Accordingly, it is determined preliminarily that bounties or grants, within the meaning of section 205, are being paid or being paid directly or indirectly, upon the manufacture, production or exportation of bicycle tires and tubes from the Republic of China. A final decision in this case is required on or before December 29, 1978.

Before a final determination is made, consideration will be given to any relevant data, views or arguments, submitted in writing with respect to the preliminary determination. Submissions should be addressed to the Commissioner of Customs, 1301 Constitution Avenue NW., Washington, D.C. 20229, in time to be received by him no later than August 28, 1978.

This preliminary determination is published pursuant to section 303(a) of the Tariff Act of 1930, as amended (19 U.S.C. 1303(a)).

Pursuant to Reorganization Plan No. 26 of 1950 and Treasury Department Order 190 Revision 15, March 16, 1978, the provisions of Treasury Department Order No. 165, Revised, November 2, 1954 and §159.47 of the Customs Regulations (19 CFR 159.47), insofar as they pertain to the issuance of a preliminary countervailing duty determination by the Commissioner of Customs are hereby waived.


HENRY G. STOECKEL, JR.,
Acting General Counsel
of the Treasury.

(FR Doc. 78-20900 Filed 7-27-78; 8:45 a.m.)

[4810-25]

Office of the Secretary

USA-JAMAICA TAX TREATY ISSUES

Public Meeting

The Treasury Department today announced that it will hold a public meeting on August 21, 1978, to solicit the views of interested persons regarding issues being considered during negotiations to develop a new income tax treaty between the United States and Jamaica.

The public meeting will be held at the Treasury Department, at 2 p.m., in room 4121. Persons interested in attending are requested to give notice in writing, by August 15, 1978, of their intention to attend. Notices should be addressed to H. David Rosenbloom, International Tax Counsel, Department of the Treasury, Washington, D.C. 20220.

Today's announcement of the August public meeting follows the recent conclusion of a further round of negotiations between representatives of the United States and Jamaica to develop a new income tax treaty for the avoidance of double taxation and the prevention of tax evasion. The income tax treaty presently in effect is an extension of Jamaica of the United States-United Kingdom income tax treaty of 1946.

In the course of the recent negotiations, many subjects of mutual concern were identified and discussed. Among the major issues being considered are: Taxation of corporations organized in one country but managed or controlled in the other country; taxation of dividends, interest, and royalties; the rules relating to permanent establishments; and the taxation of various forms of personal service income.

The Treasury seeks the views of interested persons in regard to these issues, as well as other matters that may have relevance in the context of an income tax treaty between the United States and Jamaica. The August 21 public meeting is being held to provide an opportunity for an exchange of views, as well as for the purpose of discussing the United States
position in regard to the issues presented in the negotiations.


DONALD C. LENIPEK, Assistant Secretary (Tax Policy).

[FR Doc. 78-20901 Filed 7-27-78; 8:45 am]

[4810-25]

USA-BANGLADESH TAX TREATY ISSUES

Request for Public Comments

The Treasury Department today announced that it is soliciting the views of interested persons regarding issues being considered during negotiations to develop an income tax treaty between the United States and Bangladesh.

Persons interested in commenting may do so in writing or they may request a meeting with Treasury officials. Written comments and meeting requests should be addressed to H. David Rosenbloom, International Tax Counsel, Department of the Treasury, Washington, D.C. 20222, by August 15, 1978.

Today's request for comments follows the conclusion of a further round of negotiations between representatives of the United States and Bangladesh to develop an income tax treaty for the avoidance of double taxation and the prevention of tax evasion. There is currently no tax treaty in force between the United States and Bangladesh.

In the course of the recent negotiations, many subjects of mutual concern were identified and discussed. Among the major issues being considered are: Taxation of dividends, interest, and royalties; taxation of rentals of motion picture films; the rules relating to permanent establishments; the treatment of various forms of personal service income; and the treatment of shipping profits. With respect to the taxation of shipping income, the Treasury announced that it is considering a provision that would have the effect of allowing internal law to apply in both countries. The views of interested parties on this matter are particularly sought.

The Treasury seeks the views of interested persons in regard to these issues, as well as any other matters that may have relevance in the context of an income tax treaty between the United States and Bangladesh.


DONALD C. LENIPEK, Assistant Secretary (Tax Policy).

[FR Doc. 78-20902 Filed 7-27-78; 8:45 am]

[4810-22]

STAINLESS STEEL ROUND WIRE FROM JAPAN

Antidumping Proceeding Notice

AGENCY: U.S. Treasury Department.

ACTION: Initiation of antidumping investigation.

SUMMARY: This notice is to advise the public that a petition in proper form has been received and an antidumping investigation is being initiated for the purpose of determining whether imports of stainless steel round wire from Japan are being, or are likely to be, sold at less than fair value within the meaning of the Antidumping Act, 1921, as amended. However, as there appears to be substantial doubt that imports of the subject merchandise at less than fair value are the cause of present, or likely future injury to an industry in the United States, the case is being referred to the U.S. International Trade Commission pursuant to section 201(c)(2) of the act.


FOR FURTHER INFORMATION CONTACT:


SUPPLEMENTARY INFORMATION:


For purposes of this notice, the term "stainless steel round wire" means stainless steel wire, as defined and provided for in item 609.45, Tariff Schedules of the United States.

Price information received from the petitioners tends to indicate that the prices of this merchandise sold for exportation to the United States are less than the prices in the home market. Petitioners' information also tends to indicate that home market sales have been occurring at less than the cost of production under section 201(b) of the act (19 U.S.C. 1615(b)).

There is evidence on record concerning injury to, or the likelihood of injury to, or prevention of establishment of an industry in the retail States. This evidence also indicates, however, that were alleged less than fair value sales of the subject merchandise eliminated, substantial margins of underselling of the domestic industry would still remain. Moreover, sales of fine wire are no lower in 1977 than in 1975. On the basis of such evidence it has been concluded that there is a substantial doubt of injury, or likelihood of injury, to an industry in the United States by virtue of such imports from Japan. Accordingly, the U.S. International Trade Commission is being advised of such doubt pursuant to section 201(c)(2) of the act (19 U.S.C. 160(c)(2)).

Having conducted a summary investigation as required by §163.29 of the Customs Regulations (19 CFR 153.29) and having determined as a result thereof that there are grounds for so doing, the U.S. Customs Service is instituting an inquiry to verify the information submitted and to obtain the facts necessary to reach a determination as to the fact or facts of sales at less than fair value. Should the International Trade Commission, within 30 days of receipt of the information cited in the preceding paragraph, advise the Secretary that there is no reasonable indication that an industry in the United States is being, or is likely to be, injured, or is prevented from being established by reason of the importation of such merchandise into the United States, the Department will publish promptly in the Federal Register a notice terminating the investigation. Otherwise, the investigation will continue to conclude.

This notice is published pursuant to §153.30 of the Customs regulations (19 CFR 153.30).

HENRY C. STOCKELL, JR.,
Acting General Counsel
of the Treasury.


[F.R. Doc. 78-20903 Filed 7-27-78; 8:45 am]
(4810-22)

VISCOSE RAYON STAPLE FIBER FROM BELGIUM

Anti-dumping; Modification of Determination of Sales at Less Than Fair Value

AGENCY: U.S. Treasury Department.

ACTION: Modification of determination of sales at less than fair value.

SUMMARY: This notice is to advise the public that the "Determination of Sales at Less Than Fair Value" under the Anti-dumping Act, 1921, as amended, on viscose rayon staple fiber from Belgium has been reconsidered. The determination is being modified to reflect the results of this reconsideration.


FOR FURTHER INFORMATION CONTACT:

SUPPLEMENTARY INFORMATION: On May 1, 1978, a "Determination of Sales at Less Than Fair Value" was published in the Federal Register (43 FR 18619-20). That notice states:

"Following publication of the Tentative Determination, an additional claim was made that Fabelta's home market sales had been made at less than the cost of producing the merchandise, invoicing section 205(b) of the act (19 U.S.C. 1673(b)). This allegation is currently being investigated. Should this investigation establish that some or all home market sales must be disregarded and that another basis (i.e., third country sales prices or constructed value) for determining fair value must be used, the new basis will be published and we will immediately advise the U.S. International Trade Commission of any revised LTFV margins for its consideration."

Information requested from Fabelta with respect to the cost of production of this merchandise and the prices charged by Fabelta in sales to third countries has not been received. It has therefore been concluded that a determination whether such home market sales have occurred at less than the cost of production must be made based upon the best evidence otherwise available to the Treasury Department.

The best available evidence to us of the cost of production of this merchandise in Belgium is primarily drawn from information concerning the cost of production of this merchandise by members of the American rayon staple fiber industry, with adjustments for ascertainable differences in costs of materials and direct production labor, between the United States and Western Europe, as corroborated by information from a number of sources including the Bureau of Labor Statistics and European companies affiliated with domestic producers of this merchandise.

Modified determination is being published and we will immediately advise the public that the "Determination of Sales at Less Than Fair Value" under the Act (19 U.S.C. 1673(d)).


HARRY C. STOCKELL, JR.,
Acting General Counsel of the Treasury.

[FR Doc. 78-20994 Filed 7-27-78; 8:45 am]

(FEDERAL REGISTER, VOL 43, NO. 145—FRIDAY, JULY 28, 1978)

NOTICES

The U.S. International Trade Commission is being advised of this determination.

This determination is being published pursuant to section 201(d) of the act (19 U.S.C. 160(d)).
Order. Any questions arising from this review as to the legality of such activities shall be referred by the Inspector General to the General Counsel. In connection with the activities of the OASIA representatives stationed overseas, the Inspector General shall seek to make appropriate arrangements with the State Department to provide for adequate inspection while avoiding duplication of inspection activities by the State and Treasury Department.

6. The inspection service within a bureau shall review at appropriate intervals the activities of the bureau in its relations with U.S. foreign intelligence agencies to determine whether such activities raise questions of legality or propriety. Any questions of legality or propriety arising from this review shall be referred to the Inspector General who shall report to the General Counsel any illegal activities. The procedures established by Treasury Department Order No. 240 (Revision 1), which provides for coordination and report arrangements between the Treasury Department and U.S. foreign intelligence agencies, shall remain in full force and effect.

7. Treasury Department employees shall cooperate with the Inspector General, the General Counsel, and the inspection service within their bureau and shall make available all necessary data to allow those officials to perform their duties and responsibilities under this Order.

8. Treasury Department Order No. 246 is rescinded, effective this date.


W. MICHAEL BLUMENTHAL, Secretary of the Treasury.

[FR Doc. 78-20876 Filed 7-27-78; 8:45 am]

[4810-25]

[Establishment of the Position of Inspector General]

Pursuant to the authority vested in me as Secretary of the Treasury by Reorganization Plan No. 26 of 1950, there is hereby established the position of Inspector General reporting directly to the Secretary and Deputy Secretary. The Inspector General is authorized to perform the following duties:

1. Receive and analyze allegations of (i) illegal acts, (ii) violations of the Rules of Conduct of the Treasury Department or Bureaus, (iii) violations of the merit system or (iv) any other misconduct (if the matter is one which is not appropriate for normal grievance or appeal procedure or other routine management action) concerning any official or employee of any Treasury office or Bureau.

2. Receive by referral from head of Treasury offices or Bureaus serious allegations of official or employee misconduct which the Treasury office or Bureau does not want to investigate using its own staff.

3. With regard to senior Treasury and Bureau officials:
   a. Initiate, organize, direct, and control investigations of any allegations received pursuant to paragraphs 1 or 2 against such officials which have potential validity and which, within the discretion of the Inspector General, merit such action, and,
   b. Review and report the results of investigations of senior officials conducted by the Inspector General to the General Counsel. In no case, however, shall the Inspector General review or be involved in the conduct of investigations of any allegations received pursuant to paragraphs 1 or 2 against such officials.

4. Refer allegations of misconduct to any nonsenior official or employee of a Treasury office or Bureau that does not have an inspection service within Treasury for investigation and receive a full report of the results of such investigation.

5. Refer any complaints concerning improper action of a nonsenior official or employee of a Treasury office or Bureau that has an inspection service to that service to receive a full report of the results of such investigation.

6. Conduct in exceptional situations such investigations as may be specifically directed by the Secretary or Deputy Secretary concerning any allegations or misconduct by an official or employee of any Treasury office or Bureau.

7. Review existing policies, procedures and operations for ascertaining, reporting and investigating misconduct of officials and employees of any Treasury office or Bureau and, after consulting with other Treasury officials as may be appropriate, make recommendations to the Secretary or Deputy Secretary for their change or implementation.

8. Carry out those duties and functions set forth in Treasury Department Order No. 246 (Rev.) which are required of the Department under Executive Order 12036 and relate to the oversight of foreign intelligence activities in Treasury.

9. Obtain, as needed, under prescribed procedures developed pursuant to paragraph 10, investigative and other support personnel from Inspection services within Treasury for conducting investigations under his or her direct supervision, any such detailed personnel to remain on the rolls of the services from which they are detailed but to report exclusively to the Inspector General as to the matter being investigated.

10. Develop detailed procedures and definitions for approval by the Deputy Secretary and Secretary which shall become a part of this Order.

This Order does not change or reduce the authority presently existing in Treasury offices or Bureaus having Inspection services to conduct their own investigations in accordance with their procedures with the exception of investigations being conducted by the Inspector General. Where notice is received by a Treasury office or Bureau from the Inspector General that he or she is conducting an investigation in a particular area, no investigation or similar activity will be initiated or continued in that area by any Treasury office or Bureau except with the approval of the Inspector General.


W. MICHAEL BLUMENTHAL, Secretary of the Treasury.

[FR Doc. 78-20976 Filed 7-27-78; 8:45 am]

[7035-01]

INTERSTATE COMMERCE COMMISSION

[Notice No. 687]

Assignment of Hearings


Cases assigned for hearing, postponement, cancellation, or oral argument appear below and will be published only once. This list contains prospective assignments only and does not include cases previously assigned hearing dates. The hearings will be on the issues as presently reflected in the official docket of the Commission. An attempt will be made to publish notices of cancellation of hearings as promptly as possible, but interested parties should take appropriate steps to insure that they are notified of cancellation or postponements of hearings in which they are interested.

MC 105993 (Sub-914), Morgan Drive-Away, Inc., now assigned September 28, 1978, at Little Rock, AR, is canceled and transferred to modified procedure.

MC 94201 (Sub-157), Bowman Transportation, Inc., is now assigned for hearing November 29, 1978 (2 weeks) at New Orleans, LA, at a location to be later designated.

MC-F 13400, Overnite Transportation Co.—purchase—St. Louis-Kansas City Express, Inc., is now assigned for hearing October 16, 1978 (1 week) at St. Louis, MO, at a location to be later designated.

MC 11211 (Sub-184), Western Transport, Inc., now assigned September 27, 1978, at Little Rock, AR, will be held in room 3412, Federal Office Building, 700 West Capitol Street.

MC 111231 (Sub-221), Jones Truck Lines, Inc., now assigned October 2, 1978, at Little Rock, AR, will be held in room 3412, Federal Office Building, 700 West Capitol Street.

MC 141804 (Sub-100P), Western Express, Division of Interstate Rental, Inc., is now assigned February 24, 1979.
assigned for hearing September 20, 1978 (1 day) at Los Angeles, CA, at a location to be later designated.  
MC 381284 (Sub-97), Western Express, Division of Interstate Rental Inc., is now assigned for hearing September 21, 1978 (2 days) at Los Angeles, CA, at a location to be later designated.  
MC 82492 (Sub-173), Michigan & Nebraska Transit Co., Inc., now assigned September 6, 1978, at Columbus, OH, is canceled and transferred to modified procedure.  
MC 110841 (Sub-577), Colonial Refrigerated Transportation, Inc., now assigned September 9, 1978, at Nashville, TN, is canceled; application dismissed.  

H. G. Homme, Jr., Acting Secretary.  
(F.R Doc. 78-20945 Filed 7-27-78; 8:45 am)  

[7035-01]  

(Rule 15; Ex Parte No. 241; Forty-Seventh Rev. Exemption No. 90)  

ABERDEEN AND ROCKFISH RAILROAD CO. ET AL  

Exemption Under Provision of Mandatory Car Service Rules.  

It appearing, that certain of the railroads named below own more than 50-ft. plain boxcars; that under present conditions, there are substantial surpluses of these cars on their lines; that return of these cars to the owners would result in their being stored idle; that such cars can be used by other carriers for transporting traffic offered for shipments to points remote from the car owners; and that compliance with Car Service Rules 1 and 2 prevents such use of these cars, resulting in unnecessary loss of utilization of such cars; and  

It further appearing, that there are substantial shortages of 50-ft. plain boxcars throughout the country; that the carriers identified in this exemption by the symbol (%) have 150% or more of their ownership of these cars on their lines; and that such a disproportionate use of the total supply of such cars causes shippers served by other lines to be deprived of their proper share of such cars.  

It is ordered, That, pursuant to the authority vested in me by Car Service Rule 19, plain boxcars described in the Official Railway Equipment Register, I.C.C.-R.E.R. No. 407, issued by W. J. Trehise, or successive issues thereof, as having mechanical designation "XM", and bearing reporting marks assigned to the railroads named below, shall be exempt from provisions of Car Service Rules 1, 2(a), and 2(b).  

Aberdeen and Rockfish Railroad Co.  

Reporting Marks: AR  
% The Baltimore & Ohio Railroad Co.  
Reporting Marks: B&O  
% Bessemer & Lake Erie Railroad Co.  

% Carriers having 150% or more of ownership on lines.  

NOTICES  

Effective July 15, 1978, and continuing in effect until further order of this Commission.  

INTERSTATE COMMERCE COMMISSION  

ROBERT S. TURINGTON,  
Agent.  

(F.R Doc. 78-20946 Filed 7-27-78; 8:45 am)  

[7035-01]  

(Rule 19; Ex Parte No. 241, Twenty-first Rev. Exemption No. 241)  

ATLANTA & SAINT ANDREWS BAY RAILROAD CO., ET AL  

Exemption Under Provision of Mandatory Car Service Rules.  

It appearing, that the railroads named herein own numerous 40-ft. plain boxcars; that under present conditions, there is virtually no demand for these cars on the lines of the car owners; that return of these cars to the car owners would result in their being stored idle on these lines; that such cars can be used by other carriers for transporting traffic offered for shipments to points remote from the car owners; and that compliance with Car Service Rules 1 and 2 prevents such use of plain boxcars owned by the railroads listed herein, resulting in unnecessary loss of utilization of such cars.  

It is ordered, That, pursuant to the authority vested in me by Car Service Rule 19, plain boxcars described in the Official Railway Equipment Register, I.C.C.-R.E.R. No. 407, issued by W. J. Trehise, or successive issues thereof, as having mechanical designation “XM”, with inside length 44-ft. 6-in. or less, regardless of door width and bearing reporting marks assigned to the railroads named below, shall be exempt from the provisions of Car Service Rules 1(a), 2(a), and 2(b).  

Atlanta & Saint Andrews Bay Railroad Co.  

Reporting Marks: ASAB  
Chicago, West Pullman & Southern Railroad Co.  

Reporting Marks: CWP  
Detroit and Mackinaw Railway Co.  

Reporting Marks: D&M-DM  
Illinois Terminal Railroad Co.  

Reporting Marks: ITC  
Louisville, New Albany & Corydon Railroad Co.  

Reporting Marks: LACD  

Effective 12:01 a.m. July 15, 1978, and continuing in effect until further order of this Commission.  

1Addition.  
2Addition.  
3Municipality of East Troy, Wis. deleted.
NOTICES

**Interstate Commerce Commission**

Robert S. Turkington,
Agent.

[FR Doc. 78-20954 Filed 7-27-78; 8:45 am]

[7035-01]

[Exception No. 4 to Corrected Second Rev. S.O. No. 1309]

**BURLINGTON NORTHERN INC.**

Decision


By ICC Order No. 64 under Revised Service Order No. 1252 CP Rail is authorized to reroute certain traffic it is unable to handle over its line between Fort Steele, British Columbia, and Beaverdell, British Columbia, subject to the concurrence of the receiving line. One such route selected is via the line of the Burlington Northern Inc., between Sand Point, Idaho, and Sweetgrass, Montana, thence via CP Rail beyond those points. Because of limited siding capacity and limited availability of motive power on these lines the BN agreed to accept only specified volumes of rerouted traffic from CP Rail for movement over this route. Through inadvertence CP Rail, on July 18 and 19, 1978, delivered substantially more rerouted traffic to BN for movement between these points than the BN had agreed to accept and was able to move within the time period established by Section (a)(4) of Corrected Second Revised Service Order No. 1309.

It is ordered, Pursuant to the authority vested in the Railroad Service Board by Section (a)(1)(v) of Corrected Second Revised Service Order No. 1309, the Burlington Northern Inc. (BN) is directed to forward traffic rerouted by CP Rail over the BN's lines between Sand Point, Idaho, and Sweetgrass, Montana, within ninety-six (96) hours regardless of the provisions of Section (a)(4) of the order.

By the Railroad Service Board, members Joel E. Burns, Robert S. Turkington and John R. Michael. Member John R. Michael not participating.


H. G. Homme, Jr., Acting Secretary.

[FR Doc. 78-20954 Filed 7-27-78; 8:45 am]

[7035-01]

**CHESAPEAKE AND OHIO RAILWAY CO.**

Rerouting or Diversion of Traffic

In the opinion of Robert S. Turkington, Agent, The Chesapeake and Ohio Railway Company is unable to transport promptly all traffic offered for movement through Bishop Yard at Buffalo, New York, because of a strike.

It is ordered,

(a) Rerouting traffic. The Chesapeake and Ohio Railway Company being unable to transport promptly all traffic offered for movement through Bishop Yard at Buffalo, New York, because of a strike, that line is authorized to divert or reroute such traffic via any available route to expedite the movement. Traffic necessarily diverted by authority of this order shall be rerouted so as to preserve as nearly as possible the participation and revenues of other carriers provided in the original routing.

(b) Concourse of receiving roads to be obtained. The railroad rerouting cars in accordance with this order shall receive the concurrence of other railroads to which such traffic is to be diverted or rerouted, before the rerouting or diversion is ordered.

(c) Notification to shippers. Each car utilizing cars in accordance with this order, shall notify each shipper at the time each shipment is rerouted or diverted and shall furnish to such shipper the new routing provided under this order.

(d) Inasmuch as the diversion or rerouting of traffic is deemed to be due to carrier disability, the rates applicable to traffic diverted or rerouted are subject to Section (a)(4) of this order, shall be the rates which were applicable at the time of shipments as originally routed.

(e) In executing the directions of the Commission and of such Agent provided for in this order, the common carriers involved shall proceed even though no contracts, agreements, or arrangements now exist between them with reference to the divisions of the rates of transportation applicable to traffic diverted or rerouted. During the time this order remains in force, the rates applicable to such traffic diverted or rerouted shall be those voluntarily agreed upon by and between said carriers; or, upon failure of the carriers to so agree, said divisions shall be those hereafter fixed by the Commission in accordance with pertinent authority conferred upon it by the Interstate Commerce Act.

(f) Effective date. This order shall become effective at 3 p.m., July 12, 1978.

Expiration date. This order shall exipre at 11:59 p.m., July 31, 1978, unless otherwise modified, changed, or suspended.

This order shall be served upon the Association of American Railroads, Car Service Division, as agent of all railroads subscribing to the car service and car hire agreement under the terms of that agreement, and upon the Association of American Line Railroad Association. A copy of this order shall be filed with the Director, Office of the Federal Register.


**Interstate Commerce Commission**

Robert S. Turkington,
Agent.

[FR Doc. 78-20952 Filed 7-27-78; 8:45 am]

[7035-01]

**CP RAIL**

Rerouting or Diversion of Traffic

In the opinion of Robert S. Turkington, Agent, CP Rail is unable to transport promptly all traffic offered for movement between Sand Point, Idaho, and Presque Isle, Maine, because of a washout.

It is ordered,

(a) Rerouting traffic. CP Rail being unable to transport promptly all traffic offered for movement over its lines between Brownsville Junction, Maine, and Presque Isle, Maine, because of a washout, that line is authorized to divert or reroute such traffic via any available route to expedite the movement. Traffic necessarily diverted by authority of this order shall be rerouted so as to preserve as nearly as possible the participation and revenues of other carriers provided in the original routing.

(b) Concourse of receiving roads to be obtained. The railroad rerouting cars in accordance with this order shall receive the concurrence of other railroads to which such traffic is to be diverted or rerouted, before the rerouting or diversion is ordered.

(c) Notification to shippers. Each carrier rerouting cars in accordance with this order, shall notify each shipper at the time each shipment is rerouted or diverted and shall furnish to such shipper the new routing provided under this order.

(d) Inasmuch as the diversion or rerouting of traffic is deemed to be due to carrier disability, the rates applicable to traffic diverted or rerouted shall be those which were applicable at the time of shipments as originally routed.

(e) In executing the directions of the Commission and of such Agent provided for in this order, the common carriers involved shall proceed even though no contracts, agreements, or arrangements now exist between them with reference to the divisions of the rates of transportation applicable to traffic diverted or rerouted. During the time this order remains in force, the rates applicable to such traffic diverted or rerouted shall be those voluntarily agreed upon by and between said carriers; or, upon failure of the carriers to so agree, said divisions shall be those hereafter fixed by the Commission in accordance with pertinent authority conferred upon it by the Interstate Commerce Act.

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The following publications include motor carrier, water carrier, broker, and freight forwarder transfer applications filed under sections 212(b), 206(a), 211, 312(b), and 410(g) of the Interstate Commerce Act. Each application (except as otherwise specifically noted) contains a statement by applicants that there will be no significant effect on the quality of the human environment resulting from approval of the application.

Protest against approval of the application, which may include a request for oral hearing, must be filed with the Commission on or before August 28, 1978. Failure seasonably to file a protest will be construed as a waiver of opposition and participation in the proceeding. A protest must be served upon applicants' representative(s), or applicants (if no such representative is named), and the protestant must certify that such service has been made.

Unless otherwise specified, the signed original and six copies of the protest shall be filed with the Commission. All protests must specify with particularity the factual basis, and the section of the act, or the applicable rule governing the proposed transfer which protestant believes would preclude approval of the application. If the protest contains a request for oral hearing, the request shall be supported by an explanation as to why the evidence sought to be presented cannot reasonably be submitted through the use of affidavits.

The operating rights set forth below are in synopses form, but are deemed sufficient to place interested persons on notice of the proposed transfer.


NOTICES
32919

FEDERAL REGISTER, VOL. 43, NO. 146—FRIDAY, JULY 28, 1978

INTERSTATE COMMERCE COMMISSION, ROBERT S. TURKINGTON, Agent.

[FDR Doc. 78-20953 Filed 7-27-78; 8:45 am]

[7035-01]

[Notice No. 911]

MOTOR CARRIER BOARD TRANSFER PROCEEDINGS

The following publications include motor carrier, water carrier, broker, and freight forwarder transfer applications filed under sections 212(b), 206(a), 211, 312(b), and 410(g) of the Interstate Commerce Act.

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The operating rights set forth below are in synopses form, but are deemed sufficient to place interested persons on notice of the proposed transfer.

W-417) to control the said rights through ownership of capital stock. The operating rights, as set forth in Permit No. W-353, issued to Ingram Corp., as latest amended on April 1, 1969, authorize the transferor, as set forth in certificate, to contract carrier towage service over the Mississippi River below and including Geno, WI, the Ohio River below and including Louisville, KY, and the Gulf Intracoastal Waterway and its tributaries east of and including Houston, TX. In addition, the Permit authorizes transferor to engage, at Nashville, TN, in the furnishing of towing vessels and barges without crew, owned by it, to persons other than carriers to be used by them in the transportation of their own property. Transferee presently holds no authority from this Commission.

35478 filed, June 21, 1978. Lessee: AG TRUCKING, R.R. 1 Box 206, Milford, IN 46042. Lessor: Hoosier Haulers, Inc., Company P.O. Box 38, Route 3, Goshen, IN 46528. Representative: Gregory A. Hartzler, 130 North Main Street, Goshen, IN 46528. Authority sought for lease by lessee of the operating rights, acquired by lessor pursuant to certificate filed, June 21, 1978, as set forth in certificates: MC-13367 (Sub-2), MC-13367 (Sub-4), MC-13367 (Sub-5), MC-13367 (Sub-6), MC-13367 (Sub-7), MC-13367 (Sub-8), MC-13367 (Sub-9), and MC-13367 (Sub-13), issued August 10, 1961, May 11, 1962, October 24, 1962, May 10, 1963, May 1, 1969, March 11, 1984, October 2, 1984, and October 7, 1989, respectively, as follows: Meat scraps, tankage, and dried blood, from points in IL and IN (except from Blockson Corp., to points in OH) and, on an unnumbered county road, on the one hand, and, on the other, points in the United States, except AK and HI; Returned shipments of new furnitures, and equipment, materials, and supplies, used in the manufacture and distribution of furnitures, except commodities in bulk, from points in the United States, except AK and HI, to the auction yard of Yoder & Frey, Inc., auction yard, located near Archbold, OH, on the one hand, and, on the other, points in AR, IA, KY, MI, MO, NY, NC, TN, and WV; Agricultural machinery, implements, and parts, as described in Appendix XII to the report on Descriptions in Motor Carrier Certificates, as set forth in certificate filed, June 2, 1969, as set forth in certificates, 61 MOC-200, except those requiring the use of special equipment, between the site of the Yoder & Frey, Inc., auction yard, located near Archbold, OH, on the one hand, and, on the other, points in AR, IA, KY, MI, MO, NY, NC, TN, and WV; Furniture parts and furnitures, and parts, as described in Appendix XII to the report on Descriptions in Motor Carrier Certificates, as set forth in certificate filed, June 2, 1969, as set forth in certificates, 61 MOC-200, except those requiring the use of special equipment, between the site of the Yoder & Frey, Inc., auction yard, located near Archbold, OH, on the one hand, and, on the other, points in AR, IA, KY, MI, MO, NY, NC, TN, and WV; Agricultural machinery, implements, and parts, as described in Appendix XII to the report on Descriptions in Motor Carrier Certificates, as set forth in certificates, 61 MOC-200, except those requiring the use of special equipment, between the site of the Yoder & Frey, Inc., auction yard, located near Archbold, OH, on the one hand, and, on the other, points in AR, IA, KY, MI, MO, NY, NC, TN, and WV; Returned shipments of new furnitures, and equipment, materials, and supplies, used in the manufacture and distribution of furnitures, except commodities in bulk, from points in the United States, except AK and HI; Returned shipments of new furnitures, and equipment, materials, and supplies, used in the manufacture and distribution of furnitures, except commodities in bulk, from points in the United States, except AK and HI, to the auction yard of Yoder & Frey, Inc., auction yard, located near Archbold, OH, on the one hand, and, on the other, points in AR, IA, KY, MI, MO, NY, NC, TN, and WV; Returned shipments of new furnitures, and equipment, materials, and supplies, used in the manufacture and distribution of furnitures, except commodities in bulk, from points in the United States, except AK and HI; Returned shipments of new furnitures, and equipment, materials, and supplies, used in the manufacture and distribution of furnitures, except commodities in bulk, from points in the United States, except AK and HI; Returned shipments of new furnitures, and equipment, materials, and supplies, used in the manufacture and distribution of furnitures, except commodities in bulk, from points in the United States, except AK and HI.
facture and distribution of corrugated sheets, pads, boxes, and related packaging, except commodities in bulk, from points in the states listed immediately above to the facilities of the Archbold Container Corp. at Archbold, OH. Transferee presently holds no authority from this Commission. Application has been filed for temporary authority under section 210a(b).

MC-FC-77659, filed May 12, 1978. Transferee: SUPERIOR TRANSFER, INC., 2269 Merchant Drive, Baltimore, MD 21230. Transferor: Chesapeake Motor Lines, Inc., 6748 Dorsey Road, Baltimore, MD 21227. Representatives: Ronald N. Cobert, Attorney for transferee, 1730 M Street NW, Washington, DC 20036, and Edward N. Button, Attorney for transferor. P.O. Box 1437 Hagerstown, MD 21740. Authority sought to transfer to transferee that portion of Certificate MC-52917, issued June 15, 1968, as follows: General commodities, with specified exceptions, between points in the Los Angeles Basin Area, CA, and points in the St. Louis, MO in the St. Louis Commercial Zone, as defined by the Commission. Transferee presently holds no authority from this Commission. Application has been filed for temporary authority under section 210a(b).

MC-FC-77669, filed June 21, 1978. Transferee: ANTHONY D. FIA-MINGO, d.b.a. FIAMINGO MOVING & STORAGE, P.O. Box 678, Mansfield, PA 16933. Transferor: Seymour Rail Hauling, Inc., 510 Fifth Avenue, Williamsport, PA 17701. Representative: Thomas F. X. Foley, Charts Neck Professional Plaza, State Highway, Atlantic Avenue 31, Atlantic City, NJ 08401. Authority sought for purchase by transferee of the remaining portion of the operating rights of transferor, as set forth in permit MC-141691, issued March 28, 1978, as follows: Pickles and pickle products (except frozen and in bulk), from the facilities of Viscas Foods, Inc., located at Greenville, MS to points in the United States (except MS, AK, and HI), to be performed under a continuing contract or contracts with Viscas Foods, Inc. Transferee presently holds no authority from this Commission. Application has been filed for temporary authority under section 210a(b).

MC-FC-77670, filed June 6, 1978. Transferee: CALIFORNIA-PACIFIC FREIGHT, INC., 1212 Atlon Lane, Santa Ana, CA 92705. Transferor: S & T TRANSPORT, INC., 182-10 One Lefrak City Plaza, Flushing, NY 11412. Representative: Paul M. Daniell, Attorney for transferor, P.O. Box 147, Hagerstown, MD 21740. Authority sought to transfer to transferee that portion of Certificate MC-52917, issued June 15, 1968, as follows: General commodities, with specified exceptions, between points in the Los Angeles Basin Area, CA, and points in the St. Louis, MO in the St. Louis Commercial Zone, as defined by the Commission. Application has been filed for temporary authority under section 210a(b).
NOTICES

FEDERAL REGISTER, VOL. 43, NO. 146—FRIDAY, JULY 28, 1978

INC., 31 Frederick Place, Old Bridge, NJ 08857. Transferor: Bivins Freight Service, Inc., South 15th Street, Millville, NJ 08332. Representative: Piken & Piken, Attorneys-at-Law, One Lefrak City Plaza, Flushing, NY 11368. Authority sought for purchase by transferee of the operating rights of transferor, as set forth in Certificate MC 73618, issued March 20, 1963, as follows: General commodities (with the usual exceptions), over regular routes, between Millville, NJ and Philadelphia, PA, and other specified commodities excepted. Building material, and brick, feed, grain and meat scraps, seed, fertilizer, fertilizer material, airplane engines, airplane engine parts, and airplane accessories, boat building materials, equipment, and supplies, over irregular routes, generally between Millville and other specified cities in NJ and specified cities in NY, MD, PA, DE, and DC. Transferee presently holds no authority from this Commission. Application has not been filed for temporary authority under section 210a(b).

MC-FC-7716, filed June 21, 1978. Transferee: Graham Bell, d.b.a. B & W Trucking, P.O. Box 281, 482 Essex Avenue, Gloucester, MA 01930. Transferor: Roger D. Peterson, d.b.a. Peterson Motor Transportation, 107 Portland Street, Rochester, NH. Representative: George C. O'Brien, Attorney-at-Law, 12 Vernon Street, Northwood, MA 03259. Authority sought for purchase by transferee of a portion of the operating rights set forth in Certificate MC 73618, issued November 18, 1975, as follows: General commodities (with usual exceptions), over regular routes, between Boston, and Haverhill, MA, serving all intermediate and specified and off-route points; radio tubes and supplies and containers for such commodities during the season extending from the 15th of May to the 15th of September, between Salem, MA and Corning, NY serving no intermediate points; over irregular routes, general commodities (with usual exceptions), between Boston, Quincy, Hingham, Milton, and Weymouth, MA; supplies, materials, equipment, and machinery used in the manufacture of lumber and lumber products, between Providence, RI and Boston, MA on the one hand, and, on the other, Rochester, NH; Such merchandise as is dealt in by wholesale, retail, and chain grocery and food business houses, and in connection therewith, equipment, materials, and supplies used in the conduct of such business, between points in Strafford, Rockingham, and Carroll Counties, NH, on the one hand, and, on the other, points in Androscoggin, Cumberland, Oxford, and York Counties, ME; from points in Dover, Portsmouth, and Rochester, NH, to points in a described portion of NH; from Rochester, NH, to Wallum Lake, RI; groceries and grocery supplies, fruit, and vegetables, from Boston MA to Rochester, NH and South Berwick, ME; building materials, from Walpole and Boston, MA and points within 5 miles of Boston, to Rochester; box shooks, from Rollinsford, NH to Gloucester, MA and rejected shipments of box shooks, from Gloucester, MA to Rollinsford, NH; wooden box shooks and sawdust, from Rochester, NH to Willimantic, CT; and metal screws used in the manufacture of wooden boxes, from Willimantic, CT to Rochester, NH. Transferee holds no Commission authority and does not seek section 210a(b) temporary authority.

H. G. Homme, Jr., Acting Secretary.

[Motor Carrier Transfer Proceedings - July 28, 1978 - Application filed for temporary authority under section 210a(b) in connection with transfer application under section 212(b) and transfer rules, 49 C.F.R. Part 1132.]

MC-FC 77551. By application filed July 5, 1978, OIL COUNTRY HAULERS, INC., 15714 Old Beaumont Hwy (U.S. 90), Houston, TX 77049, seeks temporary authority to transfer the operating rights of SHELDON TRUCKING CO., 15714 Old Beaumont Hwy (U.S. 90), Houston, TX 77049, under section 210a(b). The transfer to OIL COUNTRY HAULERS, INC., of the operating rights of SHELDON TRUCKING CO., is presently pending.

MC-FC-77756. By application filed July 12, 1978, C & H BUS LINES, INC., Route 1, Harrison, GA 30535, seeks temporary authority to transfer the operating rights of NATIONAL BUS SERVICE, INC., 746 Wheaton Street, Savannah, GA 31401, under section 210a(b). The transfer to C & H BUS LINES, INC., of the operating rights of NATIONAL BUS SERVICE, INC., is presently pending.

MC-FC-78767. By application filed July 18, 1978, McNULTY TANK LINES DIVISION, McNULTY INDUSTRIES, INC., d.b.a. McNULTY TANK LINES, U.S. Hwy 130, Bridgeport, NJ 08014, seeks temporary authority to transfer the operating rights of SKYLINE TRANSPORT, INC., 1910 Russell Street, Baltimore, MD 21230, under section 210a(b). The transfer to McNULTY TANK LINES DIVISION, McNULTY INDUSTRIES, INC., d.b.a. McNULTY TANK LINES, of the operating rights of SKYLINE TRANSPORT, INC., is presently pending.

By the Commission.

H. G. Homme, Jr., Acting Secretary.

[Notice No. 921]

MOTOR CARRIER TRANSFER PROCEEDINGS

By application filed for temporary authority under section 210a(b) in connection with transfer application under section 212(b) and transfer rules, 49 C.F.R. Part 1132.

By the Commission.

H. G. Homme, Jr., Acting Secretary.

[Notice No. 921]
sunshine act meetings

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government In the Sunshine Act" (Pub. L. 94-459, 5 U.S.C. 552b(e)(3)).

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[6714-01]

3

FEDERAL DEPOSIT INSURANCE CORPORATION.

TIME AND DATE: 10 a.m., August 2, 1978.

PLACE: Room 6135, FDIC Building, 550 17th Street NW., Washington, D.C.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

Applications for Federal deposit insurance: NBD-Portage Bank, a proposed new bank to be located at 6400 South Westnedge Avenue, Portage, Mich., for Federal deposit insurance.

Banco Union de Puerto Rico, a proposed new bank to be located on Igzmao Arzuaga Street, corner of Bernardo Garcia Street, Carolina, Puerto Rico, for Federal deposit insurance.

Applications for Federal deposit insurance and for consent to establish a branch (drive-in facility): Burbank Citizens Bank, a proposed new bank to be located at 333 North Gencats Boulevard, Burbank, Calif., for Federal deposit insurance and for consent to establish a branch (drive-in facility) at 372 East Olive Avenue, Burbank, Calif.

Applications for Federal deposit insurance and for consent to exercise limited trust powers:

First Bank & Trust of Carter Lake, a proposed new bank to be located at 1230 Locust Street, Carter Lake, Iowa, for Federal deposit insurance and for consent to exercise limited trust powers.

Applications for consent to establish branches:

Dixie County State Bank, Cross City, Fla., for consent to establish a branch at the northeast corner of State Road 268, south end of the river bridge approach, Unincorporated Area of Dixie County, Fla.

Umatilla State Bank, Umatilla, Fla., for consent to establish a branch on Butler Street (State Road 40) near its intersection with Alto Street, unincorporated Lake County (P.O. Astor), Fla.

The Citizens Bank of Perry, Perry, Fla., for consent to establish a branch in the southwest quadrant of the intersection of Ninth Street East and First Avenue, unincorporated area of Steinhatchee, Taylor County, Fla.

United Mutual Savings Bank, New York, N.Y., for consent to establish a branch at 556 Main Street, Islip (unincorporated area), town of Islip, N.Y.


Application for consent to establish a branch-detached facility:

The Kline State Bank, Kline, Colo., for consent to establish a branch-detached facility on Highway 86, Elizabeth, Colo.

Applications for consent to merge and to establish branches:

Albany Savings Bank, Albany, N.Y., an insured mutual savings bank, for consent to merge under its charter, and with the title of "Unibank," with Brockway Citizens Bank, Brockway, Pa., also an insured State nonmember bank, and for consent to establish the sole office of the latter institution as a branch of Albany Savings Bank.

Brockville Bank & Trust Co., Brockville, Pa., an insured State nonmember bank, for consent to merge under its charter, and with the title of "Unibank," with Brockway Citizens Bank, Brockway, Pa., also an insured State nonmember bank, and for consent to establish the sole office of Brockway Citizens Bank as a branch of the resultant bank.

Farmers Bank & Trust Co., Hanover, Hanover, Pa., an insured State nonmember bank, for consent to merge under its charter, and with the title of "First Bank of Southwest Mississippi," with Bank of McComb, McComb, Miss., also an insured State nonmember bank, for consent to establish Bank of McComb's four offices as branches of the resultant bank; for consent to reestablish its main office location to the present site of the main office of Bank of McComb; and for consent to exercise trust powers.

Recommendations regarding liquidation of a bank's assets acquired by the Corporation in its capacity as receiver, liquidation, or liquidating agent of those assets:

Case No. 43,549-L—Bank of Pleasance, Pleasance, Miss.

Case No. 43,580-L—Franklin National Bank, New York, N.Y.

Case No. 43,584-ND—United States National Bank, San Diego, Calif.

Case No. 43,588-L—First State Bank of Northern California, San Leandro, Calif.

Case No. 43,590-L—American City Bank & Trust Co., National Association, Milwaukee, Wis.

Case No. 43,591-L—The Drovers' National Bank of Chicago, Chicago, Ill.
SUNSHINE ACT MEETINGS

incurred in connection with receivership and liquidation activities:
Schall, Boudreau & Gore, San Diego, Calif., in connection with the receivership of United States National Bank, San Diego, Calif.; Trager & Trager, Fairfield, Conn., in connection with the liquidation of the Monroe Bank & Trust Co., Monroe, Conn.; Sullivan & Worcester, Boston, Mass., in connection with the receivership of Surety Bank & Trust Co., Wakefield, Mass.; Kaye, Scholer, Fierman, Hays & Handler, New York, N.Y., in connection with the liquidation of Franklin National Bank, New York, N.Y.; O'Neill & Baneo, Raco Rey, Puerto Rico, in connection with the liquidation of Banco Credito y Ahorro Ponceno, Ponce, P.R.

Memorandum and resolution proposing certain delegations of authority from the Board of Directors to the Committee on Liquidations, Loans and Purchases of Assets (Case No. 43,386).

Memorandum and resolution proposing the delegation to the General Counsel and the Director of the Division of Liquidation, or their designees, of authority to initiate litigation to which the Corporation will be a party either in its corporate capacity or as receiver of a closed bank.

Memorandum proposing the procurement of new computer equipment.

Memorandums and resolutions proposing that the Liquidators of Banco Economias, San German, Puerto Rico, and Banco Credito y Ahorro Ponceno, Ponce, Puerto Rico, be authorized to convey the properties in connection with the liquidation of the Bank of Wisconsin, Ponce, Puerto Rico, and Banco Credito y Ahorro Ponceno, Ponce, P.R.

DATE AND TIME: Wednesday, August 2, 1978, at 10 a.m.
PLACE: 1325 K Street NW, Washington, D.C.
STATUS: This meeting will be closed to the public.

MATTERS TO BE CONSIDERED:
Audits, compliance, and personnel.

DATE AND TIME: Thursday, August 3, 1978, at 10 a.m.

MATTERS TO BE CONSIDERED:
Sections open to the public:

Setting of Future Meeting Dates
Correction and Approval of Minutes
Advisory Opinion 1978-42
Advisory Opinion 1978-48
Response to Advisory Opinion Request From National Treasury Employees Union
Policy Regarding Transfers to Registered Entities From Unregistered Organizations
Quarterly Management Report
Pending Legislation
Pending Litigation
Appropriations and Budget
Liaison With Other Federal Agencies
Classification Actions
Routine Administrative Matters

PORTIONS CLOSED TO THE PUBLIC (EXECUTIVE SESSION):


PERSON TO CONTACT FOR INFORMATION:
Mr. David Fiske, Press Officer, telephone 202-523-4065.

MARJORIE W. ELMONS,
Secretary to the Commission.

[6714-01]

FEDERAL DEPOSIT INSURANCE CORPORATION.

TIME AND DATE: 10:30 a.m., August 2, 1978.
PLACE: Board room, sixth floor, FDIC Building, 550 17th Street NW., Washington, D.C.
STATUS: Open.

MATTERS TO BE CONSIDERED:

Disposition of minutes of previous meetings.
Application for Federal deposit insurance: Hickory Point Bank, a proposed new bank to be located in the Hickory Point Mall at the intersection of U.S. Highway 51 and Interstate Highway 72, Forsyth, Ill., for Federal deposit insurance.
Request by the Comptroller of the Currency for a report on the competitive factors involved in the proposed merger of Adams County National Bank, Cumberland Township (P.O. Gettysburg), Pa., and The National Bank of Arentsville, Arentsville, Pa.

recommendations with respect to payment for legal services rendered and expenses

FEDERAL REGISTER, VOL. 43, NO. 146—FRIDAY, JULY 28, 1978
SUNSHINE ACT MEETINGS

TIME AND DATE: August 2, 1978—10 a.m.
PLACE: Room 12128—1100 L Street NW., Washington, D.C. 20572.
STATUS: Open.

MATTERS TO BE CONSIDERED:
1. Proposed statement to be presented to the Senate Committee on Banking, Housing, and Urban Affairs regarding S. 211, the Regulatory Reduction and Congressional Control Act.
2. Any agenda items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION:
Mr. Joseph R. Coyne, Assistant to the Board, 202-452-3204.

GRIFFITH L. GARWOOD,
Deputy Secretary of the Board.

[7020-02]

11

UNITED STATES INTERNATIONAL TRADE COMMISSION.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: 10 a.m., Thursday, August 3, 1978.

CHANGES IN THE MEETING: Enlargement of the scope of item No. 5.
5. Copper (Inv. TA-201-32)—Vote on injury (at 2 p.m.) and briefing on remedy, if necessary.

CONTACT PERSON FOR MORE INFORMATION:
Kenneth R. Mason, Secretary, 202-523-0161.

[7020-02]

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UNITED STATES INTERNATIONAL TRADE COMMISSION.

TIME AND DATE: 10 a.m., Thursday, August 10, 1978.
PLACE: Room 117, 701 E Street NW., Washington, D.C. 20436.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:
1. Agenda.
2. Minutes.
3. Ratifications.
4. Petitions and complaints (if necessary).
5. Copper (Inv. TA-201-32)—Vote on remedy, if necessary.
6. Bicycle tires and tubes (Inv. TA-201-33)—Vote on injury.
7. Appeal of denial of information under the FOIA (if necessary).
8. Any items left over from previous agenda.
SUNSHINE ACT MEETINGS

CONTACT PERSON FOR MORE INFORMATION:
Kenneth R. Mason, Secretary, 202-523-0161.

[S-1555-78 Filed 7-26-78; 3:54 pm]

NATIONAL COUNCIL ON EDUCATIONAL RESEARCH


Agendas for these meetings and any changes in meeting dates or locations will be published in the Federal Register as promptly as possible.

PERSON TO CONTACT FOR INFORMATION:
Ella L. Jones, Administrative Coordinator, telephone 202-254-7900.

PETER H. GERBER,
Chief, Policy and Administrative Coordination, National Council on Educational Research.

[S-1548-78 Filed 7-26-78; 11:44 am]
Title 21—Food and Drugs
CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER A—GENERAL

SUBCHAPTER H—MEDICAL DEVICES

(Docket No. 77N-0155)

Classification Procedures

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This rule sets forth criteria and procedures for classifying devices intended for human use into classes of regulatory control sufficient to provide reasonable assurance of safety and effectiveness. The rule also prescribes the procedures for the submission and review of petitions for reclassification, and defines the circumstances under which information and data associated with the classification of or reclassification of devices will be released to the public. These actions are taken under the Medical Device Amendments of 1976.


FOR FURTHER INFORMATION CONTACT:

Joseph Sheehan, Bureau of Medical Devices (HFK-70), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Avenue, Silver Spring, Md. 20910, 301-427-7114.

SUPPLEMENTARY INFORMATION:
The proposal upon which this final regulation is based was published in the Federal Register of September 13, 1977 (42 FR 46028). Interested persons were given until November 14, 1977 to comment. Twenty-five comments were received on the proposal, presenting a wide range of issues.

This regulation essentially codifies existing procedures that have been followed in the classification process to date. Manufacturers and other interested persons have already become involved in the various aspects of the classification process described in this regulation. The agency has been urged to promulgate this regulation as quickly as possible to provide industry a more certain basis for production decisions. Although the Commissioner doubts that this procedural regulation will affect manufacturers' production decisions, the Commissioner has decided that it is in the best interest of the public and of all parties concerned that this regulation become effective August 28, 1978.

GENERAL

The Commissioner has made many minor editorial changes in the regulation for clarity.

1. Several comments stated that publication of panel recommendations and proposed regulations for the classification of devices before promulgation of the final regulation establishing classification procedures violates the basic principles of administrative rulemaking. The comments pointed out that an agency must provide public notice and an opportunity for interested parties to participate before implementation of a rule.

Section 513(c)(1) of the act requires the promulgation by regulation of the procedures to be followed by classification panels in making their reviews and recommendations. The section does not require, however, that the final classification procedures regulation precede every other step in the classification process. Moreover, this classification procedures regulation essentially codifies the procedures that the agency has been following in the classification process. Public notice of these procedures was provided in a notice published in the Federal Register on May 19, 1978 (42 FR 21648). Because classification panels are public advisory committees, the general procedures under which the panels operate have already been promulgated by regulation (21 CFR Part 14).

2. One comment, referring to the portion of the preamble to the proposed regulation that discussed the classification criteria (42 FR 46030), argued against consideration of such "practical matters" as the difficulty involved in enforcing general controls and the length of time required to develop performance standards. The comment stated that such considerations should be irrelevant to classification decisions, and that any inconvenience to the agency does not change the fact that adequate information may exist to allow proper classification in accordance with the statutory criteria.

The Commissioner agrees that it is important to consider whether a device will provide reasonable assurance of safety and effectiveness. The legislative history reveals both that Congress recognized that considerable time may elapse between classification of a device into class II and the development of a performance standard for the device (Ref. 1, p. 27), and that FDA has ample latitude to classify a device into the premarket approval category in instances in which use of the device poses public health concerns. The Commissioner believes also, however, that the degree of difficulty involved in enforcing general controls with respect to a particular device may well be a relevant consideration in determining whether general controls will provide reasonable assurance of the safety and effectiveness of the device.

3. A few comments expressed concern that the definition of "implant" in proposed §860.3(d) would include many devices which should not be classified into class III, such as dental fillings. The comments suggested that the proposed definition be worded so as not to include such devices.

The Commissioner acknowledges the broad scope of the proposed definition, but also notes that a device which is termed an implant is not necessarily classified into class III. Sections 513(c)(2)(C) and (d)(2)(B) of the act clearly states that an implant need not be classified into class III if such classification is not necessary to provide reasonable assurance of safety and effectiveness. The proposed definition, therefore, has been retained without change in the final regulation.

4. Several comments requested revision of the proposed definition of "life-supporting or life-sustaining device" in §860.3(e). The comment suggested that the proposed wording is redundant and vague. The comments also stated that the proposed definition is too broad because Congress intended that only devices essential to supporting or sustaining life be considered life-supporting or life-sustaining devices for classification purposes. Some comments suggested that the words "or yields information that..."
is to be used for restoration, maintenance or continuation of such function.

Other comments suggested that the definition be reworded to include only devices the discontinuance of which would result in a high probability of death.

The proposed definition has been reworded. The Commissioner believes that the special regulatory treatment afforded life-supporting or life-sustaining devices is necessary for devices which yield information essential to supporting or sustaining life, as well as for devices which are themselves life-supporting or life-sustaining. The Commissioner also rejects the idea that discontinuation of the use of a particular device must result in a high probability of death in order for that device to be properly termed life-supporting or life-sustaining. Congress expressed its intent that the phrase "life-supporting or life-sustaining" be interpreted broadly (ref. 1, p. 35). The Commissioner has reworded the definition to eliminate redundancy and to reflect more accurately the congresional intent (ref. 2, p. 56).

A few comments were objected to the fact that the classification questionnaire was included in the preamble but not in the proposed regulation. The comments stated that the questionnaire is a substantive part of the classification process and expressed concern that if it were not included in the regulation FDA could revise the questionnaire without notice.

The classification questionnaire is merely a guideline intended to aid the panels in applying the legal requirements to the practical task of device classification. Devices will be classified and reclassified only according to the criteria in section 513 of the act. The entire questionnaire process and expressed concern that if it were not included in the regulation FDA could revise the questionnaire without notice.

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be exempt from public disclosure, when the entire contents of the petition are disclosed once the deficiencies have been corrected.

The Commissioner has determined that a petitioner voluntarily surrenders the confidentiality of the contents of a nondeficient reclassification petition. As explained in the preamble to the proposed regulation, the loss of confidentiality is based in part on the necessity that reclassification proceedings be as open as possible. Because all devices within a generic type are reclassified together, one reclassification petition may affect several manufacturers, and each manufacturer affected by the petition should be afforded an opportunity to address its issue.

Because reclassification decisions concern generic types of devices, trade secrets, or other confidential information which relates only to individual devices is irrelevant to reclassification decisions. The Commissioner neither requires nor desires that manufacturers or importers submit such confidential information in reclassification petitions. Furthermore, the Commissioner has determined that the legislative intent precludes the use of such confidential information as the basis for the reclassification of devices into class III (ref. 1, pp. 48 through 50). See section 520(c) of the act (21 U.S.C. 360(c)). Consequently, petitioners should not include in their petitions any data or information that is unnecessary to a decision on the petition, especially if the petitioner wishes to keep such data or information confidential.

Because the policy of disclosure is not yet widely known by those petitioning for reclassification, all reclassification petitions will be screened for possible confidential information at the same time that they are being reviewed for deficiencies, until 180 days after the final classification regulation becomes effective. All petitioners will be offered an informational opportunity to delete any confidential data from their petition, or to withdraw the entire petition before it becomes available for public disclosure. However, 180 days after the final classification regulation becomes effective, petitioners should have become familiar with the reclassification process, and FDA will cease reviewing nondeficient petitions for confidential information and will make the entire contents of all petitions available for public disclosure once they have been determined to be nondeficient.

Because a deficient petition will not be considered on its merits until the deficiencies have been corrected, submission of a petition is not considered a surrender of the confidentiality of its contents until all deficiencies have been corrected. Following notification of a deficiency in the petition, the petitioner is allowed a period of time in which to submit supplemental material intended to correct the deficiency. To provide adequate time for response to a notification of deficiency, the period of time allowed is the period of time allowed from 20 days to 30 days. If, during this 30-day period, the petitioner wishes to withdraw the deficient petition rather than have its contents be available to the public, the Commissioner, in his discretion, may allow the withdrawal. This provision has been added to §860.5(d)(2). Once the deficient petition has been corrected, the entire contents of the petition will be available for public disclosure. The Commissioner has added the provision that any supplemental material submitted by the petitioner, together with the material in the original petition, is considered as a new petition. The new petition is reviewed for deficiencies in the same manner as the original petition, and the same procedures for notification and correction of deficiencies are followed. The Commissioner has also added the provision that a deficient petition which is not corrected within 180 days after notification of a deficiency will be returned to the petitioner, and will not be considered further unless resubmitted.

10. One comment stated that the provisions of §860.7, defining valid scientific evidence and well-controlled investigations should apply only to evidence developed or compiled after the effective date of the final regulation. The provisions in that section do not depart from traditionally recognized concepts, are flexible, are required by section 513(a)(3) of the act, and closely reflect the legislative intent in this area (ref. 1, pp. 17 and 40). Because the provisions do not require a new approach to the proper substantiation of device safety or effectiveness, there is no valid reason for their being applied only to evidence compiled or developed after the effective date of the final regulation.

The Commissioner has deleted the first sentence of §860.7(a) because it is obvious that no single standard of safety and effectiveness should apply to all devices, and it is not necessary to include that fact in the regulation.

11. Several comments addressed the safety and effectiveness factors listed in proposed §860.7(b). The comments suggested that advertising should not be considered with regard to intended conditions of use, that surgical risks should not be considered when evaluating the risks of implants, and that the reliability of a device is not a relevant factor in determining its safety and effectiveness. Several comments also suggested that classification panels should either include engineers as members or seek technical engineering advice if the reliability of devices must be considered.

The legislative history of section 513 of the act clearly reveals that Congress intended the phrase "conditions of use" to include uses promoted through advertising, but that a device should not be regarded as unsafe merely because of "collateral risks" not inherent in the use of the device (ref. 1, p. 16). The Commissioner believes that FDA must retain some discretion in determining which surgical risks are to be considered inherent in the use of any particular device, including implants. The legislative history also reveals that Congress intended that device reliability be considered in determining device safety and effectiveness (ref. 1, p. 16). Furthermore, engineers are represented on panels in order to facilitate consideration of device reliability. Consequently, §860.7(b) has been retained without change in the final regulation.

12. Several comments argued that proposed §860.7(c), by restricting consideration to valid scientific evidence when determining the safety and effectiveness of a device, does not reflect accurately the legislative intent. Several comments also questioned whether the Commissioner should have the authority, "in his discretion," to determine whether evidence submitted is valid scientific evidence. Several comments also suggested that if nonvalid scientific evidence is irrelevant in establishing the effectiveness of a device, such evidence also should be irrelevant in establishing that a device is not effective. One comment suggested that the panel should investigate and corroborate isolated case reports, random experience, and similar forms of evidence.

The purpose of the act is to assure the safety and effectiveness of medical devices intended for human use. Because such assurance necessarily demands a high standard of proof, section 513(a)(3) of the act requires that device effectiveness be established only by valid scientific evidence. The Commissioner has extended this requirement to the establishment of device safety as well. The requirement that only valid scientific evidence be used to establish device safety and effectiveness, however, does not preclude consideration of other forms of evidence when determining whether a device is safe or effective. Although it is imperative that early and sometimes informal indications of the danger or ineffectiveness of a device be considered, full evidentiary proof should be made to corroborate such evidence before acting on it. The phrase "in his discretion" has been deleted from the second sentence of §860.7(c)(1) in the final regulation because it is superfluous.
ous, but the remainder of the section has not been changed.

13. Comments on proposed § 860.7(d) requested a more objective and specific definition of what constitutes reasonable assurance of device safety, and clearer guidelines as to what constitutes "adequate efforts to demonstrate the absence of unreasonable risk of illness or injury.

The wording of the proposed section closely follows the wording of section 513 of the act. The legislative history (ref. 1, pp. 16-17) explains that determination of device safety involves balancing probable benefits of a device against its probable risks. Consequently, proof of device safety is intended to establish that the risks are not unreasonably disproportionate to the benefits. The proposed section merely expands this concept, emphasizing that only valid scientific evidence may be used to establish device safety. The Commissioner does not believe that any change in the final regulation is necessary.

14. One comment on proposed § 860.7(e) suggested that a determination of device effectiveness should be based upon whether a device meets the claims of its manufacturer.

Section 513 of the act and § 860.7(b)(2) provide that the effect which a device purports or is represented to have is to be considered in determining its effectiveness. Proposed § 860.7(e) is consistent with these requirements and has been retained in the final regulation with minor clarifying word changes.

A question has arisen concerning the number of studies required to establish the effectiveness of a device. The Commissioner agrees that Congress did not mean to require unreasonable risk of illness or injury. In the absence of safety and effectiveness data, it may be impossible to determine that no such potential risk exists. The Commissioner emphasizes the need for industry to provide collectively sufficient safety and effectiveness data to ensure the proper classification of each generic type of device. The Commissioner believes that § 860.7(f) complies with the requirements of section 519 of the act.

CLASSIFICATION

17. One comment on proposed § 860.84 suggested that a classification of a device by the Commissioner which differs from the classification recommended by the panel should be supported by valid scientific evidence. It was also suggested that panel recommendations be required to identify only unreasonable risks to health, rather than all risks to health, presented by a particular device.

The act clearly provides the basis for determining device safety and effectiveness and prescribes the criteria for device classification. All classification decisions reached by the Commissioner or by the classification panels will be made in accordance with the provisions of the act. The Commissioner may disagree with a panel recommendation if his interpretation of available scientific evidence differs from that of the panel. In addition, the Commissioner intends to evaluate carefully panel recommendations in instances where valid scientific evidence is not available to support a panel recommendation. The requirement that panel recommendations specifically include identification of the risks to health presented by a device is based on section 513(c)(2)(A)(III) of the act.

The Commissioner has redesignated some of the paragraphs in proposed § 860.84 in order to facilitate reference, but the section has been incorporated in the final regulation with no substantive changes.

18. One comment on proposed § 860.95 suggested that, in the recommendation of panels, should not be required to state the reasons for recommending that a device be exempt from the requirements of section 510, 519, or 520(f) of the act. Another comment suggested that a regulation or order classifying or reclassifying a device into class I be required to state the reasons for not granting exemptions as well as the reasons for granting exemptions.

Section 513 of the act requires that panel recommendations for classification into class I, and final regulations or orders classifying devices into class I, specify whether the device is exempted from the requirements of sections 510, 519, or 520(f) of the act. The legislative history reveals that Congress considered "general controls," such as those provided for in sections 510, 519, and 520(f), important safeguards for public health (ref. 1, p. 17). Consequently, the act provides for exemption from only certain general controls, and requires that such exemptions be justified. There is no need to justify a requirement that devices that are not exempted comply with general controls. Proposed § 860.95 has been incorporated in the final regulation without change.

RECLASSIFICATION

19. One comment on proposed § 860.120 suggested that reclassification of one device within a generic type of device should not cause reclassification of all other devices within that generic type unless all such devices present the same unreasonable risk. Another comment stated that some clarification was needed as to who may file a reclassification petition. Several comments suggested that manufacturers and importers who
have not petitioned for the reclassification of a device should be provided a reasonable time to comply with new requirements applicable to the device following its reclassification.

By definition, all devices within a generic type present the same or very similar risks to health. The similarity in health risks is fundamental to the concept of classification by generic type of device. If devices thought to be within the same generic type present different risks, it is likely that the devices are not really of the same generic type. Manufacturers and importers of devices within a generic type will be provided an opportunity to participate in all reclassification proceedings regarding the generic classification of their devices. The open nature of the reclassification process is assured by the provisions in the regulation regarding public disclosure of reclassification of petitions and panel recommendations. If compliance with a performance standard is required because of reclassification, the performance standard will be promulgated under the procedures in section 514 of the act which provide manufacturers notice and a grace period for compliance.

The Commissioner has added new §860.120(c) to clarify who may file a petition for reclassification. FDA previously announced, in 21 CFR 10.25, its general policy that any interested party (whether a manufacturer, consumer, importer, or member of the public) may petition the Commissioner to issue, amend, or revoke a regulation or order promulgated by him. As explained above, reclassification petitions are subject to the special procedures of subpart C of part 860 rather than the citizen petition procedures. However, under the policy of the Citizen Petition Procedure as applied to the classification process, any interested person is afforded an opportunity to file a petition for reclassification under the regulation based on sections 513(e), 514(b), or 515(b) of the act. The reclassification process under section 513(f) or 520(1) of the act is limited to the manufacturer or importer of the specific device involved because of the special procedural safeguards for reclassifying new devices and devices previously regarded as new drugs. The Commissioner has reorganized the remainder of proposed §860.120 for clarification, but the substance of the section has not been changed in the final regulation.

20. Two comments on proposed §860.123 questioned why reclassification petitions were not treated as citizen petitions, and why the Commissioner was not required to respond to such petitions within a definite period of time.

Section 10.30 (21 CFR 10.30) defines "citizen petitions" and provides that other sections regarding other types of petitions may include different requirements. The Commissioner has determined that petitions for device reclassification shall conform to the requirements of proposed §860.123, and has added new §860.3(j) to define the meaning of panel recommendations as it is used in part 860. The Commissioner agrees that a response time should be provided for reclassification petitions submitted under section 513(e) of the act, and §860.150 of the final regulation is accordingly. The act provides specific response times for all other reclassification petitions.

21. Several comments on proposed §860.125 objected that consultation by the Commissioner with persons other than an entire panel would defeat the effectiveness of the panel and is contrary to the legislative intent in this area. It was also mentioned that informal means of consultation, especially consultation by telephone, might result in an unsatisfactory record. One comment suggested that a petitioner should be able to request that the Commissioner consult with the classification panel at a regular panel meeting.

The Commissioner agrees that every effort should be made to consult with an entire classification panel, and that an adequate record of such consultation is essential. There will be circumstances, however, in which statutory time constraints, the request by the petitioner for a timely response, or the unavailability of panel members will require the Commissioner to consult with nonvoting members, and by means other than discussion at a regular meeting. The Commissioner had preceded the phrase "a majority of current voting panel members," in proposed §860.125(a) (1) and (2), with the words "at least." Whenever possible, the Commissioner will consult with nonvoting members, and §860.125(a) (1) and (2) has been changed accordingly.

22. Comments on proposed §860.130 suggested that the Commissioner be required to secure a panel recommendation for reclassification of a device under section 513(e), that all reclassifications of devices from class III to class II should take effect immediately, that all regulations promulgating reclassifications should identify and revoke specific requirements of the prior classification which are no longer applicable to the device, and that the Commissioner should be required to publish oral panel recommendations made under §860.125(a) (1) or (3) as well as written recommendations. One comment also noted that no deadline is provided for response to petitions submitted under this section.

Section 513(e) of the act provides that the Commissioner may act on the basis of new information to reclassify a device without seeking a panel recommendation. There will be circumstances in which the Commissioner will need to consult with a panel in order to reach a proper decision regarding such reclassifications. When a panel cannot be consulted, the advice will be recorded, whether the advice is written or oral. Oral advice will be written down. A regulation reclassifying a device will identify and revoke all requirements of the previous classification which no longer apply to the device. In the case of devices reclassified from class III to class II, section 513(e) of the act specifically provides that the effective date of a reclassification order promulgated under §860.150 will be delayed pending the development of a performance standard for the device, and FDA will take this approach when it is appropriate. The Commissioner has added the provision that petitions submitted under §860.130 will be approved or denied within 180 days after the filing of the petition.

23. One comment on proposed §860.132 suggested that the title be reworded and that the text of §860.132(b) be condensed and reorganized. The proposed title of §860.132 was "Procedures when the Commissioner initiates a performance standard or premarket approval requirement under section 514(b) or 515(b) of the act." Several comments also objected that the 15-day deadline for filing petitions is inadequate.

The Commissioner believes that the title of proposed §860.132, when read in the context of this section, means that the reclassification subpart, clearly states the subject of the section. The Commissioner recognizes no need to reorganize the section. Sections 514(b) and 515(b) of the act require the 15-day deadline for the submission of a petition. Proposed §860.132 has been incorporated in the final regulation with minor editorial changes.

24. Comments on proposed §860.134 suggested that the 210-day response time was too long, that an order denying a petition should set forth the reasons for the denial, that any decision by the Commissioner which differs from the panel recommendation should be supported by valid scientific evidence, and that any interested person should be able to petition for reclassification under this section.

The 210-day period for final action on reclassification petitions for "new devices" is established by section 513(f) of the act and is unreasonable in light of the many steps required to process such petitions. Any order denying a petition for reclassification of a new device will set forth the reasons for that decision, as will orders approving such petitions. The Commissioner's decision regarding
classification will be based upon the same criteria considered by panels in making their recommendations, and will be in accordance with the provisions of the act. Section 513(f) of the act authorizes only the manufacturer or importer of a "new device" to initiate reclassification proceedings for the device. Other interested persons may seek reclassification of the device under section 513(e) of the act and § 860.130. The Commissioner has made minor changes in the wording of the proposed section in order to follow more closely the wording of section 513(f) of the act.

REFERENCES

Background data and information upon which the Commissioner relies in promulgating this regulation have been placed on file for public review in the office of the Hearing Clerk (HEFC-20), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857. The following is a list of those documents:


Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 514, 515, 519, 520, and 701(a)), 52 Stat. 1055, 90 Stat. 540-559, 564-574 (21 U.S.C. 360c, 360d, 360e, 360f), and 371(a)(2)), and under authority delegated to the Commissioner (21 CFR 5.1), 21 CFR Chapter I is amended as follows:

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

1. Part 16 is amended in § 16.1 by adding new paragraph (b)(31), to read as follows:

§ 16.100 Applicability; cross-reference to other regulations.

(b) * * *

(31) Section 860.136 of this chapter, relating to petitions for reclassification of a medical device currently in class III by operation of section 520(c)(1) of the Federal Food, Drug, and Cosmetic Act.

PART 20—PUBLIC INFORMATION

2. Part 20 is amended in § 20.100 by adding new paragraph (c)(31), to read as follows:

§ 20.100 Applicability; cross-reference to other regulations.

(c) * * *

(31) Data and information submitted to the Commissioner or to classification panels in connection with the classification or reclassification of devices intended for human use, in § 860.5 of this chapter.

3. Part 860 is added to read as follows:

PART 860—MEDICAL DEVICE CLASSIFICATION PROCEDURES

Subpart A—General

Sec. 860.1 Scope.
860.3 Definitions.
860.5 Procedure and use of data and information submitted in connection with classification and reclassification.
860.7 Determination of safety and effectiveness.

Subpart B—Classification

860.84 Classification procedures for "old devices.
860.93 Classification of implants, life-supporting or life-sustaining devices.
860.95 Exemptions from sections 510, 519, and 520(f) of the act.

Subpart C—Redesignation

860.120 General.
860.123 Redesignation petition: content and form.
860.125 Consultation with panels.
860.130 General procedures under section 513(e) of the act.
860.132 Procedures when the Commissioner initiates a performance standard or premarket approval proceeding under section 514(b) or 516(b) of the act.
860.134 Procedures for "new devices" under section 513(f) of the act.
860.136 Procedures for transitional products under section 520(f) of the act.

Authority: Secs. 513, 514, 515, 519, 520, and 701(a), 52 Stat. 1055, 90 Stat. 540-559, 564-574 (21 U.S.C. 360c, 360d, 360e, 360f), and 371(a)(2), unless otherwise noted.

Subpart A—General

§ 860.1 Scope.

(a) This part implements sections 513, 514(b), 515(b), and 520(f) of the act with respect to the classification and reclassification of devices intended for human use.

(b) This part prescribes the criteria and procedures to be used by classification panels in making their recommendations and by the Commissioner in making the Commissioner's determinations regarding the class of regulatory control (class I, class II, or class III) appropriate for particular devices. Supplementing the general Food and Drug Administration procedures governing advisory committees (part 14 of this chapter), this part also provides procedures for manufacturers, importers, and other interested persons to participate in proceedings to classify and reclassify devices. This part also describes the kind of data required for determination of the safety and effectiveness of a device, and the circumstances under which information submitted to classification panels or to the Commissioner in connection with classification and reclassification proceedings will be available to the public.

§ 860.3 Definitions.

For the purposes of this part:

(a) "Act" means the Federal Food, Drug, and Cosmetic Act.

(b) "Commissioner" means the Commissioner of Food and Drugs, Food and Drug Administration, United States Department of Health, Education, and Welfare, or the Commissioner's designee.

(c) "Class" means one of the three categories of regulatory control for medical devices.

(1) "Class I" means the class of devices that are subject to only the general controls authorized by or under sections 501 (adulteration), 502 (misbranding), 510 (registration), 516 (banned devices), 518 (human and other remedies), 519 (records and reports), and 520 (general provisions) of the act. A device is in class I if (i) general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, and (ii) there is insufficient information from which to determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, or (iii) there is insufficient information from which to determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, or (iv) there is insufficient information from which to determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, or (v) there is insufficient information from which to determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

(2) "Class II" means the class of devices that are or eventually will be subject to the requirements of a performance standard promulgated in accordance with section 514 of the act. A device is in class II if general controls alone are insufficient to provide reasonable assurance of its safety and effectiveness and there is insufficient information to establish a performance standard to provide such assurance.

(3) "Class III" means the class of devices for which premarket approval is required in accordance with section 515 of the act. A device is in class III if insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of its safety and effectiveness and to establish a performance standard to provide such assurance and if, in addition, the device is life-
supporting of life-sustaining, or for a purpose which is of substantial importance in preventing impairment of human health, or if the device presents a potential unreasonable risk of illness or injury.

(d) "Implant" means a device that is placed into a surgically or naturally formed cavity of the human body. A device is regarded as an implant for the purposes of this part if it is intended to remain-implanted continuously for a period of 30 days or more, unless the Commissioner determines otherwise in order to protect human health.

"Life-supporting or life-sustaining device" means a device that is essential to, or that yields information that is essential to, the restoration or continuation of a bodily function important to the continuation of human life.

(f) "Classification questionnaire" means a specific series of questions prepared by the Commissioner for use as guidelines by classification panels preparing recommendations to the Commissioner regarding classification and by petitioners submitting petitions for reclassification. The questions relate to the safety and effectiveness characteristics of a device and the answers are designed to help the Commissioner determine the proper classification of the device.

(g) "Supplemental data sheet" means information compiled by a classification panel or submitted in a petition for reclassification, including:

(1) A summary of the reasons for the recommendation (or petition);

(2) A summary of the data upon which the recommendation (or petition) is based;

(3) An identification of the risks to health (if any) presented by the device;

(4) To the extent practicable in the case of a class II or class III device, a recommendation for the assignment of a priority for the application of the requirements of performance standards or premarket approval;

(5) In the case of a class I device, a recommendation whether the device should be exempted from any of the requirements of registration, record-keeping and reporting, or good manufacturing practice regulations;

(6) In the case of an implant or a life-supporting or life-sustaining device for which classification in class III is not recommended, a statement of the reasons for not recommending that the device be classified in class III;

(7) Identification of any needed restrictions on the use of the device, e.g., whether the device requires special labeling, should be banned, or should be used only upon authorization of a practitioner licensed by law to administer or use such device; and

(8) Any known existing standards applicable to the device, device component, or device material.

(b) "Classification panel" means one of the several advisory committees established by the Commissioner under section 513 of the act and part 14 of this chapter for the purpose of making recommendations to the Commissioner on the classification and reclassification of devices and for other purposes prescribed by the act or by the Commissioner.

(i) "Generic type of device" means a grouping of devices that do not differ significantly in purpose, design, materials, energy source, function, or any other feature related to safety and effectiveness, and for which similar regulatory controls are sufficient to provide reasonable assurance of safety and effectiveness.

(j) "Petition" means a submission seeking reclassification of a device in accordance with §860.123.

§860.5 Confidentiality and use of data and information submitted in connection with classification and reclassification.

(a) This section governs the availability for public disclosure and the use by the Commissioner of data and information submitted to classification panels or to the Commissioner in connection with the classification or reclassification of devices under this part.

(b) In general, data and information submitted to classification panels in connection with the classification of devices under §860.84 will be available immediately for public disclosure upon request. However, except as provided by the special rules in paragraph (c) of this section, this provision does not apply to data and information exempt from public disclosure in accordance with part 20 of this chapter: Such data and information will be available only in accordance with part 20.

(c)(1) Safety and effectiveness data submitted to classification panels or to the Commissioner in connection with the classification of a device under §860.84, which have not been disclosed previously to the public, as described in §20.81 of this chapter, shall be regarded as confidential if the device is classified in class III. Because the classification of a device under §860.84 may be uncertain only upon publication of a final regulation, all safety and effectiveness data that have not been disclosed previously are not available for public disclosure unless and until the device is classified into class I or II, in which case the procedure in paragraph (c)(2) of this section applies.

(2) Thirty days after publication of a final regulation under §860.84 classifying a device into class I or class II, safety and effectiveness data submitted for that device that had been regarded as confidential under paragraph (c)(1) of this section will be available for public disclosure and placed on public display in the office of the Hearing Clerk, Food and Drug Administration. The contents of such a petition are available for public disclosure for the 30-day period following its receipt (not longer than 30 days) during which the petition is reviewed for any deficiencies preventing the Commissioner from making a decision on it. Once it is determined that the petition contains no deficiencies preventing the Commissioner from making a decision on it, the petition will be filed with the Hearing Clerk and its entire contents will be available for public disclosure and subject to consideration by classification panels and by the Commissioner in making a decision on the petition. If, during this 30-day period of time, the petition is found to contain deficiencies that prevent the Commissioner from making a decision on it, the petitioner will be so notified and afforded an opportunity to correct the deficiencies.

Thirty days after notice to the petitioner of deficiencies in the petition,
the contents of the petition will be available for public disclosure unless, within that 30 days, the petitioner submits supplemental material intended to correct the deficiencies in the petition. The Commissioner, in the Commissioner's discretion, may allow withdrawal of a deficient petition during the 30-day period provided for correcting deficiencies. Any supplemental material submitted by the petitioner, together with the material in the original petition, is considered as a new petition. The new petition is reviewed for deficiencies in the same manner as the original petition, and the same procedures for notification and correction of deficiencies are followed. Once the petitioner has corrected the deficiencies, the entire contents of the petition will be available for public disclosure and subject to consideration by classification panels and by the Commissioner in making a decision on the petition. Deficient petitions which have not been corrected within 180 days after notification of deficiency will be returned to the petitioner and will not be considered further unless resubmitted.

(e) The Commissioner may not disclose, or use as the basis for reclassification of a device from class III to class II, any information reported to or otherwise obtained by the Commissioner under section 513, 514, 515, 516, 518, 519, 520(k), 520(g), or 704 of the act that falls within the exemption described in §20.61 of this chapter for trade secrets and confidential commercial information. The exemption described in §20.61 does not apply to data or information contained in a petition for reclassification submitted in accordance with §860.130 or §860.132, or in a petition submitted in accordance with §860.134 or §860.136 that has been determined to contain no deficiencies that prevent the Commissioner from making a decision on it. Accordingly, all data and information contained in such petitions may be disclosed by the Commissioner and used as the basis for reclassification of a device from class III to class II.

(f) For purposes of this section, safety and effectiveness data include data and results derived from all studies and tests of a device on animals and humans and from all studies and tests of the device itself intended to establish or determine its safety and effectiveness.

§860.7 Determination of safety and effectiveness.

(a) The classification panels, in reviewing evidence concerning the safety and effectiveness of a device and in preparing advice to the Commissioner, and the Commissioner, in making determinations concerning the safety and effectiveness of a device, will apply the rules in this section.

(b) In determining the safety and effectiveness of a device for purposes of classification, establishment of performance standards for class II devices or classification, establishment of class II or class III devices, the Commissioner and the classification panels will consider the following, among other relevant factors:

(1) The persons for whose use the device is represented or intended;

(2) The conditions of use of the device, including conditions of use prescribed, recommended, or suggested in the labeling or advertising of the device, and other intended conditions of use;

(3) The probable benefit to health from the use of the device weighed against any probable injury or illness from such use; and

(4) The reliability of the device.

(c) (1) Although the manufacturer, may submit evidence to the Food and Drug Administration in an attempt to substantiate the safety and effectiveness of a device, the agency relies upon only valid scientific evidence to determine whether there is reasonable assurance that the device is safe and effective. After considering the nature of the device and the rules in this section, the Commissioner will determine whether the evidence submitted or otherwise available to the Commissioner is valid scientific evidence for the purpose of determining the safety or effectiveness of a particular device and whether the available evidence, when taken as a whole, is adequate to support a determination that there is reasonable assurance that the device is safe and effective for its conditions of use.

(2) Valid scientific evidence is evidence from well-controlled investigations, partially controlled studies, and nonclinical investigations that are useful in determining whether there is reasonable assurance that a device is safe and effective. The Commissioner may make such a determination where the requirement of well-controlled investigations in paragraph (f) of this section is not reasonably applicable to the device.

(d) (1) There is reasonable assurance that a device is safe and effective when it can be determined, based upon valid scientific evidence, that the probable benefits to health from the use of the device for its intended uses and conditions of use, when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks. The valid scientific evidence used to determine the safety of a device shall adequately demonstrate the absence of unreasonable risk of illness or injury associated with the use of the device for its intended uses and conditions of use.

(2) Among the types of evidence that may be required, when appropriate, to determine that there is reasonable assurance that a device is safe and effective are investigations using laboratory animals, investigations involving human subjects, and nonclinical investigations including in vivo studies.

(e) (1) There is reasonable assurance that a device is effective when it can be determined, based upon valid scientific evidence, that in a significant portion of the target population, the use of the device for its intended uses and conditions of use, when accompanied by adequate directions for use and warnings against unsafe use, will provide clinically significant results.

(2) The valid scientific evidence used to determine the effectiveness of a device shall consist principally of well-controlled investigations, as defined in paragraph (f) of this section, unless the Commissioner authorizes reliance upon other valid scientific evidence which the Commissioner has determined is sufficient evidence from which to determine the effectiveness of a device, even in the absence of well-controlled investigations. The Commissioner may make such a determination where the requirement of well-controlled investigations in paragraph (f) of this section is not reasonably applicable to the device.

(f) The following principles have been developed over a period of years and are recognized by the scientific community as the essentials of a well-controlled clinical investigation. They provide the basis for the Commissioner's determination whether there is reasonable assurance that a device is effective based upon well-controlled investigations and are also useful in assessing the weight to be given to other valid scientific evidence permitted under this section.

(1) The plan or protocol for the study and the report of the results of a well-controlled investigation shall include the following:

(i) A clear statement of the objectives of the study;

(ii) A method of selection of the subjects that:
(4) In the case of a recommendation for classification into class I, a recommendation as to whether the device should be exempted from the requirements of one or more of the following sections of the act: section 510 (registration, product listing, and premarket notification) section 519 (records and reports) and section 520(f) (good manufacturing practice regulations) in accordance with §860.95;

(5) In the case of a recommendation for classification into class II or class III, to the extent practicable, a recommendation for the assignment to the device of a priority for the application of a performance standard or a premarket approval requirement;

(6) In the case of a recommendation for classification of an implant or a life-supporting or life-sustaining device into class I or class II, a statement of why premarket approval is not necessary reasonable assurance of the safety and effectiveness of the device, accompanied by references to supporting documentation and data satisfying the requirements of §860.7, and an identification of the risks to health, if any, presented by the device.

c) A panel recommendation is regarded as preliminary until the Commissioner has reviewed it, discussed it with the panel if appropriate, and published a proposed regulation classifying the device. Preliminary panel recommendations are filed in the Hearing Clerk's office upon receipt and are available to the public upon request.

(G) The Commissioner publishes the panel's recommendation in the Federal Register, together with a proposed regulation classifying the device, and other devices of that generic type, and provides interested persons an opportunity to submit comments on the recommendation and proposed regulation.

(2) The Commissioner reviews the comments and issues a final regulation classifying the device and other devices of that generic type. The regulation will:

(1) If classifying the device into class I, prescribe which, if any, of the requirements of sections 510, 519, and 520(f) of the act will not apply to the device and state the reasons for making the requirements inapplicable, in accordance with §860.56;

(2) If classifying the device into class II or class III, at the discretion of the Commissioner, establish priorities for the application to the device of a performance standard or a premarket approval requirement;

(3) If classifying an implant, or life-supporting or life-sustaining device, comply with §860.93(b).

§860.93 Classification of implants, life-supporting or life-sustaining devices.

(a) The classification panel will recommend classification into class III of any implant or life-supporting or life-sustaining device unless the panel determines that such classification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. If the panel recommends classification or reclassification of such a device into a class other than class III, it shall set forth in its recommendation the reasons for so doing.

(b) The Commissioner will classify an implant or life-supporting or life-sustaining device into class III unless the Commissioner determines that such classification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. If the Commissioner proposes to classify or reclassify such a device into a class other than class III, the regulation or order effecting such classification or reclassification will be accompanied by a full statement of the reasons for so doing.

"Explain the procedure for reclassification in the Federal Register.

(3) Any interested person may submit a petition for reclassification under section 513(f) or 520(i). A manufacturer or importer may submit a petition for reclassification under section 513(f) or 520(i)."

§860.123 Reclassification petition: content and form.

(a) Unless otherwise provided in writing by the Commissioner, any petition for reclassification of a device, regardless of the section of the act under which it is filed, shall include the following:

(1) A specification of the type of device for which reclassification is requested;

(2) A statement of the action requested by the petitioner, e.g., "It is requested that — devices be reclassified from class III to a class II";

(3) A completed supplemental data sheet applicable to the device for which reclassification is requested;

(4) A completed classification questionnaire applicable to the device for which reclassification is requested;

(5) A statement of the basis for disagreement with the present classification status of the device;

(6) A full statement of the reasons, together with supporting data satisfying the requirements of §860.7, why the device should not be classified into its present classification and how the proposed classification will provide reasonable assurance of the safety and effectiveness of the device;

(7) Representative data and information known by the petitioner that are unavailable to the petitioner's position;
(a) Provides adequate assurance that the subjects are suitable for the purposes of the study, provides diagnostic criteria of the condition to be treated or diagnosed, provides confirmatory laboratory tests where appropriate and, in the case of a device to prevent a disease or disorder, provides evidence of susceptibility and exposure to the condition against which prophylaxis is desired;

(b) Assigns the subjects to test groups, if used, in such a way as to minimize any possible bias;

(c) Assures comparability between test groups and any control groups of pertinent variables such as sex, severity or duration of the disease, and use of therapy other than the test device;

(iii) An explanation of the methods of observation and recording of results utilized, including the variables measured, quantitated, assessment of any subject's response, and steps taken to minimize any possible bias of subjects and observers;

(iv) A comparison of the results of treatment or diagnosis with a control in such a fashion as to permit quantitative evaluation. The precise nature of the control must be specified and an explanation provided of the methods employed to minimize any possible bias of the observers and analysts of the data. Level and methods of "blinding," if appropriate and used, are to be documented. Generally, four types of comparisons are recognized:

(a) No treatments.—Where objective measurements of effectiveness are available and placebo effect is negligible, comparison of the objective results in comparable groups of treated and untreated patients;

(b) Placebo control.—Where there may be a placebo effect with the use of a device, comparison of the results of use of the device with an ineffective device used under conditions designed to resemble the conditions of use under investigation as far as possible;

(c) Active treatment control.—Where an effective regimen of therapy may be used for comparison, e.g., the condition being treated is such that the use of a placebo or the withholding of treatment would be inappropriate or contrary to the interest of the patient;

(d) Historical control.—In certain circumstances, such as those involving diseases with high and predictable mortality or signs and symptoms of predictable duration or severity, or in the case of prophylaxis where morbidity is predictable, the results of use of the device may be compared quantitatively with prior experience historically derived from adequately documented natural history of the disease or condition in comparable patients or populations who received no treatment or who followed an established effective regimen (therapeutic, diagnostic, prophylactic).

(v) A summary of the methods of analysis and an evaluation of the data derived from the study, including any appropriate statistical methods utilized.

(2) To insure the reliability of the results of an investigation, a well-controlled investigation shall involve the use of a test device that is standardized in its composition or design and performance.

(g) (1) It is the responsibility of each manufacturer and importer of a device to assure that adequate, valid scientific evidence exists, and to furnish such evidence to the Food and Drug Administration to provide reasonable assurance that the device is safe and effective for its intended uses and conditions of use. The failure of a manufacturer or importer of a device to present to the Food and Drug Administration adequate, valid scientific evidence showing that there is reasonable assurance of the safety and effectiveness of the device, if regulated by general controls, or to make reports or provide assurance that the device is safe and effective for its intended uses and conditions of use, may support a determination that the device be classified into class III.

(2) The Commissioner may require that a manufacturer, importer, or distributor make reports or provide other information bearing on the classification of a device and indicating whether there is reasonable assurance of the safety and effectiveness of the device or whether it is adulterated or misbranded under the act.

(3) A requirement for a report or other information under this paragraph will comply with section 519 of the act. Accordingly, the requirement will state the reason or purpose for such request; will describe the required report or information as clearly as possible; will not be imposed on a manufacturer, importer, or distributor of a device classified as class III; and will be a practicable opportunity for interested persons to submit data and views on the classification of the device in accordance with part 14 of this chapter.

(b) The Commissioner refers the device to the appropriate classification panel organized and operated in accordance with section 513 (b) and (c) of the act and part 14 of this chapter.

(c) In order to make recommendations to the Commissioner on the class of regulatory control (class I, class II, or class III) appropriate for the device, the panel reviews the device for safety and effectiveness. In so doing, the panel:

(1) Considers the factors set forth in § 860.7 relating to the determination of safety and effectiveness;

(2) Determines the safety and effectiveness of the device on the basis of the types of scientific evidence set forth in § 860.7;

(3) Answers the questions in the classification questionnaire applicable to the device being classified;

(4) Completes a supplemental data sheet for the device;

(5) Provides, to the maximum extent practicable, an opportunity for interested persons to submit data and views on the classification of the device in accordance with part 14 of this chapter;

(d) Based upon its review of evidence of the safety and effectiveness of the device, and applying the definition of "substantially equivalent" to any device subject to this subpart or under section 520(1) (1) through (3) of the act because the device was regarded previously as a new drug. This subpart does not apply to a device that was previously regarded as an antibiotic drug and that is subject to section 520(3)(4) of the act. In classifying a device under this section, the Food and Drug Administration will follow the procedures described in paragraphs (b) through (g) of this section.

The Commissioner refers the device to the appropriate classification panel organized and operated in accordance with section 513 (b) and (c) of the act and part 14 of this chapter.

(c) In order to make recommendations to the Commissioner on the class of regulatory control (class I, class II, or class III) appropriate for the device, the panel reviews the device for safety and effectiveness. In so doing, the panel:

(1) Considers the factors set forth in § 860.7 relating to the determination of safety and effectiveness;

(2) Determines the safety and effectiveness of the device on the basis of the types of scientific evidence set forth in § 860.7;

(3) Answers the questions in the classification questionnaire applicable to the device being classified;

(4) Completes a supplemental data sheet for the device;

(5) Provides, to the maximum extent practicable, an opportunity for interested persons to submit data and views on the classification of the device in accordance with part 14 of this chapter;

(d) Based upon its review of evidence of the safety and effectiveness of the device, and applying the definition of "substantially equivalent" to any device subject to this subpart or under section 520(1) (1) through (3) of the act because the device was regarded previously as a new drug. This subpart does not apply to a device that was previously regarded as an antibiotic drug and that is subject to section 520(3)(4) of the act. In classifying a device under this section, the Food and Drug Administration will follow the procedures described in paragraphs (b) through (g) of this section.

(b) The Commissioner refers the device to the appropriate classification panel organized and operated in accordance with section 513 (b) and (c) of the act and part 14 of this chapter.

(c) In order to make recommendations to the Commissioner on the class of regulatory control (class I, class II, or class III) appropriate for the device, the panel reviews the device for safety and effectiveness. In so doing, the panel:

(1) Considers the factors set forth in § 860.7 relating to the determination of safety and effectiveness;

(2) Determines the safety and effectiveness of the device on the basis of the types of scientific evidence set forth in § 860.7;

(3) Answers the questions in the classification questionnaire applicable to the device being classified;

(4) Completes a supplemental data sheet for the device;

(5) Provides, to the maximum extent practicable, an opportunity for interested persons to submit data and views on the classification of the device in accordance with part 14 of this chapter;

(d) Based upon its review of evidence of the safety and effectiveness of the device, and applying the definition of "substantially equivalent" to any device subject to this subpart or under section 520(1) (1) through (3) of the act because the device was regarded previously as a new drug. This subpart does not apply to a device that was previously regarded as an antibiotic drug and that is subject to section 520(3)(4) of the act. In classifying a device under this section, the Food and Drug Administration will follow the procedures described in paragraphs (b) through (g) of this section.

The Commissioner refers the device to the appropriate classification panel organized and operated in accordance with section 513 (b) and (c) of the act and part 14 of this chapter.

(c) In order to make recommendations to the Commissioner on the class of regulatory control (class I, class II, or class III) appropriate for the device, the panel reviews the device for safety and effectiveness. In so doing, the panel:

(1) Considers the factors set forth in § 860.7 relating to the determination of safety and effectiveness;

(2) Determines the safety and effectiveness of the device on the basis of the types of scientific evidence set forth in § 860.7;

(3) Answers the questions in the classification questionnaire applicable to the device being classified;

(4) Completes a supplemental data sheet for the device;

(5) Provides, to the maximum extent practicable, an opportunity for interested persons to submit data and views on the classification of the device in accordance with part 14 of this chapter;

(d) Based upon its review of evidence of the safety and effectiveness of the device, and applying the definition of "substantially equivalent" to any device subject to this subpart or under section 520(1) (1) through (3) of the act because the device was regarded previously as a new drug. This subpart does not apply to a device that was previously regarded as an antibiotic drug and that is subject to section 520(3)(4) of the act. In classifying a device under this section, the Food and Drug Administration will follow the procedures described in paragraphs (b) through (g) of this section.

The Commissioner refers the device to the appropriate classification panel organized and operated in accordance with section 513 (b) and (c) of the act and part 14 of this chapter.

(c) In order to make recommendations to the Commissioner on the class of regulatory control (class I, class II, or class III) appropriate for the device, the panel reviews the device for safety and effectiveness. In so doing, the panel:

(1) Considers the factors set forth in § 860.7 relating to the determination of safety and effectiveness;

(2) Determines the safety and effectiveness of the device on the basis of the types of scientific evidence set forth in § 860.7;

(3) Answers the questions in the classification questionnaire applicable to the device being classified;

(4) Completes a supplemental data sheet for the device;

(5) Provides, to the maximum extent practicable, an opportunity for interested persons to submit data and views on the classification of the device in accordance with part 14 of this chapter;

(d) Based upon its review of evidence of the safety and effectiveness of the device, and applying the definition of "substantially equivalent" to any device subject to this subpart or under section 520(1) (1) through (3) of the act because the device was regarded previously as a new drug. This subpart does not apply to a device that was previously regarded as an antibiotic drug and that is subject to section 520(3)(4) of the act. In classifying a device under this section, the Food and Drug Administration will follow the procedures described in paragraphs (b) through (g) of this section.
the contents of the petition will be available for public disclosure unless, within that 30 days, the petitioner submits supplemental material intended to correct the deficiencies in the petition. The Commissioner, in the Commissioner's discretion, may allow withdrawal of a deficient petition during the 30-day period provided for correcting deficiencies. Any supplemental material submitted by the petitioner, together with the material in the original petition, is considered as a new petition. The new petition is reviewed for deficiencies in the same manner as the original petition, and the same procedures for notification and correction of deficiencies are followed. Once the petitioner has corrected the deficiencies, the entire contents of the petition will be available for public disclosure and subject to consideration by classification panels and by the Commissioner in making a decision on the petition. Deficient petitions which have not been corrected within 180 days after notification of deficiency will be returned to the petitioner and will not be considered further unless resubmitted.

(e) The Commissioner may not disclose, or use as the basis for reclassification of a device from class III to class II, any information reported to or otherwise obtained by the Commissioner under section 513, 514, 515, 516, 518, 519, 520(k), 520(g), or 704 of the act that falls within the exemption described in § 20.61 of this chapter for trade secrets and confidential commercial information. The exemption described in § 20.61 does not apply to data or information contained in a petition for reclassification submitted in accordance with § 860.130 or § 860.132, or in a petition submitted in accordance with § 860.134 or § 860.136 that has been determined to contain no deficiencies that prevent the Commissioner from making a decision on it. Accordingly, all data and information contained in such petitions may be disclosed by the Commissioner and used as the basis for reclassification of a device from class III to class II.

(f) For purposes of this section, safety and effectiveness data include data and results derived from all studies and tests of a device on animals and humans and from all studies and tests of the device itself intended to establish or determine its safety and effectiveness.

§ 860.7 Determination of safety and effectiveness.

(a) The classification panels, in reviewing evidence concerning the safety and effectiveness of a device and in preparing advice to the Commissioner, and the Commissioner, in making determinations concerning the safety and effectiveness of a device, will apply the rules in this section.

(b) In determining the safety and effectiveness of a device for purposes of classification, establishment of performance standards for class II devices, or approval of class III devices, the Commissioner and the classification panels will consider the following, among other relevant factors:

(1) The persons for whose use the device is represented or intended;

(2) The conditions of use for the device, including conditions of use prescribed, recommended, or suggested in the labeling or advertising of the device, and other intended conditions of use;

(3) The probable benefit to health from the use of the device weighed against any probable injury or illness from such use; and

(4) The reliability of the device.

(c) (1) Although the manufacturer, user, or supplier of a device may submit evidence to the Food and Drug Administration in an attempt to substantiate the safety and effectiveness of a device, the agency relies upon only valid scientific evidence to determine whether there is reasonable assurance that the device is safe and effective. After considering the nature of the device and the rules in this section, the Commissioner will determine whether the evidence submitted or otherwise available to the Commissioner is valid scientific evidence for the purpose of determining the safety or effectiveness of a particular device and whether the available evidence, when taken as a whole, is adequate to support a determination that there is reasonable assurance that the device is safe and effective for its conditions of use.

(2) Valid scientific evidence is evidence from well-controlled investigations, partially controlled studies, studies and objective trials without matching the study population, well-documented case histories conducted by qualified experts, and reports of significant human experience with a marketed device, from which it can fairly and responsibly be concluded that there is reasonable assurance of the safety and effectiveness of a device under its conditions of use. The evidence required may vary according to the characteristics of the device, its conditions of use, the existence and adequacy of warnings and other restrictions, and the extent of experience with its use. Isolated case reports, random experience, reports lacking sufficient details to permit scientific evaluation, and unsubstantiated claims are not regarded as valid scientific evidence to show safety or effectiveness. Such information may be considered, however, in identifying a device the safety and effectiveness of which is questionable.

(d) (1) There is reasonable assurance that a device is safe when it can be determined, based upon valid scientific evidence, that the probable benefits to health from use of the device for its intended uses and conditions of use, when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks. The valid scientific evidence used to determine the safety of a device shall adequately demonstrate the absence of unreasonable risk of illness or injury associated with the use of the device for its intended uses and conditions of use.

(2) Among the types of evidence that may be required, when appropriate, to determine that there is reasonable assurance that a device is safe are investigations using laboratory animals, investigations involving human subjects, and nonclinical investigations including in vitro studies.

(e) (1) There is reasonable assurance that a device is effective when it can be determined, based upon valid scientific evidence, that in a significant portion of the target population, the use of the device for its intended uses and conditions of use, when accompanied by adequate directions for use and warnings against unsafe use, will provide clinically significant results.

(2) The valid scientific evidence used to determine the effectiveness of a device shall consist principally of well-controlled investigations, as defined in paragraph (f) of this section, unless the Commissioner relies on other valid scientific evidence which the Commissioner has determined is sufficient evidence from which to determine the effectiveness of a device, even in the absence of well-controlled investigations. The Commissioner may make such a determination where the requirement of well-controlled investigations in paragraph (f) of this section is not reasonably applicable to the device.

(f) The following principles have been developed over a period of years and are recognized by the scientific community as the essentials of a well-controlled clinical investigation. They provide the basis for the Commissioner's determination whether there is reasonable assurance that a device is effective based upon well-controlled investigations and are also useful in assessing the weight to be given to other valid scientific evidence permitted under this section.

(1) The plan or protocol for the study and the report of the results of a well-controlled investigation shall include the following:

(a) A clear statement of the objectives of the study;

(b) A method of selection of the subjects that:
(4) In the case of a recommendation for classification into class I, a recommendation as to whether the device should be exempted from the requirements of one or more of the following sections of the act: section 510 (registration, product listing, and premarket notification) section 519 (records and reports) and section 520(f) (good manufacturing practice regulations) in accordance with § 860.95.

(5) In the case of a recommendation for classification into class II or class III, to the extent practicable, a recommendation for the assignment to the device of a priority for the application of a performance standard or a premarket approval requirement.

(6) In the case of a recommendation for classification of an implant or a life-supporting or life-sustaining device into class I or class II, a statement of why premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device, accompanied by references to supporting documentation and data satisfying the requirements of § 860.7, and an identification of the risks to health, if any, presented by the device.

(e) A panel recommendation is regarded as preliminary until the Commissioner has reviewed it, discussed it with the panel if appropriate, and published a proposed regulation classifying the device. Preliminary panel recommendations are filed in the FEDERAL REGISTER, together with a proposed recommendation as to whether the device will be classified into class II or class III, it shall set forth in its recommendation the reasons for so doing together with references to supporting documentation and data satisfying the requirements of § 860.7, and an identification of the risks to health, if any, presented by the device.

(f) The Commissioner publishes the panel's recommendation in the FEDERAL REGISTER, together with a proposed regulation classifying the device, and other devices of that generic type, and provides interested persons an opportunity to submit comments on the recommendation and proposed regulation.

(g) The Commissioner reviews the comments and issues a final regulation classifying the device and other devices of that generic type. The regulation will:

(1) If classifying the device into class I, prescribe which, if any, of the requirements of sections 510, 519, and 520(f) of the act will not apply to the device and state the reasons for making the requirements inapplicable, in accordance with § 860.55.

(2) If classifying the device into class II or class III, at the discretion of the Commissioner, establish priorities for the application to the device of a performance standard or a premarket approval requirement;

(3) If classifying an implant, or life-supporting or life-sustaining device, comply with § 860.93(b).

§ 860.93 Classification of implants, life-supporting or life-sustaining devices.

(a) The classification panel will recommend classification into class III of an implant or life-supporting or life-sustaining device unless the panel determines that such classification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. If the panel recommends classification or reclassification of such a device into a class other than class III, it shall set forth in its recommendation the reasons for so doing together with references to supporting documentation and data satisfying the requirements of § 860.7, and an identification of the risks to health, if any, presented by the device.

(b) The Commissioner will classify an implant or life-supporting or life-sustaining device into class III unless the Commissioner determines that such classification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. If the Commissioner proposes to classify or reclassify such a device into a class other than class III, the regulation or order effecting such classification or reclassification will be accompanied by a full statement of the reasons for so doing. A statement of the reasons for not classifying or retaining the device in class III may be in the form of concurrence with the reasons for the recommendation of the classification panel, together with supporting documentation and data satisfying the requirements of § 860.7 and an identification of the risks to health, if any, presented by the device.

§ 860.95 Exemptions from sections 510, 519, and 520(f) of the act.

(a) A panel recommendation to the Commissioner that a device be classified or reclassified into class I will include a recommendation as to whether the device should be exempted from, or all of the requirements of one or more of the following sections of the act: section 510 (registration, product listing and premarket notification), section 519 (records and reports), and section 520(f) (good manufacturing practice regulations).

(b) A regulation or an order classifying or reclassifying a device into class I will specify which requirements, if any, of sections 510, 519, and 520(f) of the act the device is to be exempted from, together with the reasons for such exemption.

(c) The Commissioner will grant exemptions under this section only if the Commissioner determines that the requirements from which the device is exempted are not necessary to provide reasonable assurance of the safety and effectiveness of the device.

(6) A statement of the reasons, together with supporting data satisfying the requirements of § 860.7, why the device should not be classified into its present classification and how the proposed classification will provide reasonable assurance of the safety and effectiveness of the device;

(7) Representative data and information known by the petitioner that are unfavorable to the petitioner's position;

Subpart C—Reclassification

§ 860.120 General.

(a) Sections 513(e) and (f), 514(b), 515(b), and 520(d) of the act provide for reclassification of a device and prescribe the procedures to be followed to effect reclassification. The purposes of subpart C are to:

(1) Specify the requirements as to form and content of petitions for reclassification;

(2) Describe the circumstances in which each of the five statutory reclassification provisions applies; and

(3) Explain the procedure for reclassification prescribed in the five statutory reclassification provisions.

(b) The criteria for determining the proper class for a device are set forth in § 860.3(c). The reclassification of any device within a generic type of device causes the reclassification of all substantially equivalent devices within that generic type. Accordingly, a petition for the reclassification of a specific device will be considered a petition for reclassification of all substantially equivalent devices within the same generic type.

(c) Any interested person may submit a petition for reclassification under section 513(f) or 520(c). A manufacturer or importer may submit a petition for reclassification under section 513(f) or 520(c).

§ 860.123 Reclassification petition: content and form.

(a) Unless otherwise provided in writing by the Commissioner, any petition for reclassification of a device, regardless of the section of the act under which it is filed, shall include the following:

(1) A specification of the type of device for which reclassification is requested;

(2) A statement of the action requested by the petitioner, e.g., “It is requested that — device(s) be reclassified from class III to a class II”;

(3) A completed supplemental data sheet applicable to the device for which reclassification is requested;

(4) A completed classification questionnaire applicable to the device for which reclassification is requested;

(5) A statement of the basis for disagreement with the present classification status of the device;

(6) A full statement of the reasons, together with supporting data satisfying the requirements of § 860.7, why the device should not be reclassified into its present classification and how the proposed classification will provide reasonable assurance of the safety and effectiveness of the device;

(7) Representative data and information known by the petitioner that are unfavorable to the petitioner's position;
§ 860.130 General procedures under section 513(e) of the act.
(a) Section 513(e) of the act applies to reclassification proceedings under the act based upon new information.
(b) A proceeding to reclassify a device under section 513(e) may be initiated:
(1) On the initiative of the Commissioner alone;
(2) On the initiative of the Commissioner in response to a request for reclassification from the classification panel for its decision with respect to the petition In accordance with § 860.125.
(c) The rulemaking procedures in § 10.40 of this chapter apply to proceedings to reclassify a device under section 513(e), except that the Commissioner may secure a recommendation with respect to a proposed reclassification from the classification panel to which the device was last referred. The panel will consider a proposed reclassification submitted to it by the Commissioner in accordance with the consultation procedures of § 860.125.
(d) Within 180 days after the filing of a petition for reclassification under this section, the Commissioner, by order published in the FEDERAL REGISTER, will either deny the petition or give notice of his intent to initiate a change in the classification of the device.
(e) If a device is reclassified under this section, the regulation effecting the reclassification may revoke any performance standard or premarket approval requirement that previously applied to the device but that is no longer applicable because of the change in classification.
(f) A regulation under this section changing the classification of a device from class III to class II may provide that such classification will not take effect until the effective date of a performance standard for the device established under section 514 of the act.

§ 860.132 Procedures when the Commissioner initiates a change in classification.
(a) Sections 514(b) and 515(b) of the act require the Commissioner to provide, by notice in the FEDERAL REGISTER, an opportunity for interested parties to request a change in the classification of a device based upon new information relevant to its classification when the Commissioner initiates a proceeding either to develop a performance standard for the device if in class II, or to promulgate a regulation requiring premarket approval for the device if in class III. In either case, if the Commissioner agrees that the new information warrants a change in classification, the Commissioner will publish in the FEDERAL REGISTER notice of the Commissioner's intent to initiate a proceeding under section 513(e) of the act and § 860.130 to effect such a change.
(b) The procedures for effecting a change in classification under sections 514(b) and 515(b) of the act are as follows:
(1) Within 15 days after publication of the Commissioner's notice referred to in paragraph (a) of this section, an interested person files a petition for reclassification in accordance with § 860.125.
(2) The Commissioner consults with the appropriate classification panel with regard to the petition in accordance with § 860.125.
(3) Within 60 days after publication of the notice referred to in paragraph (a) of this section, the Commissioner, by order published in the FEDERAL REGISTER, either denies the petition or gives notice of his intent to initiate a change in classification in accordance with § 860.130.

§ 860.134 Procedures for “new devices” under section 513(f) of the act.
(a) Section 513(f) of the act applies to reclassification proceedings initiated by a manufacturer or importer for reclassification of a device currently in class III by operation of section 513(f)(1) of the act. This category includes any device that is to be first introduced or delivered for introduction into interstate commerce for commercial distribution after May 28, 1976, unless:
(1) It is substantially equivalent to another device that was in commercial distribution before that date and has not been regulated before that date as a new drug; or
(2) It is substantially equivalent to another device that was not in commercial distribution before that date but which has been classified into class I or class II; or
(3) The Commissioner has classified the device into class I or class II in response to a petition for reclassification under this section.

The Commissioner determines whether a device is “substantially equivalent” for purposes of the application of this section. If a manufacturer or importer believes that a device is not “substantially equivalent,” but that it should not be in class III under the criteria in § 860.3(c), the manufacturer or importer may petition for reclassification under this section. A
manufacturer or importer who believes that a device is “substantially equivalent” and wishes to proceed to market the device shall submit a premarket notification in accordance with part 807 of this chapter. After considering a premarket notification, the Commissioner will determine whether the device is “substantially equivalent” and will notify the manufacturer or importer of such determination in accordance with part 807 of this chapter.

The procedures for effecting reclassification under section 513(f) of the act are as follows:

1. The manufacturer or importer of the device petitions for reclassification of the device in accordance with §860.123.

2. Within 30 days after the petition is filed, the Commissioner notifies the petitioner of any deficiencies in the petition that prevent the Commissioner from making a decision on it and allows the petitioner to supplement a deficient petition. Within 30 days after any supplemental material is received, the Commissioner notifies the petitioner whether the petition, as supplemented, is adequate for review.

3. After determining that the petition contains no deficiencies precluding a decision on it, the Commissioner refers the petition to the appropriate classification panel for its review and recommendation whether to approve or deny the petition.

4. Within 90 days after the date the petition is referred to the panel, following the review procedures set forth in §860.84(c) for the original classification of an “old” device, the panel submits to the Commissioner its recommendation containing the information set forth in §860.84(d). A panel recommendation is regarded as preliminary until the Commissioner has reviewed it, discussed it with the panel, if appropriate, and developed a proposed reclassification order. Preliminary panel recommendations are filed in the hearing clerk’s office upon receipt and are available to the public upon request.

5. The panel recommendation is published in the Federal Register as soon as practicable and interested persons are provided an opportunity to comment on the recommendation.

6. Within 90 days after the panel’s recommendation is received (and no more than 210 days after the date the petition was filed), the Commissioner denies or approves the petition by order in the form of a letter to the petitioner. If the Commissioner approves the petition, the order will classify the device into class I or class II in accordance with §860.3(c) and subject to the applicable requirements of §860.93, relating to the classification of implants, life-supporting or life-sustaining devices, and §860.95, relating to exemptions from certain requirements of the act.

7. Within a reasonable time after issuance of an order under this section, the Commissioner announces the order by notice published in the Federal Register.

§860.136 Procedures for transitional products under section 520(d) of the act.

(a) Section 520(l)(2) of the act applies to reclassification proceedings initiated by a manufacturer or importer for reclassification of a device currently in class III by operation of section 520(l)(1) of the act. This section applies only to devices that the Food and Drug Administration regarded as “new drugs” before May 28, 1976.

(b) The procedures for effecting reclassification under section 520(l) are as follows:

(1) The manufacturer or importer of the device files a petition for reclassification of the device in accordance with §860.123.

(2) Within 30 days after the petition is filed, the Commissioner notifies the petitioner of any deficiencies in the petition that prevent the Commissioner from making a decision on it, allowing the petitioner to supplement a deficient petition. Within 30 days after any supplemental material is received, the Commissioner notifies the petitioner whether the petition, as supplemented, is adequate for review.

(3) The Commissioner provides the petitioner an opportunity for a regulatory hearing conducted in accordance with part 16 of this chapter.

(4) The Commissioner consults with the appropriate classification panel with regard to the petition in accordance with §860.125.

(5) Within 180 days after the petition is filed (where the Commissioner has determined it to be adequate for review), the Commissioner, by order in the form of a letter to the petitioner, either denies the petition or classifies the device into class I or class II in accordance with the criteria set forth in §860.3(c).

(6) Within a reasonable time after issuance of an order under this section, the Commissioner announces the order by notice published in the Federal Register.

Effective date: This regulation shall be effective August 28, 1978.


SHERWIN GARDNER,
Acting Commissioner
of Food and Drugs.

[FR Doc. 78-20625 Filed 7-27-78; 8:45 am]

FEDERAL REGISTER, VOL. 43, NO. 146—FRIDAY, JULY 28, 1978
DEPARTMENT OF LABOR
Employment Standards Administration

MINIMUM WAGES FOR FEDERAL AND FEDERALLY ASSISTED CONSTRUCTION
General Wage Determination Decisions
[4510-27]

DEPARTMENT OF LABOR

Employment Standards Administration

MINIMUM WAGES FOR FEDERAL AND FEDERALLY ASSISTED CONSTRUCTION

General Wage Determination Decisions

General wage determination decisions of the Secretary of Labor specify, in accordance with applicable law and on the basis of information available to the Department of Labor from its study of local wage conditions and from other sources, the basic hourly wage rates and fringe benefit payments which are determined to be prevailing for the described classes of laborers and mechanics employed in construction activity of the character and in the localities specified therein.

The determinations in these decisions of such prevailing rates and fringe benefits have been made by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended, 40 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR 1.1 (including the statutes listed at 36 FR 306 following Secretary of Labor's order No. 24-70) containing provisions for the payment of wages which are dependent upon determination by the Secretary of Labor under the Davis-Bacon Act; and pursuant to the provisions of part 1 of subtitle A of title 29 of Code of Federal Regulations, procedure for predetermination of wage rates (37 FR 21138), and of Secretary of Labor's orders 12-71 and 15-71 (36 FR 8755, 8756). The prevailing rates and fringe benefits determined in these decisions shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged on contract work of the character and in the localities described therein.

Good cause is hereby found for not utilizing notice and public procedure thereon prior to the issuance of these determinations as prescribed in 5 U.S.C. 553 and not providing for delay in effective date as prescribed in that section, because the necessity to issue construction industry wage determination frequently and in large volume causes procedures to be impractical and contrary to the public interest.

General wage determination decisions are effective from their date of publication in the Federal Register without limitation as to time and are to be used in accordance with the provisions of 29 CFR parts 1 and 5. Accordingly, the applicable decision together with any modification issued subsequent to its publication date shall be made a part of every contract for performance of the described work within the geographic area indicated as required by an applicable Federal prevailing wage law and 29 CFR part 5. The wage rates contained therein shall be the minimum paid under such contract by contractors and subcontractors on the work.

Modifications and supersedeas decisions to general wage determination decisions are based upon information obtained concerning changes in prevailing hourly wage rates and fringe benefit payments since the decisions were issued.

The determinations of prevailing rates and fringe benefits made in the modifications and supersedeas decisions have been made by authority of the Secretary of Labor pursuant to the provisions of part 1 of subtitle A of title 29 of Code of Federal Regulations, procedure for predetermination of wage rates (37 FR 21138) and of Secretary of Labor's orders 12-71 and 15-71 (36 FR 8755, 8756). The prevailing rates and fringe benefits determined in foregoing general wage determination decisions, as hereby modified, and/or superseded shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged in contract work of the character and in the localities described therein.

Modifications and supersedeas decisions are effective from their date of publication in the Federal Register without limitation as to time and are to be used in accordance with the provisions of 29 CFR parts 1 and 5.

Any person, organization, or governmental agency having an interest in the wages determined as prevailing is encouraged to submit wage rate information and on the basis of information available to the Department. Further information and self-explanatory forms for the purpose of submitting this data may be obtained by writing to the U.S. Department of Labor, Employment Standards Administration, Office of Special Wage Standards, Division of Wage Determinations, Washington, D.C. 20210.

The cause for not utilizing the rule-making procedures prescribed in 5 U.S.C. 553 has been set forth in the original general wage determination decision.

NEW GENERAL WAGE DETERMINATION DECISIONS

Indiana—IN78-2066

MODIFICATIONS TO GENERAL WAGE DETERMINATION DECISIONS

The numbers of the decisions being modified and their dates of publication in the Federal Register are listed with each State.

California:
District of Columbia:
Florida:

Iowa:
IA77-4223; IA77-4224; IA77-4225; IA77-4226; IA77-4227; IA77-4228; IA77-4229; IA77-4230; IA77-4231; IA77-4232; IA77-4233; IA77-4234; IA77-4235. Sept. 30, 1977.

North Carolina:

Oklahoma:

Pennsylvania:
P78-3507 ........................................... Sept. 9, 1977.

Tennessee:
TN78-1058 ............................................ July 1, 1978.

SUPERSEDEAS DECISIONS TO GENERAL WAGE DETERMINATION DECISIONS

The numbers of the decisions being superseded and their dates of publication in the Federal Register are listed with each State. Supersedeas decision numbers are in parentheses following the numbers of the decisions being superseded.

Arizona:
AZ77-5115 (AZ78-5025; AZ77-5026) (AZ78-5116). June 17, 1977.

Arkansas:

Connecticut:
CT78-3603 (CT78-3655); CT78-3604 (CT78-3656) Feb. 17, 1978.

Louisiana:

Mississippi:
MS78-4070 (AR78-4074) .......................... Do.

Tennessee:
TN78-4070 (AR78-4074) .......................... Do.

Vermont:

CANCELLATION OF GENERAL WAGE DETERMINATION DECISIONS

None.

Signed at Washington, D.C., this 21st day of July 1978.

XAVIER M. VELA,
Administrator,
Wage and Hour Division.
## NEW DECISION

**STATE:** INDIANA  
**COUNTY:** *See below*  
**DECISION NO:** I978-2066  
**DATE OF PUBLICATION:** [Date]  
**DESCRIPTION OF WORK:** Building Construction (Does not include single family homes & garage type apartments up to 6 including 6twitteries)

### NEW DECISION

**#Elkhart, Jasper, Kosciusko, LaGrange, Marshall, Newton, Pulaski, & Starke**

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<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
<th>Education and/or Appl Tr</th>
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**NOTICES**

FEDERAL REGISTER, VOL. 43, NO. 146—FRIDAY, JULY 20, 1978
| PAINTERS: | Fringe Benefits Payments | | | | | | Basic Hourly Rates | H & W | Pensions | Vacation | Education/app Tr |
|----------|--------------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|
| Elk hart, Kosciusko, Marshall, Pulaski, & Stark Co: | | | | | | | | | | | | | | | | |
| Jasper & Newton Co: | Brush | 9 59 | 40 | 115 00p/yr | | | | | | | | | | | | |
| | Paperhanging | 10 50 | 64 | 50 | 02 |
| | Sandblasting | 11 65 | 64 | 50 | 02 |
| | Drywall taping | 11 55 | 64 | 50 | 02 |
| | LaGrange Co: | Brush | 8 60 | 42 | 45 | 10 |
| | Paperhanging: Rollers & Tapers | 7 60 | 42 | 45 | 10 |
| | Sandblasting: Spray & Steam cleaning | 9 60 | 42 | 45 | 10 |
| | Fitters: Plumbers & Steamfitters: | | | | | | | | | | | | | | | | |
| | Elk hart, Kosciusko, & LaGrange Co: | | | | | | | | | | | | | | | | |
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| | Jasper (Ba Co. & Newton Co: | | | | | | | | | | | | | | | | |
| | Plumbers | 12 20 | 80 | 100 | 02 |
| | Fitters: | | | | | | | | | | | | | | | | |
| | Elk hart, Kosciusko, & LaGrange Co: | | | | | | | | | | | | | | | | |
| | Jasper (2/3 of Co. & Stark Co: | | | | | | | | | | | | | | | | |
| | Newton Co (Ba Co. | | | | | | | | | | | | | | | | |
| | Roofers: | | | | | | | | | | | | | | | | |
| | Elk hart, Kosciusko, Marshall, Pulaski, & Stark Co: | | | | | | | | | | | | | | | | |
| | Jasper & Newton Co: | | | | | | | | | | | | | | | | |
| | LaGrange Co: | | | | | | | | | | | | | | | | |
| | Forklifts | | | | | | | | | | | | | | | | |
| | Pitch | | | | | | | | | | | | | | | | |

| SHEET METAL WORKERS: | Fringe Benefits Payments | | | | | | Basic Hourly Rates | H & W | Pensions | Vacation | Education/app Tr |
|------------------------|--------------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|
| Jasper, Norton, Pulaski, & Stark Co: | | | | | | | | | | | | | | | | |
| LaGrange Co: | | | | | | | | | | | | | | | | |
| SPRINKLER FITTERS | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | |

| PAID HOLIDAYS: | | | | | | | | | | | | | | | | |
| A-New Year's Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-Christmas Day |

FOOTNOTES:

a 6% for health and welfare includes pension
b 7 paid holidays: A through F, and Day after Thanksgiving Day
c Employer contributes 6% of regular hourly rate to vacation pay credit for employee who has worked in business more than 5 years; 62 for employee who has worked in business less than 5 years
d 6 paid holidays: A through F provided such employees work the last scheduled day prior to and the next scheduled work day after the holiday unless permission for not working on such days is granted by the employer
e 6 paid holidays: A through F
f 6 paid holidays: A through F

| TRUCK DRIVERS | Fringe Benefits Payments | | | | | | Basic Hourly Rates | H & W | Pensions | Vacation | Education/app Tr |
|----------------|--------------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|
| Pick-Ups | | | | | | | | | | | | | | | | |
| Single Axles | | | | | | | | | | | | | | | | |
| Tandems; Fuels | | | | | | | | | | | | | | | | |
| TRICK AXLES | | | | | | | | | | | | | | | | |
| SEMI-TRAILERS | | | | | | | | | | | | | | | | |

FOOTNOTES:

a Per week per employee
b 1 week's paid vacation for 3 years' service, 2 weeks' paid vacation for 10 years' service & 5 weeks' paid vacation for 20 years' service.

FEDERAL REGISTER, VOL. 43, NO 146—FRIDAY, JULY 28, 1978
### DECISION NO. INTL-2066

#### LABORERS

**Elkhart, Kosciusko, LaGrange, & Marshall Counties**

<table>
<thead>
<tr>
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**Jasper & Newton Counties**

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**Pulaski County**

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**Stark County**

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<tr>
<td>GROUP III</td>
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<tr>
<td>GROUP IV</td>
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<td>50</td>
<td>09</td>
</tr>
</tbody>
</table>

**GROUP I:** Building & Construction laborers; Scaffold builders (other than for masons or plasterers); Ironworker helpers; Mechanic helpers; Civil engineer helpers & surveyor helpers; Rodman & Lineman; Window washers & Cleaners; Waterboy & Toolroommen; Roofer's helpers; Railroad workers; Masonry wall washers (interior & exterior); Cement finisher helpers; Carpenter helpers; Helpers of all other crafts not listed; Mason tenders for Areas 1, IA, IB, and Counties of Adams, Allen, Decatur, Steuben, Huntington, Noble, Wabash, Wells, & Whitley. All portable water pumps with discharge up to 3 inches.

**GROUP II:** Waterproofing: Handling of creosote lumber or like treated material (excluding railroad material); Asphault workers & lumpen; Rutemen; Air tool operators, vibrators, chipping hammer operators and all pneumatic tool operators; Earth compactors; Haulmen & shovermen working ditches deeper than 6 ft in depth; Laborers working ditches 6 ft. in depth or deeper; Assembly of Undercut pump; Chain saw operators; Tile layers (cover or field) & cover pipe layers (metallic or non-metallic); Motor driven wheelbarrows & concrete bunkies; Oyster operators; Pump crete assemblers; Conveyor assemblers; Core drill operators; Cement, lime or silica Clay handers (bulk or bag); Handling of toxic materials damaging to clothing; Pneumatic spitters; Back engine & winch operators; Water main & cable laying (metallic & non-metallic)

**GROUP III:** Plasterer's tenders; Mason tenders, except for Areas 1, IA, IB, and Counties of Adams, Allen, Decatur, Steuben, Huntington, Noble, Wabash, Wells, & Whitley; Mortar mixers; Valders (asphaltic or electric); Cutting torch or burner; Concrete mixer laborers; Cement gun operators; Scaffold builders when working for plasterers; Scaffold builders when working for masons (except in Areas 1, IA, IB, and Counties of Adams, Allen, Decatur, Steuben, Huntington, Noble, Wabash, Wells, & Whitley)

**GROUP IV:** Dynamite men
TABLE 7

POWER EQUIPMENT OPERATORS

<table>
<thead>
<tr>
<th>Group</th>
<th>Basic Hourly Rates</th>
<th>Hourly Fringe Benefit Payments</th>
<th>Fringe Benefit Payments</th>
<th>Education and/or App. Tr.</th>
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<td>Group II</td>
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<td>65 85 60 60</td>
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<tr>
<td>Group III</td>
<td>1 2 3 4</td>
<td>65 85 60 60</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group IV</td>
<td>4 7 10 15</td>
<td>65 85 60 60</td>
<td></td>
<td></td>
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</tbody>
</table>

CLASSIFICATIONS

Group I: All power cranes; truck cranes; Locomotive cranes; LeTourneau tower cranes; ladders; derricks; pipe drivers; lift gates; fork lift trucks 18' 6" in height or over; water pumps; combination backhoe & loader; mechanic; conveyor systems; hoist (5 drum) & over.

Group II: All bulldozers; scrapers; pushers; concrete mixers of more than 10 cu. ft.; capacity; locomotive; rollers; stone crushers; fork lift trucks under 18' 6"; air compressors - 600 cu. ft. & over; combination of gasoline or electric driven welding machine & compressor; engineers operating throttle valve with boiler and compressor for pile driving; concrete pumps; trench machines excluding ditch cutters; calipers; hoist (2 drum)

Group III: Truck winches with frame & power winches; tractor-trailer type; drills & conveyors; small rubber tire end loaders 5 cu. yd. & under; bobcat.

Group IV: Gin poles; scissor derricks & similar hoists; firemen; oilers; one drum hoists; single drum hoist & under 500 cu. ft.; single winch trucks.

NOTICES

GROUP I: Mechanic; asphalt plant; autograde; batch plant; boro (requires two engineers); boiler & throttle valve; cement mixer; central redi mix plant; combination backhoe & loader with backhoe bucket of 1 cu. yd. & over; combination bucket hoist & air compressor; compressor; and throttle; concrete bucket (truck mounted); concrete conveyor; concrete pump over 275 cu. ft.; concrete paver 275 cu. ft. & under; concrete tower; cranes, all; cranes; tower derricks; all derricks; travel; fork lift-all type; fork lift - 10 ton & over; hoists, one, two, and three drum; hoists, two trailer one floor; hydraulic boom truck; locomotive; all pipe drivers and skid rig; pit machines; pre-stress machines; pump cranes and similar types; rock drill (self-propelled); rock drill (truck mounted); all-terrain paver; straddle buggies; tractor with boom & side boom; trenching machine; winch tractors.

CLASS I: Asphalt spreader; hoist; bulldozers; combination backhoe, front-end loader with backhoe bucket, less than 1 cu. yd.; engineer acting as conductor in charge of crew; grader; elevating grader engineer; grading machines; lift gates; shovels or front end loaders; hoists; automatic cranes; drilling machines; hoists; all elevators; hoists; tugs; single drum motor pump; post hole diggers; rollers; all scoops - tractor drawn; stone crushers; tower cranes; tower winches; winch trucks.

CLASS II: Concrete mixer (2 bag & over); conveyor, portable steam generators; tractors, farm & similar type; air compressor small 150 & under (1 to 3 not to exceed a total of 300 ft.); air compressor - large over 150 combination - small equipment operator; fork lift trucks; generators; pumps (1 to 3 not to exceed a total of 300 ft.); pumps, well points; welding machines (less than 5); winches & electric drill winches.

CLASS IV: Heaters, mechanical (1 to 5); oilers & oil tech.
### DECISION NO. IN-62-2666

**Jasper & Newton Counties**

<table>
<thead>
<tr>
<th>TRUCK DRIVERS:</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
<th>Education and/or Appr Tr</th>
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<tr>
<td>Pickup trucks</td>
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<td>H &amp; W</td>
<td>Pensions</td>
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<tr>
<td></td>
<td>57 6h</td>
<td>$18 00a</td>
<td>$21 00a</td>
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<tr>
<td>Helpers; Creedens; Tippers</td>
<td>7 7h</td>
<td>19 00a</td>
<td>31 00a</td>
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<tr>
<td>Single axles; Straight trucks; &amp; Warehousesmen</td>
<td>7 79</td>
<td>19 00a</td>
<td>31 00a</td>
</tr>
<tr>
<td>Tandem axles; Dogleg straight trucks</td>
<td>7 89</td>
<td>19 00a</td>
<td>31 00a</td>
</tr>
<tr>
<td>Bituminous Distributors</td>
<td>7 9h</td>
<td>19 00a</td>
<td>31 00a</td>
</tr>
<tr>
<td>Mechanics; Tri-axle; Semi trucks</td>
<td>8 09</td>
<td>19 00a</td>
<td>31 00a</td>
</tr>
</tbody>
</table>

**FOOTNOTES:**
- a Per week per employee
- b Six paid holidays: New Year's Day; Winter Holiday; Independence Day; Labor Day; Thanksgiving; Day; Christmas Day
- c One week's paid vacation after one year's employment; Two weeks' paid vacation after ten years' employment
- d Three weeks' paid vacation after ten years' employment

### MODIFICATIONS P. 1

**DECISION NO. CA-78-5107 - Mod. 81**

(42 FR 29464 - July 7, 1977)

<table>
<thead>
<tr>
<th>Areas</th>
<th>Light Duty</th>
<th>Medium Duty</th>
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<td>1 50a</td>
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**NOTICES:**

- Decision reference numbers on pages 29461, 29462 and 29463 to Decision No. CA-78-5107

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**FEDERAL REGISTER, VOL. 43, NO. 145—FRIDAY, JULY 28, 1978**
### Notices

#### Decision 60378-3608 - Mod. 5

- **District of Columbia; Maryland; Montgomery and Prince Georges; and D.C. Training School; Virginia - Independent City of Alexandria & Arlington**

<table>
<thead>
<tr>
<th>Channel</th>
<th>WATER &amp; SEWER LINES: (District of Columbia and Montgomery County, Maryland) Power Equipment Operators:</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
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<tr>
<td></td>
<td>Backhoes, cable ways, cable drums, dragline rock shovels, tunnel shovels, tunnel mucking machines, derricks, 1 cu yd and over</td>
<td>H &amp; W 35 Pens 45</td>
<td>Vacation 05 Education 05</td>
</tr>
<tr>
<td></td>
<td>Backhoes, cableways, cranes derricks, dragline, tunnel shovels, tunnel mucking machines up to 1 cu yd, booms, elevating graders, hoists, paving mixers, pile driving engines, batch plants concrete pumps</td>
<td>$8.49 35 45</td>
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<tr>
<td></td>
<td>Trenching machines (above 8&quot; 3&quot;)</td>
<td>8.04 35 45</td>
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<tr>
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<td>Projected machines (up to 8&quot; 3&quot;), boilers, only, well drilling machines</td>
<td>8.12 35 45</td>
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</table>

#### Decision 60378-3608 - Mod. 5 S

- **Footnote:**
  - Employer contributes to employees who have worked six (6) months or more, shall be given two and one-half days vacation or the equivalent thereof. All men in the employ of the employer for one (1) year or more shall be given one week's vacation with pay or the equivalent thereof. All men in the employ of the employer three (3) years or more shall be given two (2) week's vacation with pay or the equivalent thereof. All men in the employ of the employer ten (10) years or more shall be given three (3) weeks vacation with pay or the equivalent thereof.

#### Decision 60378-1062 - Mod. 81

- **(63 FR 70055 - July 14, 1998)** Pinellas County, Florida

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<td>7.69 35 45 05</td>
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<td>Sheet metal workers</td>
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**FEDERAL REGISTER, VOL. 43, NO. 146—FRIDAY, JULY 28, 1978**
### Decision 81177-4225-Mod. 84
(42 FR 53000-September 30, 1977)
Black Hawk County, Iowa

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### Decision 81177-4220-Mod. 83
(42 FR 53000-September 30, 1977)
Clinton County, Iowa

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### Decision 81177-4221-Mod. 84
(42 FR 53001-September 30, 1977)
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### Decision 81177-4224-Mod. 85
(42 FR 53020-September 30, 1977)
Cerro Gordo County, Iowa

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### Decision 81177-4223-Mod. 83
(42 FR 53020-September 30, 1977)
Iowa County, Iowa

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### MODIFICATIONS P 5

<table>
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<td>Millwrights 10 68 37 35 00 P/yr</td>
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### MODIFICATIONS P 7

<table>
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<tr>
<th>Decision</th>
<th>Date</th>
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FEDERAL REGISTER, VOL. 43, NO. 146—FRIDAY, JULY 28, 1978
### Modifications P 8

#### Decision E1277-4234-Mod. 83

- **(42 FR 53022—September 30, 1977)**
- Weber County, Iowa

<table>
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<tr>
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### Modifications P 9

#### Decision E1277-4235-Mod. 85

- **(42 FR 53024—September 30, 1977)**
- Woodbury County, Iowa

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</tr>
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<td>With 15 mile radius of Sioux City and all electrical contracts over $300,000</td>
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### Decision E1277-4272-Mod. 86

- **(42 FR 53007—September 30, 1976)**
- Des Moines County, Iowa

<table>
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<td>H &amp; W</td>
<td>Pensions</td>
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<td>Heavy Rates</td>
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</tr>
<tr>
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**FEDERAL REGISTER, VOL. 43, NO. 146—FRIDAY, JULY 28, 1978**
### MODIFICATIONS P 10

**Decision No. HJ78-1001 - Mod. #1**

(A Jul 7, 1978)

Stateville, North Carolina

### Basic Hourly Rates

<table>
<thead>
<tr>
<th>Basic Hourly Rates</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Appr Tr</th>
</tr>
</thead>
</table>

### MODIFICATIONS P 11

**Decision PA77-1172 - Mod. # 7**

(A Jul 11, 1977)

Cumberland, Dauphin, Perry, Juniata, New Cumberland Depot in York County, Pennsylvania

### Basic Hourly Rates

<table>
<thead>
<tr>
<th>Basic Hourly Rates</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Appr Tr</th>
</tr>
</thead>
</table>

**Change:**

Filedrivenon


### MODIFICATIONS P 12

**Decision PP78-1027 - Mod. # 1**

(A Jul 21, 1978)

Blair County, Pennsylvania

### Basic Hourly Rates

<table>
<thead>
<tr>
<th>Basic Hourly Rates</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Appr Tr</th>
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**Add:**

Elevator Constructors

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<tr>
<td>90 98</td>
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Elevator Constructors Helpers

<table>
<thead>
<tr>
<th>Elevator Constructors Helpers</th>
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</thead>
<tbody>
<tr>
<td>7 69</td>
</tr>
</tbody>
</table>

(Prob)

| 5 49                          |

### Footnotes:

a Employers contributes 6% basic hourly rate for 5 years or more of service as vacation pay credit

b Paid Holidays: New Year's Day; Memorial Day; Independence Day; Labor Day; Thanksgiving Day; Christmas Day, plus the Friday after Thanksgiving Day.
<table>
<thead>
<tr>
<th>MODIFICATIONS P 12</th>
</tr>
</thead>
<tbody>
<tr>
<td>MODIFICATIONS P 13</td>
</tr>
<tr>
<td><strong>NOTICES</strong></td>
</tr>
</tbody>
</table>

**CLASSIFICATIONS DEFINITIONS**

**Group A**—General laborers, concrete laborers, carpenter tenders, window and door trimmers, and flagmen on road and street crossings, form strippers, handling of rebar to clean buckets, great men, laborers working on demolition work, hauling, cleaning and pulling of nails from materials.

**Group B**—Paver men helpers, tenders to all travel trades and terramn work, carrying re-inforced steel, operating motorized wheel barrows, dozing and painting of pipe, railroad track laborers, make men on pipe work.

**Group C**—Sanitary and storm pipe layers or any other pipe outside of foundation, grade checkers, yamors, and pot men, steel form setters, mortar mixers, by hand or machine, power saw operators, jackhammer operators, air tool operators, regular air temp operators, molder temp operators, chipper hands, operators, hand operated ditching machine operators, ditching machine operators, concrete grinder, floor sneakup machine operators, concrete buffer and grinder power operators, personne working with concrete pumping machine, vibrator operators, and air spade operators.

**Group D**—Asphalt maker, wagon drill operators, and blasting, track drill operators, concrete saw operators, using cutter torch or burner on demolition work, flagging of work.

**Group E**—Barrow temp operators and specially designed temp operators, block top or concrete curving machine operators, and pavement breaker operators.

**Group F**—Pavement, motorized post hole digger operators and terramn machine grinders.

**Group G**—Pneumatic concrete gun operators and needlesmen.

**Group H**—Tunnel laborers.

**Group I**—Chock tender, top loader on shaft work.

**Group J**—Tunnel miners, including men required to go down in pier hole drilled mines.
## Notices

### SUPREME DECISION

**STATE:** Arkansas, Louisiana, Mississippi and Tennessee  
**Decision No.:** AR78-4074  
**Supersedes Decision No:** AR79-4070, dated June 30, 1978, in 43 FR 28722

**Discussion of Work:** For construction of all rivers, harbors and control work on the Mississippi River and tributaries (excluding the metropolitan areas of Vicksburg, Greenville and Meridian, Mississippi; Pino Balfa, Little Rock and Ft Smith, Arkansas; Windsor, Tennessee and New Orleans, Baton Rouge, Alexandria, Monroe and Shreveport, Louisiana and any contracts for any phases of construction of a lock or dam.)

<table>
<thead>
<tr>
<th>Role</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
<th>Education and/or Apprenticeship</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Carpenters</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td><strong>Laborers</strong></td>
<td></td>
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</tr>
</tbody>
</table>
| **Horse Equipment Operators:**  
  Trolley operator, mechanic (heavy equipment), crane, derrick, drayman, welder, power shovel and backhoes, mixer (concrete, 21 cu ft & over), asphalt plant operator, trenching machine (over 50”) | 6.50 | 0.05 |                                 |
| **Bucket truck (pump, mechanic helper, crane operator, tractor (farm type including disc, plow or roller)** | 4.50 | 0.05 |                                 |
| **Truck Drivers:**  
  1/4 tons or less | 3.50 | 0.05 |                                 |
| **Over 1/4 tons** | 4.00 | 0.05 |                                 |

### ASBESTOS WORKERS

<table>
<thead>
<tr>
<th>Role</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
<th>Education and/or Apprenticeship</th>
</tr>
</thead>
</table>
| **Boilermakers; Stonemasons:**  
  Zone B (0-15 miles from Tacoma) | 11.50 | 1.00 | 0.75 | 0.02 |  
| **Asbestos; Drywall Applicator** | 11.50 | 0.85 | 0.55 | 0.02 |  
| **Cement Masons** | 10.25 | 0.85 | 0.55 | 0.05 |  
| **Electricians:**  
  Zone A (0-15 miles from City Hall in Tacoma) | 9.35 | 0.45 | 0.30 | 1/2h |  
| **Glazers** | 9.42 | 0.70 | 0.30 | 0.01 |  
| **Insulators** | 11.48 | 1.24 | 1.22 | 0.08 |  

### LOCATION

**State:** Arizona  
**County:** Pima  
**Decision No.:** AZ78-5116  
**Supersedes Decision No:** AZ77-5026, dated June 17, 1977, in 43 FR 31570

**Description of Work:** Residential Construction (consisting of single family homes and garden type apartments up to and including 4 stories)

<table>
<thead>
<tr>
<th>Role</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
<th>Education and/or Apprenticeship</th>
</tr>
</thead>
</table>
| **Asbestos Workers:**  
  Zone B (30-60 miles from Tacoma) | 9.78 | 0.35 | 0.40 | 0.02 |  
| **Marble Cutters; Terrazzo Workers; Tile Setters** | 10.78 | 0.35 | 0.40 | 0.05 |  

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**Federal Register, Vol. 43, No. 146—Friday, July 28, 1978**
PLUMBERS; STONECUTTERS
FREE ZONE: 0-15 MILES
The "Free Zone" (Zone I shall
be 15 miles radius from the
stated base point in Flagstaff,
Yuma, Tucson and Douglas. The
"Free Zone" from Phoenix shall
be 15 miles radius from the
stated base point. In addition,
all areas within the City limits
of Phoenix, Chandler, Scottsdale,
Tempe, Glendale, Mesa, Kingman,
Havasu City, Prescott, Wicken
and Holbrook will be included
as Free Zones). Any work con-
tacted from outside of these
zones will be determined from
the Phoenix and Tucson basing
points.

ROOFERS:
Zone A (0-44 miles from Tucson)
Zone B (over 44 miles from
Tucson)

DIRECT RUSTIC WORKERS:
Zone A (0-22 miles from Tucson)
Zone B (22-45 miles from Tucson)
Zone C (over 45 miles from Tucson)

SOFT FLOOR LAYERS:

OFRICHER FITTERS:

TELEPHONE SETTERS;

WAREHOUSE:

SCHEDULE:
A Employer credits 44 basic hourly rate of
employee with over 5 years' service, 6
paid holidays, A through F.

PAID HOLIDAYS:
A New Year's Day; B-Memorial Day; C-Independence Day;
D-Labor Day; E-Thanksgiving Day; F-Christmas Day.

FEDERAL REGISTER, VOL. 43, NO. 146—FRIDAY, JULY 28, 1978
### LABORERS

<table>
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<tr>
<th>Group</th>
<th>Basic Hourly Rates</th>
<th>H &amp; W</th>
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<th>Vacation</th>
<th>Education and/or Appr Tr</th>
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<tr>
<td>Group 2</td>
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### POWER EQUIPMENT OPERATORS

(Except Pile driving & Steel Erection)

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<th>Basic Hourly Rates</th>
<th>H &amp; W</th>
<th>Pensions</th>
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### TRUCK DRIVERS

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<td>Group 0C</td>
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<td>65</td>
<td>06</td>
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</tbody>
</table>

### DECISION NO A778-5116

**NOTICES**

**LABORERS**

Group 1: All Helpers not herein separately classified; Constpool; Diggers and installers; Chat Box Hand; Checker, tool dispatchers; Concrete dump manhole, pipe and/or hoonan; Dumper and/or spotter; Fence builder, guard rail builder highway; Fonn strippers; Labor, general or construction; Landscape gardener and nurseryman; Paving road steel and pans; Hip rap stonemason; Astro turf layer; Cleanup, Bull gang; Trackmen-railroad

Group 2: Cement finisher tender; Concrete curer (Impervious membrane); Cutting torch operator; Fine grader (highway, engineering and sewer work only); Kettlem - Farm; Power type concrete buggy

Group 3: Hand; Chucktender (except tunnel); Crushcrete tiler; Guinea chaser; Powderman helper; Hip-rap stone paver; Sandblaster (pot tender); Spiker and wrenchers

Group 4: Cement dumpers (Skip-type mixer or handling bulk cement); Chain saw machine (on clearing and grubbing); Concrete vibrating machines; Grader and shoveler (except tunnel); Floor sanders; concrete; Hydraulic jacks, and similar mechanical tools not separately classified herein; Operators and tenders of pneumatic and electric tools; Pipe caulkers and/or backup man (piping); Pipe wrappers; Pneumatic gopher; Rigger/Signalmann (pipelining)

Group 5: Air and water wash-out nosesman; Asphalt rakers and fromers; Driller; Grade setter (pipelining); Hand guided trenched and similar operated equipment; Jackhammer and/or pavement breakers; Pipelayern (including but not limited to non-metallic, translucent and plastic pipe, water pipe, sewer pipe, drain pipe, underground tile and conduit); Rock splinter; Solder (using Bes'n'chaire or safety bolt); Tampers (mechanical - all types); Pneumatic manhole erectors

Group 6: Concrete Cutting Torch; Concrete saw (hand guided); Driller, (core, diamond, wagon or air track); Drill doctor and/or air tool repairsman; Gunman and inliner (pavement); Sandblaster (nozesman)

Group 7: Concrete Road Form Setter; Gunite nozseeman or roodman; Drillers, Joy Mustang, PH 143, 200 Gardner-Denver, Hydramatic; Powderman; Solder (drillers); Welders and/or pipe layers installing process pipes; Form setter and/or builder
POWDER EQUIPMENT OPERATORS
(Except Piledriving and Steel Erction)

Group 1: Air compressor operator; Field equipment servicer; helper; Heavy duty repair helper; Heavy duty welder helper; Oilers; Pump operator

Group 2: Conveyor operator; Generator operator—portable power grizzly operator; Self-propelled chip spreading machine—conveyor operator; Watch fireman; Welding machine operator—gasoline and diesel power

Group 3: Concrete mixer operator—skid type; Dinky operator—(under 20 tons wt.); Driver-motor paver, Slurry seal machine, and similar type equipment; Motor crane driver—Power paver operator—Self-propelled; Nose carrier or Dock lift operator; Skip loader operator—all types with rated capacity 1-1/2 cu yds or less; Wheel-type tractor operator (Ford, Ferguson, or similar type) with attachments such as seeder, push blade, push hoist, auger, mower, etc., excluding compaction equipment

Group 4: A-frame boom truck or Winch truck operator; Asphalt plant fireman; Elevator hoist operator (including Turkish hoist or similar type); Grade checker (excluding civil engineer); Multiple paver concrete saw operator; Pavement breaker, mechanical compactor operator, power propelled; Roller operator—all types except as otherwise classified; Seeding operator; Self-propelled chip spreading machine operator (including Slurry seal machine operator); Stationary pipe welding and cleaning machine operator; Tagger operator

Group 5: Aggregate plant operator (including crushing, screening and sand plants, etc.); Asphalt plant mixer operator; Bolteller machine operator; Concrete machine operator; Concrete mechanical paver, spreading or finishing machine (including Czech, Johnson or similar type); Concrete pump operator; Concrete batch plant operator, all types and sizes; Conductor, brake man, or handline; Drilling machine, including water wells; Elevating grader operator—all types and sizes (except as otherwise classified); Field equipment servicer; Highline cableway signalman; Kalman belt loader operator or similar, with belt width 48" or over; Locomotive engine operator—Operating engineer—skid type; Pneumatic-tired scraper operator (Turnbull, Euclid, Cat, D-N, Hancock and similar equipment) up to and including 12 cu yds.; Power shovel and similar type equipment operating engineer; Pneumatic-tired scraper operator (as used in heavy engineering construction); Road oil mixing machine operator; Roller operator—all types asphalt surfacing; Self-propelled compactor, with blade; Skip loader operator—all types with rated capacity over 1-1/2 but less than 4 cu yds.; Skip shovel operator (power driven lifting device for concrete forms); Soil compacting road mixing machine operator—single pass type; Stationary Central generating plant operator—rated 300 K.W. or more; Surface heater and planer operator; Traveling pipe welding machine operator

Group 5: All types (including Hole, Badger and similar type); Concrete mixer operator—paving type; and mobile mixer; Concrete pump operator with boom attachment (truck mounted); Crane operator—crawler and pneumatic type, under 100 ton capacity HSC; Crawler type tractor operator—(with boom attachment); Derrick operator; Forklift operator for hoisting personnel; Grade-all operator; Helicopter hoist; Highline cableway operator (less than 20 tons rated capacity); Hose excavator operator (150 Burycon Erie and similar types); Mechanical hoist operator (two or more drums); Motor grader operator—any type power blade; Motor grader operator with elevating grader attachment; Pneumatic-tired tractor operator; Power-driven crane operator; Pneumatic-tired crane operator—(portable, stationary or skid rig); Pneumatic-tired scraper operator—all types and sizes (Turnbull, Euclid, Cat, D-N, Hancock and similar equipment over 45 cu yds.; Nuclear) Power driven ditch lining or ditch trimming machine operator; Skip loader operator—all types with rated capacity 4 cu yds.; but less than 6 cu yds.; Skip form giving machine operator (including Concrete, Zimmerman and similar types); Specialized power digger operator (attached to wheel-type tractor); Tower crane (or similar type) operator; Tractor operator (Pusher, Bulldozer, Scraper (400 net horsepower and over)); Tagger operator (two or more); Universal equipment operator—(Shovel, Backhoe, Dragline, Channell, etc. up to 6 cu yds.

Group 7: Crane operator—pneumatic or crawler (100 ton hoisting capacity and over 125 rating); Helicopter pilot—P.A.A. qualified when used in construction work; Highline cableway operator, over 20 ton rated capacity and using traveling head and tail tower; Remote control earth moving equipment operator; Skip loader operator—all types with rated capacity of 6 cu. yds. or more; Universal equipment operator—Shovel, Backhoe, Dragline, Channell, etc., 6 cu yds. and over.

NOTICES

FEDERAL REGISTER, VOL. 43, NO. 146—FRIDAY, JULY 28, 1978
TRUCK DRIVERS

Group 1: Teamsters; Pickups; Station Wagons; Hanahul driver

Group 2: Dump or flatrack (2 or 3 axle); Water truck (under 2500 gallons); Ditcher (1 cu yd or less); Tiresman; Bus drivers, ambulance driver, self-propelled street sweeper; Warehouseman

Group 3: Dump or flatrack (4 axle); Dumper or dumper (less than 7 cu yds); Water truck (2500 gallons but less than 4000 gallons)

Group 4: Dumper or dumper (7 cu yds but less than 16 cu yds); Dump or flatrack (5 axle); Water truck (4000 gallons and over); Shuttle type equipment or loader; Flusher spreader or similar type equipment or loader; Tarp (2 axles or less)

Group 5: Dump or flatrack (6 axle); Transit mix (over 2 cu yds but less than 10 cu yds); Rock truck (i.e., Rock, Euclid and other similar types); Concrete pump (when integral part of transit mix truck); Dump or flatrack (7 axle)

Group 6: Transit mix (over 10.5 cu yds but less than 16 cu yds); Crane Carrier; Fork lift or lift truck; Hydro lift; Swedish crane (Zone 300 and similar types); Concrete pump (when integral part of transit mix truck); Dump or flatrack (8 axle)

Group 7: Dump or flatrack (8 axles)

Group 8: Off-highway equipment driver including but not limited to: 2 or 4 wheel power unit, 1.o., Cat, DH Series, Euclid; International and similar type equipment, transporting material when top loaded or by external means including pulling water tanks, fuel tanks or other applications under Teamster Classifications; Rock trucks (Dart, Euclid, or other similar and dump types); 16 cu yds and over; Excavator; Dumper or dumper (16 cu. yds and over); Dump or flatrack (9 axles)

Group 8A: Heavy duty mechanic/welder; Body and fender man

Group 8B: Field equipment service man or fuel truck driver

Group 8C: Heavy duty mechanic/welder helper

SUPERSIDEGAS DECISION

STATE: Arizona
COUNTY: Maricopa
Decision Number: 3-275-5115
Decision Number: A-277-5025 dated June 17, 1977, in 42 FR 51065
Description of works: Residential Construction (consisting of single family homes and garden type apartments up to and including 4 stories)

<table>
<thead>
<tr>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
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<tbody>
<tr>
<td></td>
<td>M &amp; W</td>
</tr>
<tr>
<td>ARABITOS WORKERS</td>
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</tr>
<tr>
<td>13.50</td>
<td>1.07</td>
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<tr>
<td>BOILERSMEN S:</td>
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<tr>
<td>Zone A (0-25 miles)</td>
<td>11.77</td>
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<tr>
<td>Zone B (25-40 miles)</td>
<td>12.71</td>
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<tr>
<td>Zone C (40-70 miles)</td>
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<td>Zone D (70-100 miles)</td>
<td>13.30</td>
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<td>Zone E (100-200 miles)</td>
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<td>Zone F (200 miles and over)</td>
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<td>CARPENTERS:</td>
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<td>9.78</td>
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<td>CEMENT MASON:</td>
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<td>10.00</td>
<td>0.44</td>
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<td>DRYWALL:</td>
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<tr>
<td>10.22</td>
<td>0.85</td>
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<td>DRYWALL (from Courthouse in Phoenix, Mesa, including Williams AFB and Luke AFB):</td>
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<td>Zone A (0-40 miles)</td>
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<tr>
<td>Zone B (41-60 miles)</td>
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<td>Zone C (61 miles and over)</td>
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<td>Texture Spraymen:</td>
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<td>Zone B (41-60 miles)</td>
<td>10.81</td>
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<tr>
<td>Zone C (61 miles and over)</td>
<td>12.06</td>
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FEDERAL REGISTER, VOL. 45, NO. 146—FRIDAY, JULY 28, 1978
### ELECTRICIANS

Zone A (beginning at the northeast corner, a line extending southward on Bush Highway to McKellips Road; a line extending east on McKellips Road to a point one mile east of the intersection of State Highway 88 and U S 60 and 70 near Apache Junction; southward to Baseline Road; west on Baseline Road to the intersection of Baseline Road and Ellsworth Road; South on Ellsworth Road to Hunt Highway; west on Hunt Highway to Pecos Road; a line extending south on Pecos Road five miles, then extending straight west to a point five miles west of Interstate 10; then northeast on a line parallel with Interstate 10 to intersect with Pecos Road; west on Pecos to intersect with Cotton Lane; north on Cotton Lane to Bolsa Road; west on Bolsa Road to Airport Road; north on Airport Road in a straight line to intersect Waddell Road; east on Waddell Road to intersect with Cotton Lane; north on Cotton Lane to Deer Valley Drive and east on Deer Valley Drive to intersection with Bush Highway and including Luke and Williams Air Force Base.)

<table>
<thead>
<tr>
<th>Basic Hourly Rates</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Appr Tr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electricians</td>
<td>$12.70</td>
<td>96</td>
<td>34% 80</td>
<td>2/4th</td>
</tr>
<tr>
<td>Cable Splicers</td>
<td>12.64</td>
<td>.95</td>
<td>34% 80</td>
<td>2/4th</td>
</tr>
</tbody>
</table>

### ELECTRICIANS (Cont'd)

Zone B (area outside of Zone A and bounded by a line formed by measuring sixteen (16) road miles from the outer boundary of an area enclosed by the following boundaries: Power Road on the east from Hunt Highway on the south to one mile south of Pinnacle Peak Road on the north. One mile south of Pinnacle Peak Road to Cotton Lane on the west, Cotton Lane to Pecos Road on the south. Pecos Road to Price Road and from Price Road to Hunt Highway on the south Hunt Highway to Pecos Road on the east.)

<table>
<thead>
<tr>
<th>Basic Hourly Rates</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Appr Tr</th>
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<td>96</td>
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<td>14.05</td>
<td>96</td>
<td>34% 80</td>
<td>2/4th</td>
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### ELECTRICIANS (Cont'd)

Zone C (outside edge of Zone B and extend to the outside limits of the Union's jurisdiction.)

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<th>Basic Hourly Rates</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
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<td>96</td>
<td>34% 80</td>
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### ELECTRICIANS (Cont'd)

ELEVATOR CONSTRUCTORS' HELPERS

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<th>Vacation</th>
<th>Education and/or Appr Tr</th>
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</table>
| $11.75 | 74% 56 | 34% 80 | 02%

### ELECTRICIANS (Cont'd)

ELEVATOR CONSTRUCTORS' HELPERS (POSS.)

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<th>Basic Hourly Rates</th>
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<th>Vacation</th>
<th>Education and/or Appr Tr</th>
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| $10.20 | 74% 56 | 34% 80 | 02%

### ELECTRICIANS (Cont'd)

GLASSERS

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<th>Vacation</th>
<th>Education and/or Appr Tr</th>
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</table>
| $9.42 | 70 | 20 | 01

### ELECTRICIANS (Cont'd)

IRONWORKERS

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<th>Vacation</th>
<th>Education and/or Appr Tr</th>
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</thead>
</table>
| $11.40 | 1.24 | 2.22 | .08

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**NOTICES**
### Notices

#### Painters:

<table>
<thead>
<tr>
<th>Zone A (0-40 miles from Court House in Phoenix, Mesa and including Luke and Williams Air Force Bases)</th>
<th>Basic Hourly Rates</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Appr Tr</th>
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</thead>
<tbody>
<tr>
<td>Brush; Stripers</td>
<td>$9.85</td>
<td>60</td>
<td>40</td>
<td>0.08</td>
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<tr>
<td>Spray; Paperhangers</td>
<td>$12.10</td>
<td>60</td>
<td>40</td>
<td>0.08</td>
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<tr>
<td>Zone B (41-60 miles from Court House in Phoenix)</td>
<td>10.85</td>
<td>60</td>
<td>40</td>
<td>0.08</td>
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<tr>
<td>Brush; Stripers</td>
<td>11.10</td>
<td>60</td>
<td>40</td>
<td>0.08</td>
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<tr>
<td>Spray; Paperhangers</td>
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<td>60</td>
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<td>Zone C (61 and over from Court House in Phoenix)</td>
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<td>Brush; Stripers</td>
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<td>0.08</td>
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<td>85</td>
<td>0.08</td>
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**Plasterers (Northern 1/4 of County):**

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<th>Zone A (0-35 miles from Phoenix)</th>
<th>Basic Hourly Rates</th>
<th>H &amp; W</th>
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<th>Vacation</th>
<th>Education and/or Appr Tr</th>
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<tr>
<td>9.045</td>
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<td>85</td>
<td>0.035</td>
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<td>Zone B (35-60 miles from Phoenix)</td>
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<td>0.035</td>
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<td>0.035</td>
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**Plasterers (Southern 1/4 of County):**

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<td>Zone C (40-50 miles from Tucson)</td>
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<tr>
<td>Zone D (50 miles and over from Tucson)</td>
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<td>60</td>
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**Plasterers' Tenders:**

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<tr>
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<th>Vacation</th>
<th>Education and/or Appr Tr</th>
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<td>9.16</td>
<td>85</td>
<td>95</td>
<td>10</td>
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### Plumbers; Steamfitters:

**FREE ZONE 0-15 MILES**

The "Free Zone" (Zone I) shall be 15 road miles from the stated base points in Flagstaff, Yuma, Tucson and Douglas. The "Free Zone" from Phoenix shall be 15 mile radius from the state base point. In addition, all areas within the City limits of Phoenix, Chandler, Scottsdale, Tempe, Glendale, Mesa, Kingman, Havasu City, Prescott, Winslow and Holbrook will be included as Free Zones. Any work contracted from outside of these zones will be determined from the Phoenix and Tucson busing points.

<table>
<thead>
<tr>
<th>Zone</th>
<th>Basic Hourly Rates</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Appr Tr</th>
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<tbody>
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<td>1.35</td>
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<tr>
<td>Zone II (30-40 miles)</td>
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<td>75</td>
<td>1.35</td>
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<tr>
<td>Zone III (40-60 miles and over)</td>
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**Roofers:**

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<th>Education and/or Appr Tr</th>
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<tr>
<td>9.66</td>
<td>845</td>
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**Sheet Metal Workers:**

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<th>Basic Hourly Rates</th>
<th>H &amp; W</th>
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<th>Vacation</th>
<th>Education and/or Appr Tr</th>
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<tr>
<td>Zone II (25-50 miles including Luke and Williams ABF)</td>
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<td>30+</td>
<td>80</td>
<td>1.30</td>
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<tr>
<td>Zone III (50 and over)</td>
<td>11.48</td>
<td>30+</td>
<td>80</td>
<td>1.30</td>
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**Sofft Air Ducts:**

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<th>Education and/or Appr Tr</th>
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**Sprinkler Fitters:**

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<tr>
<th>Basic Hourly Rates</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
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### Notes:

- Employer contributes 4% of basic hourly rate for 6 months to 5 years' service as Vacation Pay Credit. Six Paid Holidays:
  - New Year's Day
  - Memorial Day
  - Labor Day
  - Thanksgiving Day
  - Christmas Day
  - Independence Day

FEDERAL REGISTER, VOL. 43, NO. 146—FRIDAY, JULY 28, 1978
### LABORERS

<table>
<thead>
<tr>
<th>Group</th>
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<th>Fringe Benefits Payments</th>
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### POWER EQUIPMENT OPERATORS

(Except Piledriving & Steel Erection)

| Group 1 | 8 60               | 95 95 95 06             |                          |
| Group 2 | 8 97               | 95 95 95 06             |                          |
| Group 3 | 9 43               | 95 95 95 06             |                          |
| Group 4 | 9 56               | 95 95 95 06             |                          |
| Group 5 | 10 09              | 95 95 95 06             |                          |
| Group 6 | 10 30              | 95 95 95 06             |                          |
| Group 7 | 11 13              | 95 95 95 06             |                          |

### TRUCK DRIVERS

| Group 1 | 8 19               | 95 95 95 06             |                          |
| Group 2 | 8 32               | .95 .95 .95 .06         |                          |
| Group 3 | 8 43               | 95 95 95 06             |                          |
| Group 4 | 8 54               | 95 95 95 06             |                          |
| Group 5 | 9 05               | 95 95 95 06             |                          |
| Group 6 | 9 23               | 95 95 95 06             |                          |
| Group 7 | 9 37               | 95 95 95 06             |                          |
| Group 8 | 9 70               | 95 95 95 06             |                          |
| Group 9 | 10 05              | 95 95 95 06             |                          |
| Group 10| 10 35              | 95 95 95 06             |                          |
| Group 11| 10 64              | 95 95 95 06             |                          |
| Group 12| 10 84              | .95 .95 .95 .06         |                          |

### NOTICES

**LADIES**

Group 1: All helpers not herein separately classified; Cookpool; Diggers and installers; Chat box men; Chookers, tool dispatcher; Concrete dump man and/or; Ripped and/or spotter; Fence builder; Guard rail builder; Highway; Pump and oilers; Labor; General or construction; Landscape gardener; Nurserymen; Packing rod steel and pipe; Rip-cap stonemason; Water turf layer; Clean-up, bull gang; Trackman-railroad

Group 2: Cement binder tender; Concrete curar (Immovable membranes); Cutting torch operator; Pipe grader (highway, engineering and sewer work only); Kottamian-Taran; Power type concrete buggy

Group 3: Rando: Chalktender (except tunnel); Creanot's stonemason; Gausa shaper; Powderman helper; Rip-cap stonemason; Sandblaster (pot tender); Spiker and wrenchers

Group 4: Cement dumpers (skip-type mixers or handling bulk cement); Chain saw machines (on clearing and grading); Concrete vibrating machines; Bagger and shaker (except tunnel); Floor sanders; Concrete molding machines; Shovel; and similar mechanical tools now separately classified herein; Operators and tenders of pneumatic and electric tools; Pipe caulker and/or backup man (pipelines); Pipe wrappers; Pneumatic grinders; Rig: (pneumatic (pipelines)

Group 5: Air and water wash-out nozzlemen; Asphalt rakers and ironers; Driller; Grade setter (pipelines); Hand guided trenchers and类似操作者: Sandblaster and/or pavement brokers; Pipelaya (including but not limited to non-metallic, transit and plastic pipe, water pipe, sewer pipe, drain pipe, underground tile and conduits); Rock cutter; Scrapper (using hoist's chains or safety belt); Tarpaulin; (mechanical - all types); Pre-cast manhole excavators

Group 6: Concrete Cutting Torch; Concrete saw (hand guided)

Driller, core, diamond, wagon or air train; Drill doctor and/or air tool repairman; Duncan and mixerman (quintal); Sandblaster (nozzlemen)

Group 7: Concrete Road Worn Setter; Gunite nozzlemen or roadmen; Drillers, Joy Huntong, Fh 1/3, 200 Gardner-Denver, Hydromatlon; Powdermen; Scaler (drillers); Welders and/or pipelayers installing process piping; Form setter and/or builder

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**FEDERAL REGISTER, VOL. 43, NO. 145—FRIDAY, JULY 28, 1978**
POWER EQUIPMENT OPERATORS
(Except Pile Driving and Steel Erection)

Group 1: Air compressor operator; Field equipment service man helper; Heavy duty welder helper; Oilier; Pump operator

Group 2: Conveyor operator; Generator operator — portable; Power grizzly operator; Self-propelled chip spreading machine — conveyor operator; Watch fireman; Welding machine operator — gasoline and diesel power

Group 3: Concrete mixer operator — skip type; Dinky operator — under 20 tons wt.; Driver-note paver, slurry seal machine, and similar equipment; Motor crane operator; Power sweeper operator — self-propelled; Hose carrier or fork lift operator; Slip loader operator — all types with rated capacity 1-1/2 cu. yds or less; Wheel type tractor operator (Ford, Ferguson, or similar type) with attachments such as fireman, push blade, post hole auger, mower, etc., excluding compacting equipment

Group 4: A-frame boom truck or winch truck operator; Asphalt plant fireman; Elevator hoist operator (including Turley hoist or similar type); Grade checker (excluding civil engineer); Multiple power concrete saw operator; Paver paver, mechanical compactor operator; Power paver; Roller operator — all types — except as otherwise classified; Seed operator; Self-propelled chip spreading machine operator (including slurry seal machine operator); Stationary pipe wrapping and cleaning machine operator; Tugger operator

Group 5: Aggregate plant operator (including crushing, screening and sand plants, etc.); Asphalt plant mixer operator; Baler operator; Boring machines operator; Concrete mechanical tamper, spreading or finishing machine (including Clary, Johnson or similar types); Concrete pump operator; Concrete batch plant operator, all types and sizes; Conductor, brakeman, or handler; Drilling machine, including water wells; Elevating grader operator — all types and sizes (except as otherwise classified); Field equipment serviceman; Highline cableway signalman; Rollan belt loader operator or similar, with belt width 48" or over; Locomotive engineer (including Dinky — 20 tons wt. and over); Motor-paver or similar type equipment operator; Operating engineer riggers; Pneumatic-tired scraper operator (Turn- pull, Euclid, Cat, D-9, Hancock and similar equipment) up to and including 12 cu. yds; Power jumbo form setter operator; Pressure grout machine operator (as used in heavy engineering construction); Roll all mixing machine operator; Roller operator — on all types asphalt pavement; Self-propelled compactor, with blade; Slip loader operator — all types with rated capacity over 1-1/2 but less than 4 cu. yds; Slip form operator (power driven lifting device for concrete forms); Soil compact road mixing machine operator — single pass type; Stationary Central generating plant operator — rated 300 K W or more; Surface heater and planer operator; Traveling pipe wrapping machine operator

Group 5-A: Heavy duty mechanic and/or welder; Pneumatic tired scraper, all sizes and types over 12 cu. yds up to and including 45 cu. yds; MHC (Turnpail, Euclid, Cat, D-9, Hancock and similar equipment); Tractor operator (Pusher, Bulldozer, Scraper) up to 400 net horsepower rating; Trenching machine operator

Group 6: Auto-Grader machine (CHI and similar equipment); Boring machine operator (including D-9, Badger and similar type); Concrete Mixer operator — paving type, and mobile mixer; Concrete pump operator with boom attachment (truck mounted); Crane operator — crawler and pneumatic type, under 100 ton capacity MHC; Crawler type tractor operator — with boom attachment; Derrick operator; Forklift operator for hoisting personnel; Grade-all operator; Helicopter hoist; Highline cableway operator (less than 20 tons rated capacity); Hose excavator operator (150 Bueyres Erio and similar types); Mechanical hoist operator (two or more drums); Motor grade operator — any type power blade; Motor grade operator with elevate grader attachment; Mucking machine operator; Overhead crane operator; Pilot — driver engineer (portable, stationary or rigid rig); Pneumatic-tired scraper operator — all sizes and types (Turnpail, Euclid, Cat, D-9, Hancock and similar equipment over 45 cu. yds, MHC); Power driven ditch lining or ditch trimming machine operator; Slip loader operator — all types with rated capacity 4 cu. yds, but less than 6 cu. yds; Slip form paving machine operator (including Gunner, Simonian and similar types); Specialized power digger operator — attached to wheel-type tractor; Power crane (or similar type) operator; Tractor operator (Pusher, Bulldozer, Scraper (400 net horsepower and over)); Tugger operator (two or more); Universal equipment operator — Shovel, Backhoe, Dragline, Clamshell, etc., up to 8 cu. yds

Group 7: Crane operator — pneumatic or crawler (100 ton hoisting capacity and over MHC rating); Helicopter pilot — FAA qualified when used in construction work; Highline cableway operator, over 20 ton rated capacity and using traveling head and tail tower; Remote control earth moving equipment operator; Slip loader operator — all types with rated capacity of 8 cu. yds or more; Universal equipment — Shovel, Backhoe, Dragline, Clamshell, etc., 8 cu. yds and over

NOTICES
TRUCK DRIVERS

Group 1: Tractors; Pickups; Station Wagon; Manhaul driver

Group 2: Dump or flatbed (2 or 3 axle); Water truck (under 2500 gallons); Nuggymobile (1 cu. yd. or less); Tiresman; Bus drivers; ambulance driver, self-propelled street sweeper; Warehouseman

Group 3: Dump or flatbed (4 axle); Dumpton or dumpster (less than 7 cu. yd.); Water truck (2500 gallons but less than 4000 gallons)

Group 4: Dumpton or dumpster (7 cu. yd. but less than 16 cu. yd.); Dump or flatbed (5 axle); Water truck (4000 gallons and over); Slurry type equipment or leverman; Flaherty spreader or similar type equipment or leverman; Transit mix (6 cu. yd. or less)

Group 5: Dumpton or flatbed (6 axle); Transit mix (over 6 cu. yd. but less than 10 5 cu. yd.); Rock truck (i.e. Dart, Euclid and other similar type end dump, single unit less than 16 cu. yd.)

Group 5A: 608 tankers or spreaders and/or foottamp, retortman or leverman

Group 6: Transit mix (over 10 5 cu. yd. but less than 14 cu. yd.); Ross Carrier; Fork lift or lift truck; Hydro lift, Swedish crane Iowa 300 and similar types; Concrete pump (when integral part of transit mix track); Dump or flatbed (7 axle)

Group 7: Dump or Flatbed (8 axle)

Group 8: Off-highway equipment driver including but not limited to: 2 or 4 wheel power units, 1 cu. yd., Cat, EH Series, Euclid, International and similar type equipment, transporting material when top loaded or by external means including pulling water tanks, fuel tanks or other applications under Teamster Classification; Rock trucks (Dart, Euclid, or other similar end dump types) 16 cu. yd. and over; Erect-a-load Dumpster or dumpster (16 cu. yd. and over); Dump or Flatbed (9 axle)

Group 8A: Heavy duty mechanic/welder; Body and fender man

Group 8B: Field equipment service man or fuel truck driver

Group 8C: Heavy duty mechanic/welder helper

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<table>
<thead>
<tr>
<th>DECISION NO</th>
<th>CT78-3055</th>
<th>Fringe Benefits Payments</th>
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| GATHERS | 8 51 | 35 | 20 | 01 | Bridge | 12 00 | 15 | 20 | 00 | Fairfield Co. Bridgeport, E任何人都无法阅读这张图片。
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<td><strong>Steel &amp; Swing stage &amp; boat Trim</strong></td>
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<td>45</td>
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<td><strong>Chair</strong></td>
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<td><strong>Spray</strong></td>
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**FEDERAL REGISTER, VOL. 43, NO. 146—FRIDAY, JULY 28, 1978**
### DECISION NO C78-3055

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<th>Fringe Benefits Payments</th>
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**SHEET METAL WORKER:**
- Fairfield Co., Litchfield Co.
- Windham Co.

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**FILE SETTERS’ HELPERS:**
- Fairfield Co., Burien, Greenwich, Stamford, Norfolk & Westport

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<thead>
<tr>
<th></th>
<th>Base Hourly Rates</th>
<th>Fringe Benefits Payments</th>
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**NOTICES**

**PAID HOLIDAYS:**

- A: New Year's Day
- B: Memorial Day
- C: Independence Day
- D: Labor Day
- E: Thanksgiving Day
- F: Christmas

**FOOTNOTES:**

- a: 7 paid holidays: A, C, D, E, F, Decoration Day, Good Friday.
- b: 1 paid holiday: Good Friday. Employees must work 3 days during the work week in which the holiday falls, if scheduled, and if scheduled, the working day before and the working day after the holiday.
- c: 4 paid holidays: B, C, D, and Good Friday. Employees must be employed 14 consecutive days immediately prior to the holiday.
- d: 3 paid holidays: C, D, and E.
- e: 67 00 per day.
- f: 3 paid holidays: B, C, and D.
- g: The last 4 regular working hours prior to Christmas shall be paid half day.
- h: 6 paid holidays: A through P.
- i: Employer contributes 4% of basic hourly rate for 5 years or more of service or 2% basic hourly rate for 6 months to 5 years of service plus vacation pay credit.
- j: 9 paid holidays: A through P, Washington's Birthday, Good Friday, and Columbus Day.
- k: 9 paid holidays: A through P, Washington's Birthday, Good Friday, and Columbus Day.
- l: The last 4 hours on Christmas Eve is a paid half day if employee has worked 5 consecutive days prior to Christmas Eve.
- m: 9 paid holidays: A through P, Washington's Birthday, Good Friday, and Christmas Eve provided the employee has worked 45 full days for the employer during the 100 days prior to the holiday and is available for work the day preceding and following the holiday.
- n: 24 of the gross electrical labor payroll.
- o: Employer contributes $1.50 per day to a supplemental unemployment fund.
- p: 9 paid holidays: A through P, Washington's Birthday, Good Friday, and a floating holiday per year provided the employee has been employed for a period of 5 working days prior to the holidays and works the scheduled work days immediately preceding and following the holidays.
- q: 1 paid holiday: St. Patrick's Day.
- r: 2 paid holidays: C and D providing the employee works the day before and the day after the holiday.
- s: 4 paid holidays: B, C, D, and E providing the employee works the day before and the after the holiday.
- t: 2 paid holidays: B and D and half day paid holiday the Friday after Thanksgiving and the last working day before Christmas and Good Friday paid half day.
- u: 1 paid holiday: B.
- v: 36 of gross earnings to ESGTI.
<table>
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<tr>
<th>DECISION NO 7C78-3055</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
<th>Education and/or Appr Tr</th>
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<td>Pensions</td>
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</tr>
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<td>(Building Construction)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Derrick; Hoisting engineer 2</td>
<td>11.55</td>
<td>.90</td>
<td>85</td>
</tr>
<tr>
<td>Dredging; Forklift - over 4' lift; Front end loader - Toy or over; Grader; Hoisting engineer (all)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>types of equipment where a drum and cable are used to hoist, pull, motive power or operation; Kneeling booster loader and/or boil master</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mechanism shown; 40 tower crane</td>
<td>11.13</td>
<td>.99</td>
<td>90</td>
</tr>
<tr>
<td>Maintenance engineer</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Central mix operator; Concrete mixer; Concrete pump; Concrete mixing machine; Concrete truck</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>mix plant; Center of interest equipment; combination hop and hoist over 4 1/2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>yard conveyors - regardless of motive power; Front end loader; Joy, up to 7 cy.; Joy drill limited to joy, heavy weigh champion or equivalent; Bucking machines; Post hole digger; Pile driver machine; Hooking machine; Vibratory hammer;</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>welder &amp; welder</td>
<td>10.07</td>
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<tr>
<td>Concrete mixer operator</td>
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<td>.90</td>
<td>85</td>
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<tr>
<td>Bulldozer; Carry-all operator; Grader; &amp; Scraper</td>
<td>10.79</td>
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<tr>
<td>Combination hop and loader</td>
<td>10.74</td>
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<table>
<thead>
<tr>
<th>DECISION NO 7C78-3055</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
<th>Education and/or Appr Tr</th>
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<tbody>
<tr>
<td></td>
<td>H &amp; W</td>
<td>Pensions</td>
<td>Vacation</td>
</tr>
<tr>
<td>Air and steam valve compressor; generator; pump</td>
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<td>85</td>
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<tr>
<td>and well point; welding machine</td>
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<td>85</td>
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<tr>
<td>Fork lift not over 4'; Forklift and mobile hoist</td>
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<td>Mechanical hoist</td>
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<tr>
<td>Roller</td>
<td>10.52</td>
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<tr>
<td>Dinky machine; power pavement breaker</td>
<td>10.36</td>
<td>.90</td>
<td>85</td>
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<tr>
<td>pictures (High pressure)</td>
<td>9.50</td>
<td>.90</td>
<td>85</td>
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<tr>
<td>Oil burner</td>
<td>9.02</td>
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<tr>
<td>Crane with boom, excluding 5lb, over 150' &amp; 8,000; Crane with boom, excluding 5lb, over 200' &amp; 8,000; Construction</td>
<td>95</td>
<td>.90</td>
<td>75</td>
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<tr>
<td>Laborers</td>
<td></td>
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FEDERAL REGISTER, VOL. 43, NO 146—FRIDAY, JULY 28, 1978
### DECISION NO 2776-3055

#### Daily Hourly Rates

<table>
<thead>
<tr>
<th>Laborer</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacations</th>
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<tr>
<td>Laborer</td>
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### Falls Benefits Payments

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<tr>
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<tr>
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### Power Equipment Operators

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<th>Vacations</th>
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<td>11.42</td>
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<td>3</td>
<td>11.08</td>
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<tr>
<td>4</td>
<td>10.88</td>
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<td>5</td>
<td>10.73</td>
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<td>13</td>
<td>9.82</td>
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### Classifications - Power Equipment Operators

<table>
<thead>
<tr>
<th>CLASS</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>Erecting and handling structural steel; front end loader (7yd. or over)</td>
</tr>
<tr>
<td>2</td>
<td>Pile driver; Power shovel and crane; Dragline; Grader; Trenching machine; Lighter derrick; Paver (concrete); Derricks (stiff leg and guy)</td>
</tr>
<tr>
<td>3</td>
<td>Drill (6 ft heavy weight, shank or equivalent); side boom; loader (w/10 l); Mucking machine; Pumps; Rock and earth boring machine; Post hole digger; Wall driller; Hammer (vibratory); Central mix</td>
</tr>
<tr>
<td>4</td>
<td>Asphalt spreader</td>
</tr>
<tr>
<td>5</td>
<td>Front end loader (7yd. or over); Grader; Power stone spreader; Combination boom and loader</td>
</tr>
<tr>
<td>6</td>
<td>Asphalt roller; Bulldozer; Carryall maintenance engineer; Concrete mixer (5 bags and over); Welder</td>
</tr>
<tr>
<td>7</td>
<td>Front end loader (under 7yd.); Rollers; Power chippers; Fork lift; Finishing machine; Asphalt plant; Power pavement breakers; Dinky machine</td>
</tr>
<tr>
<td>8</td>
<td>Compressor; Pump</td>
</tr>
<tr>
<td>9</td>
<td>Fireman (high pressure)</td>
</tr>
<tr>
<td>10</td>
<td>Well point system</td>
</tr>
<tr>
<td>11</td>
<td>Compressor battery</td>
</tr>
<tr>
<td>12</td>
<td>Oiler</td>
</tr>
<tr>
<td>13</td>
<td>Batch plant; Bulk cement plant</td>
</tr>
</tbody>
</table>

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FEDERAL REGISTER, VOL. 43, NO. 146—FRIDAY, JULY 28, 1978
### Notices

**STATE:** Connecticut  
**COUNTIES:** *See Region*  
**DECISION NUMBER:** C78-3055  
**DATE OF PUBLICATION:** February 17, 1978, in 43 FR 7117

**DESCRIPTION OF WORK:** Building construction (excluding single family homes and garden type apartments up to and including 4 stories), heavy (excluding tunnel construction) and highway construction.

<table>
<thead>
<tr>
<th>TRUCK DRIVERS (Building, Heavy and Highway Construction)</th>
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<tbody>
<tr>
<td><strong>CLASS</strong></td>
</tr>
<tr>
<td>-----------</td>
</tr>
<tr>
<td>CLASS 1</td>
</tr>
<tr>
<td>CLASS 2</td>
</tr>
<tr>
<td>CLASS 3</td>
</tr>
<tr>
<td>CLASS 4</td>
</tr>
<tr>
<td>CLASS 5</td>
</tr>
<tr>
<td>CLASS 6</td>
</tr>
</tbody>
</table>

**CLASSIFICATIONS:** TRUCK DRIVERS

- CLASS 1: Two axle trucks; helpers
- CLASS 2: Three axle trucks; two axle ready mix
- CLASS 3: Four axle trucks; heavy duty trailer-up to 40 tons
- CLASS 4: Three axle ready mix
- CLASS 5: Four axle ready-mix; specialized earth moving equipment other than conventional type on-the-road trucks and mini-trailer (including Euclid)
- CLASS 6: Heavy duty trailer-40 tons and over

**PAID HOLIDAYS:**
- A-New Year's Day
- Memorial Day
- Independence Day
- Labor Day
- Thanksgiving Day
- Christmas Day

**FOOTNOTE:**
- a 7 paid holidays: A through P and Good Friday

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**FEDERAL REGISTER, VOL. 43, NO 146—FRIDAY, JULY 29, 1978**
<table>
<thead>
<tr>
<th>DECISION NO</th>
<th>C78-3056</th>
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</thead>
<tbody>
<tr>
<td>Bricklayers (Cont'd):</td>
<td></td>
</tr>
<tr>
<td>S. Windsor, Suffield, Thompsonville, N. Hartford, Middletown, Windsor, Windsor Locks, Tolland Co.;</td>
<td></td>
</tr>
<tr>
<td>Andover, Bolton, Columbia,</td>
<td></td>
</tr>
<tr>
<td>Coventry, Enfield, Haddam,</td>
<td></td>
</tr>
<tr>
<td>Mansfield, Somers, Stafford,</td>
<td></td>
</tr>
<tr>
<td>Storrs, Tolland, Union, Vernon &amp; Willington</td>
<td></td>
</tr>
<tr>
<td>Hartford Co.; Berlin, New</td>
<td></td>
</tr>
<tr>
<td>Britain, Newington, &amp;</td>
<td></td>
</tr>
<tr>
<td>Southington; New Haven Co.; Meriden, Wallingford,</td>
<td></td>
</tr>
<tr>
<td>Cheshire (North of Route 68)</td>
<td></td>
</tr>
<tr>
<td>Hartford Co.; Canton</td>
<td></td>
</tr>
<tr>
<td>10 05</td>
<td>75</td>
</tr>
<tr>
<td>Hingham Co.; &amp; New London Co.</td>
<td></td>
</tr>
<tr>
<td>New Haven Co.; Bethany, Branford, E. Haven, Guilford,</td>
<td></td>
</tr>
<tr>
<td>Hanover, Madison, New Haven, N. Branford, N. Haven, Orange,</td>
<td></td>
</tr>
<tr>
<td>W. Haven, Woodbridge, Ncm of Wallingford</td>
<td></td>
</tr>
<tr>
<td>New Haven Co.; Ansonia, Derby,</td>
<td></td>
</tr>
<tr>
<td>Oxford, Seymour &amp; Southbury</td>
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</tr>
<tr>
<td>Hartford Co.; Bristol, Plainville, New Haven Co.,</td>
<td></td>
</tr>
<tr>
<td>Beacon Falls, Middletown, Haddam,</td>
<td></td>
</tr>
<tr>
<td>Naugatuck, Prospect,</td>
<td></td>
</tr>
<tr>
<td>Waterbury &amp; Wolcott</td>
<td></td>
</tr>
<tr>
<td>New Haven Co.; Milford (West of Indian River to the Orange</td>
<td></td>
</tr>
<tr>
<td>Town line)</td>
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<tr>
<td>10 05</td>
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<tr>
<td>Bricklayers (Heavy &amp; Highway Construction):</td>
<td></td>
</tr>
<tr>
<td>Carpenters; Millwrights; Pile-</td>
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</tr>
<tr>
<td>Driver/Drainage Resilient Floor Laying; (Building Construction)</td>
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</tr>
<tr>
<td>Hartford Co.; Hartford, West</td>
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</tr>
<tr>
<td>Hartford, Avon, Farmington,</td>
<td></td>
</tr>
<tr>
<td>Simsbury, Bloomfield,</td>
<td></td>
</tr>
<tr>
<td>Windsor, East Granby, Granby,</td>
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<tr>
<td>Windsor Locks, Suffield,</td>
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</tr>
<tr>
<td>Enfield, East Windsor, South</td>
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<tr>
<td>Windsor, East Hartford, Nor-</td>
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<table>
<thead>
<tr>
<th>DECISION No</th>
<th>C78-3056</th>
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</thead>
<tbody>
<tr>
<td>Chester, Glastonbury, Rocky</td>
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</tr>
<tr>
<td>Hill, Westerfield, Hartford;</td>
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<tr>
<td>Tolland Co.; Stafford, Somers,</td>
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<tr>
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<td>Plainville, Burlington, Canton,</td>
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<tr>
<td>Bristol; New Haven Co.; Meriden,</td>
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<td>also north of Route 1 and east</td>
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</tr>
<tr>
<td>Waterbury, Wolcott, Middlebury,</td>
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<tr>
<td>Bethany, Beacon Falls, Wood-</td>
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<tr>
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<tr>
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<tr>
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<td>that part west of Orange Center</td>
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<tr>
<td>Rd and south of Route 1, and</td>
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<td>that part south of Route 1 and</td>
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<tr>
<td>Seymour</td>
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### DECISION No. CT78-3056

<table>
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<td>Berlin, Bristol, New Britain, Newington, Plainville &amp; Southington</td>
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<td>Suffield &amp; Enfield (portion of Thompsonville West of George Washington Road and North of Hazard Ave)</td>
</tr>
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<td>Hartford, New Haven Co., Beacon Falls, Middlebury, Naugatuck, Oxford, Prospect, Seymour, Southbury, Waterbury &amp; Wolcott</td>
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<td>Hartford Co.:</td>
<td>Wolcott of Co.</td>
</tr>
<tr>
<td><strong>Caterers:</strong></td>
<td>Hartford Co.; Bristol, Southington; New Haven Co., Beacon Falls, Bethany, Cheshire, Meriden, Middlebury, Naugatuck, Oxford, Prospect, Southbury, Waterbury &amp; Wolcott</td>
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</table>

<table>
<thead>
<tr>
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<td>Pensions</td>
<td>Vacation</td>
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**Notice:**

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<th>Education and/or Appr Tr</th>
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<tr>
<td>9</td>
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**Masons:**


**Ironworkers:**


**Caterers:**


**Ironworkers:**


**Caterers:**

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FEDERAL REGISTER, Vol. 43, No. 146—Friday, July 28, 1978
### Notices

#### Decision No: C78-3056

**Basic Hourly Rates**

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**FEDERAL REGISTER, VOL. 43, NO. 146—FRIDAY, JULY 28, 1978**

### Footnotes:

- a. 7 paid holidays: A through F and Good Friday
- b. 6 paid holidays: Good Friday, Good Friday
- c. 4 paid holidays: B, C, D, Good Friday
- d. 3 paid holidays: C, D, and E
- e. § 50 per worker per year
- f. 3 paid holidays: D, C, and D
- g. The last 4 regular working hours prior to Christmas Day shall be paid half day
- h. 6 paid holidays: A through F
- i. Employer contributes 48 of base hourly rate for 5 years of more of service or 36 basic hourly rate for 6 months to 5 years of service as vacation pay credit
- j. 9 paid holidays: A through F, Washington's Birthday, Good Friday, and Columbus Day
- k. 9 paid holidays: A through F, Washington's Birthday, Good Friday, and Columbus Day
- l. The last 4 hours on Christmas Eve is a paid half day if employee has worked 5 consecutive days prior to Christmas Eve
- m. 9 paid holidays: A through F, Washington's Birthday, Good Friday, and Columbus Day
- n. Employer has worked 45 full days for the employer during the 120 days prior to the holidays and works the scheduled work days immediately preceding and following the holidays
- o. 9 paid holidays: A through F, Washington's Birthday, Good Friday, and Columbus Day
- p. Employer contributes 48 of base hourly rate for 5 years of more of service or 36 basic hourly rate for 6 months to 5 years of service as vacation pay credit
- q. Employer has worked 45 full days for the employer during the 120 days prior to the holidays and works the scheduled work days immediately preceding and following the holidays
- r. 9 paid holidays: A through F, Washington's Birthday, Good Friday, and Columbus Day
- s. Employer has worked 45 full days for the employer during the 120 days prior to the holidays and works the scheduled work days immediately preceding and following the holidays
- t. 9 paid holidays: A through F, Washington's Birthday, Good Friday, and Columbus Day
- u. Employer has worked 45 full days for the employer during the 120 days prior to the holidays and works the scheduled work days immediately preceding and following the holidays
- v. Employer has worked 45 full days for the employer during the 120 days prior to the holidays and works the scheduled work days immediately preceding and following the holidays
- w. Employer has worked 45 full days for the employer during the 120 days prior to the holidays and works the scheduled work days immediately preceding and following the holidays
- x. 9 paid holidays: A through F, Washington's Birthday, Good Friday, and Columbus Day
- y. Employer has worked 45 full days for the employer during the 120 days prior to the holidays and works the scheduled work days immediately preceding and following the holidays
<table>
<thead>
<tr>
<th>DECISION NO: CP78-3056</th>
<th>Fringe Benefits Payments</th>
<th>Basic Hourly Rates</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Apprenticeship</th>
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<tbody>
<tr>
<td><strong>POWER EQUIPMENT OPERATORS:</strong> (BUILDING CONSTRUCTION)</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>Derrick; Holster; engineer 2, drum and over; Holster; structural steel; Pile driver; &amp; Setting stone</td>
<td>11 55</td>
<td>90</td>
<td>85</td>
<td>a</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>Dragline; Fork lift - over 4' lift; Front end loader - 7 cy or over; Gradall; Holster; engineer (all types of equipment whose a drum and cable are used to hoist, pull, or drag material regardless of motive power or operation); Hoisting motor loader and/or hoist; master mechanics; shovel &amp; tower crane</td>
<td>11 43</td>
<td>90</td>
<td>85</td>
<td>a</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>Maintenance engineer; Central mix operator; Coleman loader and screening plant or similar equipment; combination hoe and loader over 4 yd; Conveyors - regardless of motive power; Front end loader - 3 cy up to 7 cy; High pressure portable boiler; Joy drill - limited to low weight; Champion or equivalent; mucking machines; post hole digger; pugmills machine; rock boring machine; vibratory hammers; welder; &amp; Well digger</td>
<td>11 07</td>
<td>90</td>
<td>85</td>
<td>a</td>
<td>10</td>
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</tr>
<tr>
<td>Compressor; Battery operator; Air compressor; Air compressor, portable; Air compressor, truck mounted; &amp; Scissors pan</td>
<td>10 26</td>
<td>90</td>
<td>85</td>
<td>a</td>
<td>10</td>
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</tr>
<tr>
<td>高低; Carry-all operators; Grader; &amp; Scraper pan</td>
<td>10 79</td>
<td>90</td>
<td>85</td>
<td>a</td>
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<tr>
<td>Combinationhoe and loader machine; concrete mixer - 5 bags or over; Front end loader under 3 cy; &amp; Powerstone spreader</td>
<td>10 74</td>
<td>90</td>
<td>85</td>
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<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
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<tr>
<td>Air and steam valve; Compressor; generator; pump and well point; welding machine</td>
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<td>90</td>
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<td>a</td>
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<tr>
<td>Fork lift not over 4' &amp; Steam</td>
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<td>90</td>
<td>85</td>
<td>a</td>
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<tr>
<td>Mechanical heater</td>
<td>9 72</td>
<td>90</td>
<td>85</td>
<td>a</td>
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<tr>
<td>Roller</td>
<td>10 52</td>
<td>90</td>
<td>85</td>
<td>a</td>
<td>10</td>
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</tr>
<tr>
<td>Dinky machine; Power pavement breaker</td>
<td>10 36</td>
<td>90</td>
<td>85</td>
<td>a</td>
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<tr>
<td>Fireman (High pressure)</td>
<td>9 50</td>
<td>90</td>
<td>85</td>
<td>a</td>
<td>10</td>
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<td>Oil</td>
<td>9 02</td>
<td>90</td>
<td>85</td>
<td>a</td>
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<tr>
<td>Crane with boom, excluding jib, over 150° - 22 60 extra; Crane with boom, excluding jib, over 150° - 22 60 extra</td>
<td>10 95</td>
<td>90</td>
<td>85</td>
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<tr>
<td>Laborers (Heavy and Highway Construction)</td>
<td>7 95</td>
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<td>70</td>
<td>10</td>
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<tr>
<td>Laborers</td>
<td>8 20</td>
<td>50</td>
<td>70</td>
<td>10</td>
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<tr>
<td>Laborers (Street and Highway Construction)</td>
<td>8 45</td>
<td>50</td>
<td>70</td>
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<td>Laborers (Construction)</td>
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<tr>
<td>DECISION NO</td>
<td>C72-3056</td>
<td>Basic Hourly Rates</td>
<td>Fringe Benefits Payments</td>
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<td>H &amp; W</td>
<td>Pensions</td>
<td>Vacation</td>
<td>Education and/or Appr. Tr.</td>
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<td>LABORERS (Building Construction)</td>
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<tr>
<td>Laborers</td>
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<tr>
<td>Asphalt takers, concrete &amp; power buggyops, concrete saw ops, chain saw ops, fence &amp; guard rail erectors, form setters, pipe layers, dry stone wall builders, mason tenders, pneumatic gas &amp; electric drill ops, powdermen &amp; wagon drill ops</td>
<td>7.95</td>
<td>50</td>
<td>70</td>
<td>10</td>
<td></td>
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<tr>
<td>Air track ops, block pavers, and curb setters</td>
<td>6.20</td>
<td>50</td>
<td>70</td>
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<tr>
<td>Blasters</td>
<td>8.45</td>
<td>50</td>
<td>70</td>
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<tr>
<td>Open Air Caisson, Cylindrical Work and Boring Crew Top man</td>
<td>7.95</td>
<td>50</td>
<td>70</td>
<td>10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bottom man</td>
<td>9.45</td>
<td>50</td>
<td>70</td>
<td>10</td>
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<tr>
<td>POWER EQUIPMENT OPERATORS: (HEAVY &amp; HIGHWAY CONSTRUCTION)</td>
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<tr>
<td>Class 1</td>
<td>11.50</td>
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<td>Class 3</td>
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<td>Class 4</td>
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<td>Class 5</td>
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<td>Class 6</td>
<td>10.53</td>
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<td>.85</td>
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<tr>
<td>Class 7</td>
<td>10.32</td>
<td>.90</td>
<td>.85</td>
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<tr>
<td>Class 8</td>
<td>9.41</td>
<td>.90</td>
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<td></td>
</tr>
<tr>
<td>Class 9</td>
<td>9.52</td>
<td>90</td>
<td>85</td>
<td>a</td>
<td>10</td>
<td></td>
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<tr>
<td>Class 10</td>
<td>9.89</td>
<td>90</td>
<td>85</td>
<td>a</td>
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<tr>
<td>Class 11</td>
<td>10.24</td>
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<td>85</td>
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<tr>
<td>Class 12</td>
<td>9.05</td>
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<tr>
<td>Class 13</td>
<td>9.62</td>
<td>.90</td>
<td>.85</td>
<td>a</td>
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<tr>
<td>Crane with 150' boom - $25 extra</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Crane with 200' boom - $50 extra</td>
<td></td>
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</tbody>
</table>

POWER EQUIPMENT OPERATORS CLASSIFICATIONS

Class 1: Erecting and handling structural steel; front end loaders (7 cy. or over)
Class 2: Pile drivers; Power shovel and crane; dragline; graders; gradall; trenching machine; lighter derricks; power (concrete) derrick (stiff leg and guy); diesel pile shooters; hoisting loaders (shooped); master mechanic
Class 3: Drill (heavy weight champion or equivalent); Side boom loader (Pomol); Rocking machines; Pumpcrete; Rock and earth boring machines; post hole digger; wall digger; & hammer (vibratory); central mix; Combination hole & loader (over 4yd)
Class 4: Asphalt
Class 5: Front end loader (3 yds or over); spreader; stone spreader; combination hoe and loader
Class 6: Asphalt roller; bulldozer; carryall; maintenance engineer; concrete mixer (5 high and over); welder
Class 7: Front end loader (under 3 yds); roller; power chippers; fork lift; finishing machines; asphalt plant; power pavement breakers; dry mix machine
Class 8: Compressor; pump
Class 9: Fireman (high pressure)
Class 10: Well point system
Class 11: Compressor battery
Class 12: Oilers
Class 13: Batch plant; Bulk cement plant
### NOTICE

**Decision No. CT72-3556**

<table>
<thead>
<tr>
<th>TRUCK DRIVERS (Building, Heavy &amp; Highway Construction)</th>
<th>Fringe Benefits Payments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class 1: Two axle trucks; helpers</td>
<td>H &amp; W</td>
</tr>
<tr>
<td>Class 2: Three axle trucks; two axle ready-mix</td>
<td>7.01</td>
</tr>
<tr>
<td>Class 3: Four axle trucks; heavy duty trailer-up to 40 tons</td>
<td>7.01</td>
</tr>
<tr>
<td>Class 4: Three axle ready mix</td>
<td>7.96</td>
</tr>
<tr>
<td>Class 5: Four axle ready mix; specialized earth moving equipment other than conventional type on-the-road trucks and semi-trailers (including Excavators)</td>
<td>8.06</td>
</tr>
<tr>
<td>Class 6: Heavy duty trailer-40 tons and over</td>
<td>8.11</td>
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</tbody>
</table>

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**SUPERSEDES DECISION**

**States:** Vermont

**Decision No. VT70-2067**

Supercedes Decision No. VT70-2067 (above counties only) dated December 10, 1976 in 41 FR 54146

**Description of Work:** Highway Construction

<table>
<thead>
<tr>
<th>Truss Drivers:</th>
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<tbody>
<tr>
<td>H &amp; W</td>
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<tr>
<td>-------</td>
</tr>
<tr>
<td>Chittenden, Franklin, Grand Isle, and Orleans Counties:</td>
</tr>
<tr>
<td>Carpenters</td>
</tr>
<tr>
<td>Cement Masons</td>
</tr>
<tr>
<td>Painters</td>
</tr>
<tr>
<td>Drillers: Chittenden County</td>
</tr>
<tr>
<td>Remainder of Counties</td>
</tr>
<tr>
<td>Truck Drivers:</td>
</tr>
<tr>
<td>2 axle</td>
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<tr>
<td>3 axle</td>
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<tr>
<td>Power equipment operators:</td>
</tr>
<tr>
<td>Augers</td>
</tr>
<tr>
<td>Backpacker</td>
</tr>
<tr>
<td>Bulldozer</td>
</tr>
<tr>
<td>Compactor:</td>
</tr>
<tr>
<td>Grader: Chittenden Co.</td>
</tr>
<tr>
<td>Remainder of Counties</td>
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</tbody>
</table>

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**Footnotes:**

- a: 2 paid holidays: Memorial Day, Independence Day. Provided to employees who have worked at least 7 days in the calendar week in which the holiday falls.


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**FEDERAL REGISTER, VOL. 43, NO. 146—FRIDAY, JULY 28, 1978**
<table>
<thead>
<tr>
<th>Addison County:</th>
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<tr>
<td>Cement masons</td>
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<tr>
<td>Ironworkers:</td>
<td>Reinforcing</td>
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<tr>
<td>Structural</td>
<td>7.40</td>
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<tr>
<td>Laborers</td>
<td>3.85</td>
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<tr>
<td>Driller</td>
<td>4.00</td>
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<tr>
<td>Asphalt paving</td>
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<tr>
<td>Air tool operators</td>
<td>4.10</td>
</tr>
<tr>
<td>Truck drivers:</td>
<td>2 axle</td>
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<tr>
<td>3 axle</td>
<td>5.50</td>
</tr>
</tbody>
</table>

Power equipment operators:
- Roller: 7.75 35 50 b 05
- Grader: 7.95 35 50 b 05
- Mechanic: 7.75 35 50 b 05
- Paver: 7.75 35 50 b 05
- Backhoe: 8.20 35 50 b 05
- Bulldozer: 7.75 35 50 b 05
- Crane: 8.20 35 50 b 05
- Front end loader: 7.75 35 50 b 05
- Spreader: 7.75 35 50 b 05
- Compactor roller: 7.20 35 50 b 05

Footnotes:
- a 2 paid holidays—Memorial Day and Indep. Day, provided the worker worked 2 full days in the calendar week in which the holiday falls.

[FR Doc. 78-20678 Filed 7-27-78; 8:45 am]
DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

National Institutes of Health

RECOMBINANT DNA RESEARCH

Proposed Revised Guidelines.
DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
National Institutes of Health

RECOMBINANT DNA RESEARCH

Proposed Revised Guidelines

STATEMENT BY JOSEPH A. CALIFANO, JR., SECRETARY OF HEALTH, EDUCATION, AND WELFARE

The Director of the National Institutes of Health is publishing proposed revisions to the NIH guidelines on research involving recombinant DNA molecules. The original guidelines are being updated in light of NIH's experience operating under them and in light of our increasing knowledge about the potential risks and benefits of this research technique. As experience accumulates, we should review and evaluate the evidence to assure that the restrictions imposed are appropriate to potential risks—strengthening restrictions where needed, relaxing regulation where justified.

In publishing these proposals for public comment, I recognize the extraordinarily difficult challenge that developing sensitive but effective regulations in this field poses for NIH, for the research community, and for the concerned public.

Necessarily, this task poses difficult questions that we will never be able to answer with complete certainty. I hope that those concerned will analyze the proposed revisions with care and give us their views on the strength of the evidence that supports the proposed revisions, the specific scientific and research containment procedures that the proposed revisions require, and the procedures and the standards they establish for future changes in the guidelines and for the exercise of discretion under them.

We particularly seek comment on the sections in the proposed revisions that establish the mechanisms for administering and revising the guidelines. For example, do the proposed revisions strike the proper balance in establishing: the procedures for permitting otherwise prohibited experiments and for exempting classes of research from the guidelines; the standards for the exercise of administrative discretion under the guidelines; the composition of the Department's Recombinant DNA Advisory Committee and of the institutional biohazard committees. To review the comments on the proposed revisions, I am establishing a departmental review committee, consisting of Mr. Peter Libassi, the Department's General Counsel (Chairperson); Dr. Donald Fredrickson, the Director of NIH (Vice-Chairperson); Dr. Julian Richmond, Assistant Secretary for Health; and Dr. Henry Aaron, Assistant Secretary for Planning and Evaluation.

I have asked this committee to hold a public hearing to insure full and complete opportunity for comment. In order to hold this hearing and to issue the revised guidelines on a reasonably prompt schedule, no extension of the 60-day period for public comment will be possible.

In preparing these revisions, the National Institutes of Health have already held 19 hours of public hearings and have received continual advice from the scientific community and from the public. I want this open process to continue. I urge those concerned to help us find the proper balance by providing us with comments on NIH's proposed revisions.


JOSEPH A. CALIFANO, JR.,
SECRETARY

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

NATIONAL INSTITUTES OF HEALTH

RECOMBINANT DNA RESEARCH

PROPOSED REVISED GUIDELINES—NIH

This will introduce three related documents that the National Institutes of Health (NIH) is publishing for public comment: (1) a Decision of the Director, NIH, to publish revised NIH guidelines for research involving recombinant DNA molecules, (2) the Proposed Revised Guidelines—NIH, and (3) an Environmental Impact Assessment of the proposed action. The Secretary of Health, Education, and Welfare has approved the release of these documents for public comment.

As stated in the Secretary's preface, we are particularly concerned that public comments be invited on the scientific and procedural aspects of the proposed guidelines. A public hearing on these proposed revisions will be held in late September at the Hubert H. Humphrey Building, Washington, D.C. All comments received on or before September 25, 1978, will be considered, and no extension of the comment period will be granted. Within 45 days after the comment period, final guidelines will be promulgated with a notice in the Federal Register.

The events leading to the proposed revisions are described in the "Introduction and Overview" to the Decision and in the "Foreword" to the Assessment. This preface will orient the reader to the topics that are directly related to the present publication. One is the current Recombinant DNA Research Guidelines, effective since June 23, 1976 (published in the Federal Register, July 7, 1976). Another is the Environmental Impact Statement (EIS) on those guidelines, published in 1977. The EIS, which contains a copy of the guidelines, is available from the Government Printing Office (stock No. 143-375) and in GPO depository libraries throughout the country. A third related document is Proposed Revised Guidelines on Recombinant DNA Research, which the NIH Recombinant DNA Advisory Committee (RAC) recommended to the NIH Director on September 1, 1977. The RAC proposal was published in the Federal Register, September 27, 1977, for public comment.

The RAC-proposed revisions were discussed at a public meeting of the Advisory Committee to the Director (DAC), held at NIH on December 15-16, 1977. The DAC and special consultants heard witnesses from environmental groups, the scientific community, industry, etc. All correspondence from the public in response in the Federal Register publication was available to those present and will be published, with the transcript of the meeting and other documents, as part of a continuing public record of NIH activities concerning recombinant DNA. The Director, NIH, acting in light of the 2-day discussion, all commentaries, and the DAC's recommendations, has arrived at the present proposal—the Proposed Revised Guidelines (NIH)—and offers it for public review.

The current (1976) guidelines contain an appendix entitled "Supplementary Information on Physical Containment." This has been omitted from the present proposed guidelines but, in revised and expanded form, will be available on request as "Laboratory Safety Monograph—A Supplement to the NIH Guidelines for Recombinant DNA Research." For a copy, write to the Office of Recombinant Activities, Building 31, Room 4A52, National Institutes of Health, Bethesda, Md. 20014.

The Environmental Impact Assessment is based on an intensive analysis of the current guidelines, the RAC-proposed alternative, and the present NIH alternative. The conclusion of this analysis is that there would be no adverse impact of the NIH-proposed changes upon the environment.

The guidelines as presently proposed are designed to discharge the continuing obligation of NIH to assure that recombinant DNA research goes forward under standards of safety reflecting the latest scientific knowledge, so that NIH and other NIH activities are protected from any hazards while deriving the full benefits of the recombinant DNA technique.
Written comments and inquiries concerning the Proposed Revised Guidelines should be addressed to the Director, National Institutes of Health, Bethesda, Md. 20014. All comments received will be available for public inspection at the Director's office on weekdays (Federal holidays excepted) between the hours of 8:30 a.m. and 5 p.m.


DONALD S. FREDERICSON, Director, National Institutes of Health.

DECISION OF THE DIRECTOR, NATIONAL INSTITUTES OF HEALTH, TO ISSUE REVISED GUIDELINES FOR RECOMBINANT DNA RESEARCH


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INTRODUCTION AND OVERVIEW

Today, with the concurrence of the Secretary of Health, Education, and Welfare, and the Assistant Secretary for Health, I am proposing revisions to the NIH Guidelines for Recombinant DNA Research. These Guidelines were first issued on June 25, 1976. The proposed revisions result from a continuing process of scientific and public exchange similar to that of the 1976 edition. This overview sketches the background for proposed revisions and summarizes the proposed changes. It references accompanying documents and other pertinent sources of information.

The probable risks and benefits of recombinant DNA research—the larger subject of which the NIH Guidelines are a part—have been discussed in numerous forums since first addressed in 1973.(2) Congress has held multiple hearings on related issues, including proposals to convert the Guidelines to Federal regulations(3) and redefine recombinant DNA research to narrow the range of experiments subject to regulations. Early in 1977 the NIH Recombinant DNA Advisory Committee (RAC), the scientific and technical committee responsible for proposing revisions to the Guidelines, began its task of identifying changes needed in the Guidelines and for setting priorities for me for consideration. In order that public comments could be heard on the RAC-proposed revisions, published in September 1977,(4) a meeting of the Advisory Committee to the Director, NIH (DAC), was held November 10-11, 1977. The public oversight, was held in December, The extensive record of this hearing bears witness to almost unanimous agreement that the original Guidelines badly need updating, and suggest numerous directions in which revisions might move.(5)

Much of the discussion at the December 1977 meeting of the DAC affirmed the need for continuous reevaluation of the safety premises underlying the original Guidelines. Since Asilomar,(2) growing evidence has suggested that other experts sought to review the concerns of the molecular biologists who first raised questions about the safety of recombinant DNA research. Scrutiny from experts in infectious diseases, epidemiology, virology, botany, ecology, laboratory safety, and other disciplines has been needed. NIH sponsored a workshop at the 1977 meeting in Falmouth, Mass., 6 months before the DAC meeting. Here, old and new information about E. coli K-12—the host most used in recombinant DNA experiments—was interpreted carefully. From this came a consensus that the chances of this host being convertible to an epidemic pathogen are negligible.

Those attending the December DAC meeting also heard complaints that containment levels were set too stringently for recombinant DNA work on viruses and plants. This applied both to the original Guidelines and to the revisions proposed in September 1977. A decision was made to address the issues through workshops without delay.

One of these workshops, held at Ascot, England, dealt specifically with viruses.(7) Here, experts from several countries including others from the Soviet Union, discussed the present regulations for recombinant DNA experiments. This meeting stated that the risks of handling the parent virus alone. They also stressed that defective viruses pose little risk of infection when used as vectors for cloning viral DNA in eukaryotic cells, since the cells cannot be infected by defective viruses, and the risks of handling the parent virus alone. They also stressed that defective viruses pose little risk of infection when used as vectors for cloning DNA.
NOTES

Scarcity to do.(10) Moreover, factual bases for the greater stringency of the U.S. (NIH Guidelines cannot be shown.

Five years after concerns were first raised about the hypothethical hazards of laboratory experiments with recombinant DNA. The thousands of individual applications of such techniques have produced much useful knowledge, but no evidence has come to light of a product created by these techniques that has been harmful to man or the environment. Foreign genes inserted into prokaryotic host-vector systems have been faithfully replicated and produced in quantities valuable to science. On the other hand, prokaryotes generally have not been able to translate eukaryotic genes into biologically active proteins. No new facts or considered older ones have emerged to support the fears of harmful effects, and one prominent early proponent of guidelines has repudiated his support for them.(11) At least, there is growing sentiment to place some proof in shifting toward those who would restrict recombinant DNA research.(12) Although clearly the time has come to revise the original NIH Guidelines for Recombinant DNA research, it has not the time to conclude that they are being altered in preparation for their early abandonment. Understanding of gene regulation and expression is increasing inexorably and at an awesome pace. We may predict that ways will be found to achieve and control the translation of foreign genes by a variety of hosts.(13) As the barriers to translation are dropped, some of the larger promise of recombinant technology will be realized. In some proportion to the harvest of positive results, a capability must be maintained for observing any capacity of these experiments to produce products and for communicating this to all who have an interest in similar experiments.

In preparation for this next phase of recombinant DNA research, several shifts in NIH guidance are necessary. Experiments posing no threat to safety must be exempted from the Guidelines; and provisions must be made to remove others as soon as their harmlessness becomes evident. Any universal rules imposed on this area of activity derive validity from continual modification dictated by results of the experimentation they govern.

Primary responsibility for compliance with the rules must be located where the work is done. There it must be shared fully by principal investigators, those who work in their laboratories, institutional biosafety committees, and the institutional leaders. The NIH Office of Recombinant DNA Activities (ORDA) should be relieved of its burden of obligatory prior approval of certain experiments, so that it can better carry out, along with the RAC, two central functions. These are the processes of synthesis and interpretation of the Guidelines and the maintenance of full communication among all who must use them.

To recapitulate, these new proposed Guidelines arose from a proposal made to me by the RAC in September 1977. Numerous amendments have been made on the basis of public comments received at the December 1977 hearing, in extensive correspondence before and after that, and recommendations of special expert workshops whose reports were then assessed by the RAC in April 1978. The proposal and the amendments have been the products of long and intense participation by numerous persons representing many points of view. I now summarize the more important proposed changes. The basis for decision on each element of revision is provided in detail in subsequent sections of this document.

SCOPE AND APPLICABILITY OF THE GUIDELINES

Recombinant DNA containing synthetic sequences is now explicitly part of the definition of what is included under the Guidelines. The standards of the Guidelines now apply to all recombinant DNA experiments conducted in an institution that receives any support from NIH for recombinant DNA research. This includes a registration requirement.

The original Guidelines contain a number of prohibited experiments. There was little sentiment for the removal of all the original prohibitions—although it has been noted that the U.S. (NIH) Guidelines are the only national guidelines to stipulate prohibited activities. The original prohibitions, with one modification and a necessary "flexibility" clause,(14) are therefore retained in the proposed revision. They immediately precede a new section called "Exemptions"—a juxtaposition chosen to emphasize that the prohibitions still override.

The first exemption from the Guidelines covers the handling of DNA outside a host organism or virus. Such "naked DNA" has been handled in laboratories for years and is rapidly inactivated in nature.

The exempted experiments of the second class consist essentially in rearrangements, for deleting from, molecules of nonchromosomal or viral DNA. No foreign DNA is involved. An example would be the introduction of a DNA molecule formed from pieces of SV40 virus into eukaryotic cells in tissue culture. Since there is little if any basis for presuming such "rearrangement" or "deletion" experiments to be hazardous, they are now excluded.

A third class of exemptions are experiments called "self-cloning," in which DNA found naturally in a host may be reinserted into that host. These are reproductions in the laboratory of events that occur in nature.

Similarly, provision is made in the proposed guidelines for exemption of a fourth class of experiments that involve donor-host pairs that normally exchange DNA. Such genetic exchange is known to occur widely between various species of bacteria and is generally mediated by certain plasmids or viruses. Experimental recombinations of this type are only an imitation of what nature is able to accomplish handily in the absence of Federal regulation. A list of donor-host pairs to be exempted is begun in this revision, and will be expanded periodically as knowledge grows. The initial choice from several possible lists submitted to me by the RAC is a conservative one, and will be expanded, if necessary, as experience justifies.

Finally, a fifth exemption is provided for removal of other recombinations when they are shown to be safe. The two examples given are "naked" plasmids or viruses. Experimental combinations of the type that was so lacking in the original. Provision will be made for public input to such decisions, either by announcement of proposed exemptions prior to consideration by the RAC or before a decision by the Director becomes effective.

CONTAINMENT

I have made one decision that will not be regarded with equal pleasure by all engaged in recombinant DNA research. P1 containment previously permitted mouth pipetting. In accord with a previous recommendation by the European Molecular Biology Organization (EMBO), its virus Working Group strongly recommended prohibiting this practice; and so did NIH safety advisors. The RAC at its meeting on April 27-28, 1978, recommended that mouth pipetting be prohibited only for those P1 recombinant DNA experiments involving viral DNA. Rather than create two separate classes of P1, and in recognition of the present availability of efficient mechanical devices for pipetting, I am proposing that mouth pipetting no longer be permitted in P1 containment. Since it is already prohibited in P2-P4 containment, this bans the use of mouth pipetting for any experiment covered by the Guidelines.

CONTAINMENT GUIDELINES FOR COVERED EXPERIMENTS

The recommendations of the RAC, arising from the Ascot-Bethesda work-

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shops, represent the first realistic appraisal of any hazards that might lie in the use of viral vectors or the cloning of viral DNA. Recombinant techniques offer access to areas of viral biology that are vitally important. Such studies should not be impeded unnecessarily. I have accepted the April 1978 recommendations of the RAC in this area with minor amendments. The revised guidelines emphasize the current dictum that any hazards of working with viruses in recombinant DNA experiments are maximal at the first stage, when the virus itself with its full genomic complement is handled.

The RAC unanimously approved modest changes in containment for plant experiments. I have also approved them provisionally, contingent upon concurrence by the Department of Agriculture.

A new sentence has been added to the guidelines giving much needed flexibility in the setting of containment levels.(15)

ROLES AND RESPONSIBILITIES

Two years' experience with the guidelines has offered valuable tutelage in the limits of external (Federal) control of laboratory experimentation. Scientists and their co-workers have long experimented with pathogenic organisms, poisonous plants and animals, and hazardous chemicals. The laboratory is not among the more notorious occupational settings for accidents or illness, and damage to community or environment by basic laboratory research is almost unknown. Control over the use of radioisotopes in the laboratory, long a Federal preserve, is not comparable to use of recombinant DNA techniques; for the risks of using radioisotopes are calculable and mistakes are easily measured. Thus realistic and durable standards can be established. Without a basis for the setting of such standards, conventional regulation is difficult at best, and at worst can be preposterous.

In the case of recombinant DNA technology, we are in the midst of a search for any risks, and thus for applicable standards. The scientists who raised the possibility of risks also realized that the only effective safeguards lay in a maximum enhancement of the collective nature of the scientific process. The usual communications networks of science had to be augmented and the evaluation of results and the reaching of consensus accelerated. These actions, as was reasoned, would help establish a set of initial rules and there was the added assumption that, they could and should be kept up to date. All using the new techniques would sign a "memorandum of understanding" to the effect that, until things became clearer, the basic currency of scientific inquiry would be especially emphasized in any work with recombinant DNA techniques.

The power of the Government to require disciplinary action and to grant it was an attractive reason for the scientists to request Federal intervention. And the Federal capacity to achieve the essential communication and consensus-building has been one of the most positive results of this experiment in administration. But the price of Federal intervention includes a heavy tax of formalism. In the instance of these guidelines, diverse pressures have made difficult the appropriate balancing of substance and procedure. I have already alluded to one of the undesirable results—a chilling inflexibility of the original guidelines—and its proposed correction by revision.

Prior NIH clearance is mandatory for new NIH grants and contracts involving recombinant DNA techniques and for all projects in P4 facilities. In the present context, prior NIH clearance is no longer required for changes at the P1-P3 levels. These changes must be approved by the institutional biosafety committee (IBC), and NIH will then review the IBC action. This proposal reverses an October 1977 issuance stating that changes in ongoing projects require prior NIH clearance. The requirement resulted in numerous delays in projects which could not be justified on grounds of safety.

The proposed guidelines would strengthen institutional responsibilities and authorities in determining compliance. A full partnership with all investigators and their institutions is intended. The role of the IBC is particularly enhanced through delegation of some discretionary powers that were previously reserved for NIH and the RAC. To better meet these obligations, the RAC, IBC or P4 containment is required under the proposed guidelines to have a qualified biological safety officer.

Experience gained in the past 5 years in explaining recombinant DNA techniques has shown how valuable can be a community's activities. At least one member of the IBC is to be a "public member"—i.e., one who has no financial connection with the institution. Further, to ensure opportunity for public participation at the national level, procedural are set forth, as explained in Part IV of the decision, that provide public notice and solicit comment on the major actions of NIAID. The proposed revision of the guidelines is that failure of compliance can lead to suspension of NIH support for recombinant DNA research.(16)

Provision is now made for the private sector to register voluntarily its recombinant DNA activities with NIH. Also, other consulting services, including certification of host-vector systems, will be provided. The service will be accompanied by provision of proposed data as mandated by law.

NIH issued a draft environmental impact statement on the guidelines in September 1976. This was revised after public comment and issued in final form in October 1977. It concluded that the activities covered by the guidelines had no predictable impact on the environment, since all the risks discussed were hypothetical. The EIS was examined by a Federal district court in 1978.

In parallel with the process of revising the guidelines, NIH has conducted an environmental impact assessment, including an analysis of how current experiments supported by NIH will be affected by this revision. Again, the activities covered by the revised guidelines deal only with hypothetical risks, and thus the assessment reveals no predictable impact on the environment.

ORGANIZATION OF THE REMAINDER OF THIS DOCUMENT AND ABBREVIATIONS USED

The Recombinant DNA Molecule Program Advisory Committee is sometimes referred to below as the Recombinant DNA Advisory Committee or Recombinant Advisory Committee or RAC.

The meeting of the Advisory Committee under the Director, NIH, which took place in December 1977 is sometimes referred to below as the meeting of the Director's Advisory Committee or of the DAC or the December 1977 public hearing.

"The NIH Guidelines for Research Involving Recombinant DNA Molecules" as issued on June 23, 1976, and updated in the Federal Register on July 7, 1976, are sometimes referred to below as the original guidelines or the 1976 guidelines or the current guidelines.

The proposed revised guidelines prepared by the RAC and published in the Federal Register on September 27, 1977, are referred to below as the PRG-RAC.

The proposed revised guidelines which are being proposed now by NIH are referred to below as the PRG-NIH.

The remainder of this document is divided into four parts corresponding to the four parts of the guidelines; i.e., I. Scope of the Guidelines; II. Containment; III. Containment Guidelines for Recombinant Experiments; and IV. Roles and Responsibilities.

Within each of these four parts there are two subsections; i.e., Review of RAC-Proposed Guidelines and Review of Comments and NIH-Proposed Guidelines. The first subsection
describes how the PRG-RAC differs from the 1976 guidelines; the second describes (1) the public comments received both before and after the December 1977 DAC meeting, concerning the PRG-RAC, and (2) the changes which have been made in response to these comments leading to the PRG-NIH.

FOOTNOTES TO INTRODUCTION AND OVERVIEW

(1) In addition to the proposed revised guidelines and this "Decision Document," there is also being released an Environmental Impact Assessment, including numerous appendices.

(2) The capability to perform DNA recombinations, and the potential hazards, had become apparent to scientists at the Gordon Conference on Nucleic Acids in July 1973. At their behest the National Academy of Sciences created a committee that organized an international conference held in February 1975 at Asilomar Conference Center, Pacific Grove, Calif. Approximately 150 scientists, of whom a third were from foreign countries, were present. The committee also called on the National Institutes of Health to establish an advisory committee to draft guidelines for the conduct of this research. Temporary guidelines were issued at Asilomar pending issuance of NIH guidelines.

In response, the NIH Recombinant Advisory Committee (formally "NIH Recombinant DNA Molecule Program Advisory Committee") was established in October 1974 to advise the Secretary of HEW, the Assistant Secretary for Health, and the Director of NIH to accomplish these tasks. The several members of the committee, a number of scientific and public representatives had been invited to participate. There was ample opportunity for comment and an airing of the issues, both by the committee members and the public. Major points of view were broadly represented.

The proposed guidelines were reviewed by the Director, NIH, in the light of comments and suggestions made at the public hearing as well as extensive written correspondence received after the meeting. When the final guidelines were released in June 1976, an accompanying decision paper described in great detail all relevant public comments and the reason for accepting or rejecting specific recommendations in preparing the final guidelines. The NIH guidelines and the Decision of the Director, NIH, were published in the FEDERAL REGISTER on July 7, 1976. In addition, copies of the guidelines were widely distributed to foreign embassies, medical and scientific journals, NIH grantees and contractors, and professional research societies.

(3) The following committees have held hearings and/or markup sessions on Recombinant DNA legislation:

- House-The Subcommittee on Health and the Environment and its parent, the Committee on Interstate and Foreign Commerce, has not held any hearings or markup sessions on this topic.
- Senate-The Subcommittee on Health and Scientific Research and Technology, and its parent, the Committee on Commerce, Science, and Transportation.

The proposed guidelines were reviewed by the NIH Recombinant Advisory Committee developed its proposed guidelines. In 1975 were announced in the FEDERAL REGISTER and were open to the public. The committee, after preparing several drafts of versions of guidelines, reached agreement on a recommended revised version, which was referred to the NIH Director for review in December 1975.

A special meeting of the public advisory Committee to the Director, NIH, was convened in February 1976 to review these proposed guidelines. In addition to current members of the committee, a number of former committee members as well as other scientific and public representatives had been invited to participate. There was ample opportunity for comment and an airing of the issues, both by the committee members and the public. Major points of view were broadly represented.

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(4) The Recombinant Advisory Committee considered its proposed guidelines meetings throughout 1977. The version proposed to the Director, NIH, in September 1977, appeared in the Federal Register on September 27, 1977.

(5) This meeting of the Director's Advisory Committee took place in Bethesda on December 15-16, 1977. A summary of the meeting appeared in the recombinant DNA technical bulletin, and the complete record will shortly be published by NIH in vol. 3 of the series recombinant DNA.

(6) The NIH-sponsored meeting at Plymouth, Mass., on June 20-22, 1977, was chaired by Dr. Sherwood Gorbach. A complete record of this meeting appears in the "Journal of Infectious Diseases" (May 1978).

(7) The "U.S.-EMBO Workshop to Assess Risks for Recombinant DNA Experiments Involving the Genomes of Animal, Plant, and Insect Viruses" was held on January 20-21, 1976, in Ascot, England, by experts on viruses from the United States, Britain, and other European countries, a majority of whom were not engaged in recombinant DNA research. The primary purpose of the meeting was to conduct a scientific and technical analysis of possible risks associated with cloning eukaryotic viral DNA segments in E. coli K-12 host-vector systems and with the use of eukaryotic viruses as cloning vectors in animal, plant, and insect systems. The report of the workshop was published in the FEDERAL REGISTER on March 31, 1978, and appears as appendix B to the accompanying environmental impact assessment. The report was considered by the Recombinant Advisory Committee at its April 27-28, 1978, meeting.

(8) The "Workshop on Risk Assessment of Agricultural Pathogens" was held on March 20-21, 1978, in Washington, D.C., under the auspices of the National Science Foundation, the Department of Agriculture, and the National Institutes of Health. A copy of the report of this workshop appears as appendix C to the accompanying environmental impact assessment.

(9) The United Kingdom guidelines, also known as the "Williams report," were issued in August 1978. A comprehensive review of the international aspects of recombinant DNA research, including issuance of national guidelines, is contained in the "Report of the Federal Interagency Committee on Recombinant DNA Research/International Activities," November 1977. This is available from the Office of Recombinant DNA Activities, National Institutes of Health, Bethesda, Md. 20014.

(10) Under the NIH guidelines, experiments using prokaryotic cells other than E. coli K-12 are severely limited whereas such experiments are proceeding in Europe, especially with Bacillus subtilis. Certain other categories of experiments rely on the NIH guidelines, either P4+EK2 or P4+EK3 containment. Since no EK system...
has as yet been certified and since the first F4 facility has only recently been certified, these experiments were effectively forbidden. The same experiments require significantly lower containment under some European guidelines.

(11) Prof. James Watson, in testimony at the December 1977 DAC meeting and in print, has sought reelection for his earlier activities in support of special precautions for recombinant DNA research.

(12) The report, "Science Policy Implications of DNA Recombinant Molecule Research," March 1978, of the Subcommittee on Science, Research, and Technology of the Committee on Science and Technology, U.S. House of Representatives, says, "The burden of proof of safety factors should not be borne exclusively by proponents of recombinant DNA research, and the potential consequences of failure to meet these criteria may include the loss of a significant portion of the primary research in this area, and result in the synthesis of DNA and novel proteins."

(13) Significant differences exist between prokaryotes and eukaryotes in the ways polypeptides are synthesized under genetic direction, and these account for limitations on the apparent success of many recombinant DNA experiments to date. A major thrust of current recombinant DNA research is in the direction of overcoming these differences. There is every reason to believe that this research will succeed. At my invitation, Malcolm Martin of NIH has drawn up this brief analysis of the state-of-the-art:

The potential use of recombinant DNA techniques to produce biologically useful reagents is predicated on: (a) the faithful replication of a segment of foreign DNA in a new host cell; (b) the synthesis of messenger RNA, RNA complementary to the inserted DNA; and (c) the efficient translation of the mRNA into a polypeptide. In nearly all cases that have been examined to date, DNA, from both eukaryotic and prokaryotic sources, has been amplified in prokaryotic host-vector systems. The fidelity of this process has been verified in several instances in which prokaryotic DNA segments have been cloned in E. coli and resulted in the synthesis of new polypeptides. Thus, in such cases, the informational content contained in the inserted prokaryotic DNA is expressed as evidenced by the synthesis of mRNA and novel proteins.

With few exceptions (some yeast insert), the expression of eukaryotic DNA in the form of biologically active or biochemically detectable polypeptides in prokaryotes has not been achieved using chromosomal DNA inserts and unmodified vectors. In nearly all cases where the system has been rigorously examined, it has been shown that eukaryotic DNA has replicated in E. coli in some instances, RNA complementary to the inserted eukaryotic DNA has been identified.

Messenger RNA synthesis and function in E. coli. The synthesis of messenger RNA (mRNA) in a prokaryote, such as E. coli, proceeds in a linear fashion along the DNA template of individual gene segments or groups of related genes. In nearly all cases examined, the mRNA molecules are the faithful colinear transcripts of prokaryotic genetic information and can be used in an unmodified form to direct the synthesis of prokaryotic polypeptides. The informational content of mRNA corresponds directly to the nucleotide sequence of DNA in such systems (i.e., all nucleotides present in a prokaryotic gene are transcribed into messenger RNA, which, in turn, programs the synthesis of the corresponding polypeptide). Control of this phase of gene expression appears to be solely at the level of RNA synthesis.

In prokaryotes (and eukaryotes), nucleotide sequences preceding the sequences corresponding to the actual gene products play a major role in determining (a) whether a given DNA sequence will be transcribed into RNA, or (b) whether the RNA so synthesized will efficiently bind to ribosomes, a prerequisite for protein synthesis. For example, certain DNA sequences encoding regions of RNA polymerase and thereby participate in the initiation of RNA synthesis; they are not represented in the final RNA product. DNA sequences specifying binding to ribosomes are physically located between those for initiation of RNA synthesis and sequences encoding the amino acids of a particular protein, and are contained in the functional mRNA molecules.

Messenger RNA synthesis and metabolism in eukaryotes. Our understanding of gene regulation and expression in eukaryotic cells has increased markedly during the past 10 months. A common feature of all systems that have been carefully evaluated is that the initial faithful transcription of the DNA is extensively modified to produce a functional form of mRNA. The final mRNA contains only a fraction of the protein originally present in the original RNA product. That is, to say portions of large mRNA molecules are removed by mechanisms that are, at present, poorly understood and the remaining segments have been cloned in E. coli, and resulted in the synthesis of new polypeptides. These mechanisms are often joined together.

Support for the concept of complex modification leading to functional mRNA in eukaryotic cells has recently come from recombinant DNA experiments in which chromosomal DNA of animal origin has been inserted into E. coli. When individual cloned eukaryotic genes are carefully analyzed, intervening DNA sequences which encode a bacterial amino acid sequence have yet been inserted. This arrangement will facilitate the transcription of the inserted DNA and enable the mRNA so synthesized to bind to bacterial ribosomes. This embodiment has already been used to maximize the expression of a bacteriophage gene and human somatostatin DNA in a plasmid vector system.

References for Footnote 13


(14) Prohibition (1) in the original guidelines forbids experiments with "oncogenic viruses classified by NCI as moderate risk." The recognition of these viruses will lead to formation of agents harmful to man and the potential for obtaining useful new knowledge, relevant to the development of antiviral chemotherapy. In general, supports the removal of the prohi-
The provision of an open-ended listing was recommended rather than issuance or a blanket exemption, because this would allow the RAC and NIH to consider evidence that the putative gene transfers do take place naturally and (2) their exemption from the guidelines is justifiable (see footnote 1 of the PRG-RAC). Although the PRG-RAC deals with prohibited experiments under Part III, this decision document, for purposes that become apparent below, will consider the definition, exemptions, and prohibitions together under section I. The "prohibitions" section was called section III-A, "Experiments That Are Not To Be Performed," in both the 1976 guidelines and PRG-RAC. Changes from the 1976 guidelines, proposed in the PRG-RAC, included minor wording changes in items (ii), (iv), and (vi).

The ability to grant exemptions for certain experiments from the "prohibitions" was limited in the 1976 guidelines to only the sixth prohibition (large-scale experiments with recombinant DNA's known to make harmful products). In the PRG-RAC the Director, NIH, is given the authority to grant exemptions from any of the six prohibitions. Such a determination must be based upon the recommendation of the RAC, and must be made with the purpose of protecting the public health or the environment. I base this conclusion on the fact that such techniques have been used in the laboratory for decades with no known harmful effects on either the public health or the environment. I should also emphasize that the entire area of laboratory safety is of primary concern to NIH and is the subject of constant review and attention. A description of NIH activities in these areas is presented in the environmental impact assessment.

A commentator suggested that the language be deleted stating that "...
the revised guidelines have the intent of erring on the side of caution. While believing that the guidelines are, and should be, deliberately restrictive, I agree with the criticism that scientists should not enter into an activity with the intent of erring. The PRG-NIH now reflects this opinion by the phrase:

"...conservatively..."

Another commentator suggested that the guidelines should contain language requiring all publications dealing with recombinant DNA activities to include a description of the physical and biological containment procedures used. While the PRG-NIH urges that "...all publications dealing with recombinant DNA activity..." and diverts the language to the following sections, each of which is discussed further below:

- Purpose: Definition of Recombinant DNA Molecules; General Applicability; Prohibitions; Exemptions; and General Definitions.
- Purpose: The introduction to the 1976 guidelines states that "...the purpose of these guidelines is to recommend safeguards for research on recombinant DNA molecules."
- As noted above, to eliminate "naked" recombinant DNA from the guidelines, the PRG-RAC proposed this passage to read that the purpose is to "establish procedures for handling organisms and viruses containing recombinant DNA molecules."
- This proposed revision would have had the effect of removing from coverage by the guidelines certain experiments which are prohibited by the 1976 guidelines—for example, deliberate formation of naked recombinant DNA containing genes for the biosynthesis of potent toxins. I have decided to resolve this issue conservatively. The language in the PRG-NIH, therefore, clearly states that the guidelines are intended to pertain to the construction and handling of naked recombinant DNA molecules as well as of organisms and viruses containing such molecules.

General applicability

Many commentators urged that a statement of general applicability of the guidelines be included in an early part. The issues relate to (1) the applicable source of funding recombinant DNA research at institutions receiving NI

funds for this purpose, (2) the applicability of the guidelines to NIH-supported recombinant DNA research conducted in foreign countries, and (3) the location of responsibility for insuring compliance with the guidelines. Therefore, a section entitled "General Applicability" now appears after the "Purpose" section in Part I of the PRG-NIH.

The existence of guidelines for recombinant DNA research assumes their general application. Partial adherence within an institution would defeat the purpose of extending maximal protection to the community. Thus, it would be inconsistent for NIH to provide funds for biomedical research activities to an institution that did not meet the standards of the guidelines in all of its recombinant DNA research, regardless of the source of funding. This principle is now stated explicitly in the PRG-NIH, and we intend to consider withholding NIH funds as a sanction against violation.

Rules must be established for the conduct of recombinant DNA activities funded by NIH in other countries. Generally, the requirements in force in the MUA (memorandum of understanding and agreement) must still be filed with NIH, indicating specifically which guidelines will govern the activities; and NIH reserves the right to withhold funds as a sanction against practices to be employed are not comparable to the NIH guidelines. An explicit statement about this has been inserted in the PRG-NIH.

Part IV of the PRG-NIH describes the responsibilities of all individuals and organizations involved in the conduct and review of a recombinant DNA activity. Two years of experience with administering the NIH guidelines has demonstrated that the ultimate responsibility for insuring compliance must be borne by the institution where the research is being done. This implies some discretion under well-defined limits for interpretation of common standards, and imposes a requirement for local expertise other than the investigator's. Accordingly, Part I of the PRG-NIH now requires that an individual receiving NIH support for recombinant DNA research be associated with an institution that is willing and able to accept the responsibilities and conditions of local governance, described more fully in Part IV of the PRG-NIH.

Definition of recombinant DNA molecules

It became apparent from the comments received that the PRG-RAC definition was inadequate in that it did not address the handling of recombinant DNA molecules containing segments of chemically synthesized DNA. I have decided that the most effective way to achieve this goal is to include "natural or synthetic DNA" in the definition of a recombinant DNA molecule, and this has been inserted in the PRG-NIH definition. A new section, therefore, has also been added to Part I of the PRG-NIH giving containment levels for work with recombinant DNA molecules containing synthetic DNA.

I have also revised what I perceived to be an ambiguity in the PRG-RAC definition by itself was not defined. The PRG-NIH definition language explicitly stating that DNA molecules which result from the replication of recombinant DNA molecules are subject to the safety provisions of the guidelines. Indeed, an apparent force of deleting the PRG-RAC definition evoked as much comment as did the wording to exclude "non-novel" recombinant DNA from the standards. The ambiguity of such phrases as "known to exchange chromosomal DNA" and "by natural physiological processes" was strongly noted, and I agree with the commentators that we must strive for a greater degree of clarity and objectivity. Thus, in the PRG-NIH the two conditions cited above as criteria for exemption from the guidelines. Staff discussions of the public comments made it clear that inclusion of exemption provisions within the PRG-NIH definition language did not bear careful scrutiny.

Given this situation, and also my opinion that certain categories of recombinant DNA experiments are indeed so apparently free of causing harm that they should not come under the guidelines, it was my decision to remove the criterion of "novelty" from the definition and use it as a basis for the development of a new section entitled "Exemptions."

Exemptions

The nature of the public comments on the PRG-RAC exclusion of non-novel exchangers can be divided into categories—those that pertain to the proposed standards and those to the proposed process.

The standards proposed by the PRG-RAC were that novel recombinant DNA's are those consisting of "segments of any DNA from different species not known to exchange chromosomal DNA by natural physiological processes."

In general recombinant DNA molecules will not be considered novel when all the components are derived from genomes known to replicate within the organism used to propagate the recombinant DNA. This is qualified, however, by a footnote stating that the "recombinant DNA formed between segments of eu-
It proved impossible to reconcile these differences of opinion in the definition itself, but in my opinion the “Exemptions” section of the PRG-NIH as drafted does so successfully. This section was drafted by NIH staff in conjunction with a working group of the RAC, it was then modified slightly and endorsed by the full RAC at its meeting on April 27-28, 1978, and subsequently modified slightly for clarity by NIH staff. Before proceeding to a discussion of these exemptions, however, I want to emphasize that no provision of this section may be cited to exempt from the guidelines an activity listed in the “Prohibitions” section.

The first exemption concerns recombinant DNA molecules that are not in organisms or viruses. To clarify this concept which the RAC tried to convey in the “Prohibitions” section, the following comments were directed toward the procedures whereby exemptions would be made:

The fifth exemption allows the Director, NIH, on the recommendation of the RAC, after appropriate notice and opportunity for public comment, to exempt other classes of recombinant DNA molecules if he finds that “they do not present a significant risk to health or the environment.” The exemption of classes of experiments that do “not present a significant risk to health or the environment” is the language used in proposed legislation (H.R. 11192), recently reported out of the committee on Interstate and Foreign Commerce and the Committee on Science and Technology of the U.S. House of Representatives.

In addition to comments pertaining to the standards for exemption in the PRG-RAC, the following comments were directed toward the processes whereby exemptions would be made:

- Rather than compile a list of nonnovel exchanges exempted from the guidelines, the burden of proof should be on the Director, NIH, to compile a list of novel exchanges which are subject to the guidelines.
- The procedures and criteria used in the development of the list should be explained thoroughly, and adequate opportunity should be given for public review and comment.
- Before being placed on the list, all the data pertaining to the application should be available for public review.

In response to these comments, the PRG-NIH specifies that for exemptions I-E-4 and I-E-5—the two exemptions which involve the development of “lists”—these lists will be prepared by the Director, NIH, on the advice of the RAC, after appropriate notice and opportunity for public comment. Publication of the PRG-NIH includes appendix A giving an initial proposed list for exemption I-E-4. As part of the public comment which I am soliciting on the entire PRG-NIH, I include appendix A. In the future, no additions will be made to appendix A, nor will any items be listed as exemptions under exemption I-E-5, without ap-
prostitute notice and opportunity for public comment.

**Prohibitions**

Two changes in this section have been initiated to make it more compatible with the new "Definition" and "Exceptions" sections. The first was to transfer this section from part III of the guidelines to part I. This is again to emphasize that the exemptions are not applicable to the activities listed as being prohibited. The second was to drop all references to novel recombinant DNA's and natural genetic exchange. My other actions were based upon the following comments:

- **There was general endorsement of the proposal in this section which grants to the Director, NIH, upon the recommendation of the RAC, the authority to waive any of the prohibitions. The widespread support for this authority reflects the realization that many imminent risk-assessments experiments may not be able to proceed otherwise. NIH is now supporting and will continue to support experiments that will yield knowledge contributing to a better understanding of the nature of potential risks of recombinant DNA. This section has been expended in the PRG-NIH to indicate that if any experiments are exempted from the prohibitions, they will "at that time be assigned appropriate levels of physical and biological containment."**

- **It was urged that the advice of other Government agencies, such as the Environmental Protection Agency (EPA) and the Occupational Safety and Health Administration (OSHA), should be sought when the Director, NIH, considers invoking this waiver authority. The Federal Interagency Committee on Recombinant DNA Research, coordination of policies in this area. EPA and OSHA are represented on the Committee. The advice of relevant research and regulatory agencies will continue to be sought when appropriate.**

- **It was suggested that the RAC as presently constituted should not be the sole advisory body because societal as well as scientific considerations must enter into the waiver decision. As explained in greater detail in part IV of this document, the membership of the RAC will be broadened modestly as needed for expertise, but provisions for public notice and opportunity to comment, and other appropriate administrative practices, can be used to ensure adequate public input when the issues warrant.**

- **It was suggested that an Environmental Impact Assessment or Statement should accompany each waiver. My waiver decisions will include a careful consideration of the potential environmental impact, and certain decisions may be accompanied by a formal assessment or statement. This must be determined on a case-by-case basis.**

- **It was suggested that waiver of the prohibition on the large-scale use of culture of recombinant DNA's be issued on the basis of industry's experience in dealing with such cultures. While such experience will surely be weighed in the decisionmaking, I believe that it should not be the sole criterion for granting such a waiver.**

- **Agricultural scientists noted the importance to their research community of being allowed eventually to release organisms containing recombinant DNA into the environment. When the original guidelines were presented to me in draft form in 1976, the release of organisms containing recombinant DNA molecules into the environment was considered. If a series of controlled tests had been done to leave no reasonable doubt of safety, at that time I rejected this waiver provision because of the limited scientific evidence available that any of the potential environmental consequences such a release were near realization.**

The prohibition of deliberate release into the environment of recombinant DNA-containing organisms can be waived if all of the requirements for a waiver are met (and if the requirements of the National Environmental Policy Act are considered). Given the limited experience of NIH in agricultural research, the U.S. Department of Agriculture would be deeply involved in this process. I have given written notice of this decision to the appropriate officials of the USDA.

The Standing Advisory Committee on Recombinant DNA Research of the European Molecular Biology Organization (EMBO) has noted that the list of pathogenic organisms under prohibition 1-D-1, especially those in class 5, may not be appropriate for all European countries and that "the decision as to which pathogenic organisms should be classified as too dangerous to use must be the responsibility of national or regional authorities." In response to this footnote could be added to the guidelines stating that prohibition 1-D-1 relates only to research in the United States. I have decided, however, not to include such a footnote, because these guidelines are directed to NIH grantees and contractors, almost all within this country. In other countries, different criteria may govern.

A final change in the PRG-NIH relates to prohibition 1-D-1. As discussed below in this document in part III, considerable changes have been made in the sections dealing with the use of viral DNA in recombinant DNA experiments. The history leading to these changes, including the report of the "Ascot" workshop (appearing as appendix E to the accompanying Environmental Impact Assessment) and the report of the working group held on April 6-7, 1978 (appearing as appendix F to the accompanying Environmental Impact Assessment), are discussed in detail in part III of this document under the heading "Recombinant DNA Experiments Involving Viral DNA."

One of the Working Group's recommendations, arising out of the "Ascot" report and endorsed by the RAC at its April 27-28, 1978, meeting and endorsed by me, is that the previous prohibition on the use in recombinant DNA experiments of Vesicular Stomatitis Virus (VSV) and of oncogenic viruses classified by the National Cancer Institute (NCI) as "moderate risks" should be lifted; instead, use of these viruses should be permitted under containment conditions to be specified in part III of the guidelines. The reasoning behind this is that recombinant DNA experiments with pieces of these viruses cloned in E. coli K12 are no more risky, and actually appear to pose clearly less risk, than work with the whole infectious virus itself. Since the Center for Disease Control (CDC) and NCI recommend that work with these viruses not be prohibited, but rather be performed under containment conditions similar to F3, there is no scientific reason to prohibit recombinant DNA work with these viruses. Therefore, prohibition 1-D-1 in the PRG-NIH no longer prohibits the use of VSV or oncogenic viruses classified by NCI as moderate risk; containment conditions for their use are specified in part III of the guidelines.

**General Definitions**

In response to commentators' suggestions that terms be more precisely defined, I have agreed with the PRG-NIH with such definitions. Many of these terms are further discussed in part IV of PRG-NIH.

In summary, part I of the PRG-NIH has been extensively modified from that proposed in the PRG-RAC. In an effort to be responsive to the suggestions of commentators and to make the guidelines more comprehensible, the definition of recombinant DNA molecules has been simplified and clarified, the "Prohibitions" section has been transferred from part III to part I, and new sections have been added to part I including "Exemptions," part I, now entitled "Scope of the Guidelines," is composed of the following sections:

- **Purpose**
- **Definition of Recombinant DNA Molecules**
It should be noted that the Prohibitions appear before the Exemptions. This will again emphasize the fact that the latter provisions cannot be used to claim relief from the former.

II. CONTAINMENT

The object of these revised guidelines is to assure that experimental DNA recombination will have no ill effects on the researchers, on the general public, or on the environment. The essence of their construction, as in the case of the 1976 Guidelines, is subdivision of potential experiments by class, and assignment to these of certain procedures for containment.

Containment is both physical and biological. Physical containment involves the isolation of the research by procedures that have evolved over many years of experience in laboratories studying infectious micro-organisms. P1 containment—the first physical containment level—is that used in most routine bacteriology laboratories. P2 and P3 afford increasing isolation of the research from the environment. P4 represents the most extreme measures used for containing virulent pathogens, and permits no escape of contaminated air, waste, or untreated materials. Biological containment is the use of biological agents that are crippled by mutation so as to be incapable of surviving under natural conditions.

PHYSICAL CONTAINMENT

Review of RAC-Proposed Guidelines

Two major changes were proposed in the physical containment section of the PRG-RAC. One deals with the organization of the section; the other incorporates into the PRG-RAC the philosophy and guidance of the report of the NIH European Molecular Biology Organization (EMBO) Workshop on parameters of physical containment.

Physical containment requirements for each P level have been organized under the topic headings Laboratory Practices, Containment Equipment, and Special Laboratory Design. This was done to emphasize the importance of laboratory practices and containment equipment in achieving the desired safety objective.

Other revisions contained in the "Physical Containment" section reflect a conscious effort to encourage international uniformity with respect to recombinant DNA guidelines. This has been achieved by revising the containment descriptions so that they are consistent with the guidance provided in the NIH/EMBO report. In addition, some statements have been rewritten and others added in order to clarify the basic requirements for each level of containment. The most significant clarifications were made in the areas on containment equipment and special facility design. The revisions, however, have not resulted in changing the purpose or intent of the physical containment descriptions in the 1976 Guidelines.

Two specific additions to the Guidelines that originated from the NIH/EMBO report are particularly notable. The first is that Tables I and II have been added to the P3 and P4 sections, respectively. These tables show combinations of safeguards that provide similar protection. The combinations are dependent on the level of biological containment. This approach allows flexibility in selecting containment equipment for a particular study without compromising safety.

The second specific addition is the inclusion of laboratory design criteria for an area in which personnel wear positive-pressure suits ventilated by life-support systems. This added approach provides a level of physical containment equivalent to that afforded by the glove-box cabinet requirement at the P4 level.

Other important changes are summarized below:

- Certain specific microbiological practices are mandated at the P1 level in the PRG-RAC (whereas in the 1976 Guidelines they were merely encouraged);
- At the P2 level, prohibitions against eating, drinking, smoking, and storage of food have been extended from the work area to the entire laboratory;
- The universal biohazard sign is now required at the P2 level. Use of these signs has been extended to equipment such as freezers and refrigerators in which organisms containing recombinant DNA molecules are stored;
- Access procedures in controlled areas adjacent to P3 laboratories have been specified;
- Installation of foot-operated, or automatically-operated facilities for washing hands is now required in P3-level laboratories;
- Specific guidance on containment equipment appropriate for laboratory animals has been added to the P3 and P4 sections;
- The labeling requirements for shipment of plasmid agents now apply to all organisms containing recombinant DNA molecules. Thus, the Center for Disease Control, U.S. Public Health Service, must be notified in the event of any accidental breakage during shipment. Also, agents requiring P4 containment must be packaged according to strict Federal standards and be shipped by registered mail in an enclosed system that provides for notifying the shipper upon delivery.

I have carefully reviewed the recommendations of the PRG-RAC relating to physical containment and propose to adopt them with certain modifications. The modifications, based on issues raised by the Director's Advisory Committee and public commentators, are discussed below.

Review of comments and NIH-proposed guidelines

As reported in the "Decision Document" which accompanied the release of the 1976 guidelines, comments on the containment section of the original Guidelines were directed to the definitions of both physical and biological containment and to the safety and effectiveness of the prescribed levels. Several commentators at that time found the concept of physical containment imprecise and subject to human error. Others questioned the concept of biological containment in terms of its safety and purported effectiveness in averting potential hazards. The commentators were divided on which method of containment would provide the most effective and safe system.

Several suggested that each of the physical levels be explained more fully. The physical containment section of the 1976 guidelines—and now of the PRG-NIH—is directly responsive to many of these commentators. In addition, the NIH has considered, and public comment has been made on the topic of certain recommendations of the PRO-RAC relating to standards for physical and biological containment. Commentators on the PRG-RAC have expressed particular concern over (1) the flexibility which allows various combinations of containment safeguards, (2) the design of containment systems, and (3) the adequacy of training in laboratory safety practices. The Standing Advisory Committee on Recombinant DNA Research of the European Molecular Biology Organization (EMBO) made a number of recommendations that NIH has considered, and public commentators have provided additional suggestions relating to specific levels of physical containment and to shipment of recombinant DNA materials. These are examined below.

Concept of "Flexibility." Some commentators have expressed concern over the flexibility provided in Tables I and II that allows various combinations of containment safeguards. For
example, some feel that work in a P3 facility conveys a desirable sense of hazard, whereas a reduction to the P2 level will promote an undesirable relaxation of vigilance. It has also been suggested that the increase in the options increases the difficulty of control and implementation of the guidelines. Some commentators object to specific options provided at the P3 and P4 levels. NIH has been urged to include a better explanation of the rationale for this flexibility.

Indeed, the calculus of switching physical and biological containment levels has been questioned. Does an increase in biohazard at the P3 level from EK1 to EK2 truly compensate a reduction in physical containment from P3 to P2?

The scale of either form of containment from least to greatest is not necessarily linear, and substitutions are only roughly approximate. Nevertheless, there are some numerical bases for comparison.

For example, a class III biological safety cabinet is required at the P4 level (if a positive pressure suit is not used); whereas at P3, one can work in an open-front biological safety cabinet. The class III cabinet is virtually an absolute containment system. It is certified gas-tight when tested under negative pressure. It is operated under negative pressure to gain optimum safety. It provides at least a 10,000- to 100,000-fold increase in safety over that provided by a Class I or II cabinet, which does not maintain a negative pressure.

The relative safety of these two containment cabinets is based on the efficiency of their exhaust-air treatment systems. The exhaust-air treatment system for the class III cabinet is provided by two HEPA filters installed in series. This arrangement gives a containment efficiency of at least 99.99 percent. The exhaust-air treatment for class I and II cabinets, with only one HEPA filter, provides a containment efficiency of 99.99 percent. The potential for escape of microorganisms across the open front of the class I and II cabinets is similar to that for escape through the exhaust-air treatment system under operating conditions. These cabinets must meet a performance criterion which permits fewer than 20 microorganisms to escape through the open front when $1 \times 10^9$ (100,000,000) to $8 \times 10^8$ (800,000,000) microorganisms are experimentally released within the cabinet. The degree of protection provided by the class I or II cabinets is equivalent to the increase in safety at the P3 level over that provided at the P1 level which allows open-front operations.

The symbol HV (Host-Vector) is used in the PRG-NIH entitled, "Laboratory Safety Monograph" certain elements in these emergency plans. Moreover, NIH staff have recently met with representatives of the center for Disease Control (CDC) to establish a mechanism for providing advice, consultation, or assistance, if necessary, in case of an emergency, such as an accident in the laboratory.

Laboratory safety. A number of commentators felt that the PRG-RAC was vague in regard to the training in safety of researchers, students, and janitors. It was urged that specific curricula be developed and that a requirement for certification in training be stipulated in the guidelines (a recommendation also made by the EPA Study Group on Recombinant DNA). It has been suggested, further, that NIH develop curricula for training.

At the present time, NIH has a contract with the American Society for Microbiology (ASM) to develop minimum standards for training participants in recombinant DNA research. The ASM Work Committee will consider what standards of training in microbiological techniques are appropriate for the conduct of experiment requiring P1 through P3 containment conditions. The Panel will solicit views from the scientific community on additional minimum requirements for training. The Panel's report will be available to the IBC's and Investigators to set standards for all who participate in this research. In view of these developments, the issue of training was deferred.

Other commentators stressed the need for more stringent measures in regard to safe practices. In particular, these commentators urged regular monitoring of laboratory facilities, preferably at all P levels. This would include monitoring of microbiological practices, serological monitoring, and CDC review of incidence of infections. It was also suggested that regular inspections be performed by individuals not associated with the institution (to preclude conflict of interest); that the guidelines require a member of the work force to be represented on the institutional biosafety committee; and that penalties (other than cutoff of funds) be imposed on violators as a deterrent. I have accepted many of these proposals; the specific NIH actions in regard to them are discussed in Part IV of this document.

Appendix D, "Supplementary Information on Physical Containment," was added to the 1976 guidelines in response to numerous requests for greater specificity in describing containment requirements. Commentators noted the absence of this document from the PRG-RAC and urged that it be retained and further expanded. Ac-
cordingly, a special committee of safety and health experts was convened by W. Emmett Barkley, Ph.D., Director of the Office of Research Safety, National Cancer Institute, to review and revise this supplementary information. Several sections have been extensively rewritten, and new sections have been added and deleted. Revisions were made to ensure consistency with the guidelines already authorized to certify safety practices and procedures; however, to respond more directly to the above suggestion, a special section on certification of biological safety cabinets has been included in the supplement to the PRG-NIH entitled "Laboratory Safety Monograph."

The EMBO Standing Advisory Committee on Recombinant DNA Research observes that in the case of a P3 facility, the proposed revisions do not absolutely require the installation of the autoclave. Furthermore, that the autoclave is not a suitable instrument to separate potable water systems from laboratory process water. Additional precautions have been required at the P4 level. Standard design practice is felt to be appropriate at the P3 level.

Some commentators have pointed out that the PRG-RAC did not require an autoclave in the P3 laboratory itself but only within the building. The 1976 guidelines require that for P3 laboratories an autoclave be available "within the building and preferably within the controlled laboratory area." Some believe an autoclave in the P3 laboratory should be required. One commentator felt that the autoclave should be "as close as possible" to the controlled area of the P3 laboratory, not merely available in the same building. He pointed out that from an operational point of view, the closer the autoclave can be to the solid waste, the better. This is especially true in the larger medical research complexes, where transport of wastes from the laboratory to the autoclave might involve passage "via some rather sensitive patient areas of the institution." He prefers that the autoclave be located either in the controlled area or as close to it as possible, with such explicit language in the guidelines. The language in the 1976 guidelines stating that in a P3 laboratory "an autoclave shall be available within the building and preferably within the controlled laboratory area" has been reinserted in the PRG-NIH. However, an absolute requirement that the autoclave must be within the controlled area is not considered appropriate, since contaminated materials can be safely transported. Such a requirement would exclude the use of autoclaves in waste staging areas that have been conveniently sited to support an entire facility.

The PRG-RAC states that P4 work can be done in either (1) a class III cabinet system or (2) a class II cabinet system in a special area where all personnel wear one-piece, positive-pressure suits. Some investigators apparently prefer use of pressure suits rather than work in the class III cabinet. NIH requirements for such suits are especially useful in working with experimental animals in a P4 facility or with large amounts of material. At present, however, most recombinant DNA studies are handled more practically in a class III without need for a suit.

In 1976, several commentators advocated that NIH arrange for sharing of P4 facilities, both by investigators from the NIH intramural program and from institutions supported through NIH awards. In response to these suggestions and those of recent commentators, we have arranged to make our recently established P4 facilities at the Frederick Cancer Research Center (Fort Detrick) available to outside scientists.

Shipment. Some commentators have urged that stricter controls be required on shipping recombinant DNA molecules in or out of the country. It has been recommended, for example, that shipping procedures differentiate between types of substances being transported. We wish to emphasize that requirements for shipping organisms that contain recombinant DNA molecules are consistent with relevant Public Health Service, Department of Transportation, and Civil Aeronautics Board regulations. In compliance with the World Health Organization recommendations on the international shipment of biologic agents. It should be noted that organisms containing recombinant DNA molecules all require the same containment conditions as for the most hazardous known agents.

The EMBO Standing Advisory Committee on Recombinant DNA Research recommends that before a shipment is made, the recipient of organisms containing recombinant DNA molecules should affirm to the donors that they are following the safety standards and practices of their country. NIH considers this a sound recommendation and requires the following (as stated in the NIH Guide for grants and contracts):

All memora of understanding and agreement (MOU's) submitted with competitive and noncompeting applications involving recombinant DNA research must indicate that the principal investigator (program director, fellow, or grantee) agrees to comply with the NIH Guidelines and other specific NIH regulations pertaining to the proposed project. Included in the provisions are the following pertinent to shipment or transfer of recombinant DNA materials:

A. Prior to shipment or transfer of recombinant DNA materials to other Federally funded laboratories within the United States, the sending laboratory shall obtain a letter from the requesting laboratory stating that:

1. Research involving recombinant DNA molecules shall be conducted in compliance with the NIH Guidelines and other NIH instructions, and that the requesting laboratory shall not transfer the recombinant DNA materials to other laboratories.

2. The requesting laboratory has been reviewed by its Institutional Biosafety Com-

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mittee which has certified that facilities, procedures, and the training and expertise of the personnel involved are adequate;

3. An application for a certificate is on file with the funding agency of the requesting laboratory;

4. A certificate is on file with the requesting laboratory's Institutional Bioshards Committee.

B. Prior to shipment or transfer of recombinant DNA materials, the sending laboratory shall obtain a letter from the requesting laboratory stating all of the containment levels specified by the NIH Guidelines, or applicable national guidelines if such have been adopted by the country in which the research is to be conducted, and that the requesting laboratory shall not transfer the recombinant DNA material to other laboratories.

D. The sending laboratory shall maintain a record of all shipments of recombinant DNA materials and shall provide NIH with a complete list of such shipments in the annual report for NIH grants and contracts.

Mouth-pipetting at the P1 level.

Both the 1976 guidelines and the PRG-RAC prohibit mouth-pipetting at the P2, P3, and P4 levels. For the P1 level, however, they state, "Although pipetting by mouth is permitted, it is preferable that mechanical pipetting devices be used. When pipetting by mouth, cotton-plugged pipettes shall be employed." A number of commentators have urged that mouth-pipetting be prohibited at the P1 level of physical containment. This is strongly endorsed by NIH safety experts, who point out that this is an important safety feature, and that efficient new mechanical pipetting aids should not greatly hamper researchers. Also, the EMBO/Primary Organization on Recombinant DNA Research believes that mouth pipetting should be prohibited at the P1 level in the laboratory, as it is prohibited in P2-P4 laboratories. In addition, a number of American virologists which met on April 6-7, 1978, to review the report of the U.S.-EMBO Workshop to Assess Risks for Recombinant Experiments Involving the Genomes of Animal, Plant, and Bacterial Viruses1 wrote the following in their report:

In its deliberations, the Working Group was impressed with the safeguards afforded by a ban on mouth pipetting for recombinant DNA experiments involving E. coli K-12 host-vectors. The group felt that the only plausible way E. coli K-12 could gain entry to the laboratory was by oral ingestion. The analysis contained in the U.S.-EMBO Report was predicated on the idea that at the P1 level, containing caryokaryotic viral DNA, would be swallowed and the viral DNA insert would be delivered to a tissue in the body which would be chronically infected by the virus. A prohibition of mouth pipetting would clearly prevent this sequence of events from even beginning. The Working Group therefore recommended that no mouth pipetting be allowed at any level of physical containment (including P1) when working with E. coli K-12.

On the other hand, when I request ed that the RAC, at their April 27-28, 1978, meeting reconsider whether mouth pipetting should not be banned at the P1 level, it was their consensus that many experiments classified as P1 need not include a ban on mouth-pipetting, and that therefore P1 in general should not be redefined. Instead, they recommended that only certain classes of P1 experiments be designated as requiring no mouth-pipetting.

In resolving this issue, I have decided to adopt the conservative position and ban mouth-pipetting. Accordingly, language has been inserted in the PRG-NIH saying that at the P1 level, "Mechanical pipetting devices shall be used; mechanical pipetting shall be prohibited." Since mouth-pipetting had already been banned at the P2-P4 levels, this means that it is now banned for all experiments covered by these guidelines.

BIological containment
Review of RAC-proposed guidelines
The proposed revised guidelines define some biological barriers as a means of containment. In fact, there are natural barriers to applications of highly specific biological barriers as a means of containment. In fact, there are natural barriers to applications of highly specific biological containment, which they call "host-vector systems." The PRG-RAC provides criteria for host-vector systems other than those based on E. coli K-12, and that such experiments should be permitted so long as the proposed HV system provides equivalent biological containment. The new HV1 criteria provide a structure for approval of systems that meet these requirements.2

Definitions of host-vector systems. A new nomenclature—HV1, HV2, and HV3—has been developed to incorporate a variety of hosts and vectors into the framework initially established for E. coli K-12. In particular, the PRG-RAC provides criteria for HV1 systems other than E. coli K-12. In the 1976 guidelines recombinant DNA experiments involving E. coli K-12 were to be considered only if superior to E. coli K-12 in containment properties; but it is now recognized that many useful experiments can be conducted in HV systems other than those based on E. coli K-12, and that such experiments should be permitted so long as the proposed HV system provides equivalent biological containment. The new HV1 criteria provide a structure for approval of systems that meet these requirements.2

The proposed criteria are that any recombinant DNA molecules shall be contained when the vectors or vehicles (plasmids or virus) to specific hosts, or its dissemination to applications of highly specific biological containment, which they call "host-vector systems." The PRG-RAC provides criteria for host-vector systems other than those based on E. coli K-12, and that such experiments should be permitted so long as the proposed HV system provides equivalent biological containment. The new HV1 criteria provide a structure for approval of systems that meet these requirements.2

1The history of the U.S.-EMBO Workshop and the April 6-7, 1978, working group is discussed in detail in P. III of this document under the heading "Recombinant DNA Experiments Involving Viral DNA" and the report of the working group appears as App. E to the accompanying environmental impact assessment.

2Under the proposed revisions, HV1s other than E. coli K-12 need not offer a distinct advantage over E. coli K-12 host-vectors, need not be capable of modification to pHEV2 and HV3, and need not be class 1 etiological agents.
Certification of host-vector systems. A new section has been added detailing the responsibility for certification of HV1, HV2, and HV3 systems, the types of data to be submitted, and the mechanisms for distributing strains once certified. The guidelines also detail the procedures used by the RAC for the past 2 years and therefore represents a change from practices under the 1976 guidelines.

Review of comments and NIH-proposed guidelines

I have reviewed the biological containment selection of the PRG-RAC in the light of comments and suggestions made by participants of the Director's Advisory Committee (DAC) as well as written comments received before and after, and have adopted the recommendations of the PRG-RAC with some revisions. An analysis of the specific issues raised by commentators and the basis for my decision follow.

Development of Alternative Host-Vector Systems. Many commentators from the scientific community believe that the PRG-RAC discriminates against alternate host-vector systems other than E. coli K-12. They urge development of other systems, maintaining that new systems will be needed increasingly, both in pure research and in industry, and should be certified as soon as possible. It is unlikely, according to one commentator, that agriculture will be served through the use of E. coli K-12 (or E. subtilis), and that alternate host-vector systems are therefore essential if the potential of recombinant DNA technology for agriculture is to be realized. In view of the support evident at the 1976 DAC meeting for NIH to encourage development of alternate host-vector systems, one commentator expressed disappointment that there was not now a large NIH contract program in this area.

Others view the introduction of alternate HV systems with some misgivings. It was pointed out, for example, that if uncertainty continues to surround research into well-studied organism as E. coli K-12, our ignorance must be that much greater with regard to any other organism—its ecological involvement, the organisms with which it can exchange DNA, etc. Moreover, the guidelines, which have been developed around the use of E. coli K-12, are primarily focused on dangers to man, and the introduction of new systems may affect other life forms with which we should be equally concerned. In the view of commentators who urge restraint, the larger the number of systems certified, the greater the problem of monitoring the work.

Clearly, however, research addressed to the development of other host-vector systems must proceed. This is particularly evident in the agricultural sector, where the potential for immediate benefits to man is great. At present, a number of alternate systems, including those using B. subtilis and Saccharomyces cerevisiae, are being developed. The interest shown by numerous investigators in developing new host-vector systems means that NIH need not develop a special program to promote research in this area.

Adequate protection for man, and the Introduction Vector Systems. Moreover, the guidelines, which have been developed around the use of E. coli K-12, will also apply to any new host-vector systems to be certified in the future.

Risk Assessment. Many commentators advocate more studies in risk assessment. It has been maintained that assumptions about biological containment may not be valid and that all components should be tested. Concern has been expressed that the biological containment/safety systems may fail altogether.

Some risk assessment studies are prohibited by the 1976 guidelines. Under the PRG-RAC, however, the RAC, on request, may carry out an experiment which, in the judgment of the RAC, would have discretion to permit such risk assessment experiments by granting a waiver from a specific prohibition. There was virtually unanimous support for this discretion at the DAC hearing in December 1976. Of course, its exercise must be consistent with standards of due process for the scientific community and the public.

Risk assessment studies are proceeding both within and outside the United States. For example, the "polyoma" experiment, which was delayed in this country because of litigation and the renovations necessary to meet the extremely stringent P4 requirements, has now begun here, and a similar experiment is proceeding in Europe. The work of Robin Hood and his colleagues on the safety of biological accidents is also noteworthy (see appendix P of the October 1977 Environmental Impact Statement).

NIH is committed to the conduct and support of risk analysis studies to determine the extent to which certain potentially harmful effects from recombinant DNA molecules may occur. It is intended that the NIH P4 facilities both in Bethesda, Md., and at the Frederick Cancer Research Center will serve as a focal point for many such studies. Provision has already been made to share these facilities with non-governmental scientists.

It should be stressed that prior to certification as EK2, each candidate EK2 host-vector system is analyzed in detail by the RAC and NIH. Much data must be submitted, a good deal of which is risk assessment data.

Safety of E. coli K-12. In 1976, there was considerable comment regarding the use of E. coli K-12 as a host, including recommendations that its use be prohibited. Some recent commentators have also questioned the safety of E. coli K-12, noting that the Falmouth Workshop proceedings had not been published for public review. On the other hand, one commentator urged that, based on the safety of E. coli K-12, essentially all experiments employing E. coli K-12, be exempted from the Guidelines. An extensive discussion of E. coli K-12 together with new scientific information on its safety are presented in part III of this document and in a special section of the Environmental Impact Assessment.

The proceedings of the Falmouth Workshop have now been published in the May 1978 issue of Journal of Infectious Diseases. Reprints are available from the Office of Recombinant DNA Activities, NIH, Bethesda, Md. 20201. As noted in a letter of July 14, 1977, from Dr. Sherwood Gorbach, moderator of the Falmouth Workshop and Chief of Infectious Disease and Professor of Medicine at Tufts University School of Medicine, "The participants arrived at unanimous agreement that E. coli K-12 cannot be converted into an epidemic pathogen by laboratory manipulations with DNA inserts."

Comments on Specific Containment Levels. One commentator sought clarification of section II-D-1-a of the PRG-RAC, which defines HV1. According to the second sentence, "the host should have a low potential for survival in its natural environment." As the commentator noted, "natural environment" could be ambiguous, in practice. Presumably many of the host cells that may wish to use have no natural environment other than the laboratory." I referred this comment to the RAC at its April 27-28, 1978, meeting. The RAC agreed that this sentence is ambiguous and recommended that it be deleted. I have done so in the PRG-NIH.

A question was raised on whether HV1 hosts could be wild type organisms or if they are always "meant to harbor containment mutations." If wild type organisms can qualify as HV1, then the definition of HV1 should be reworded to state this explicitly. The answer to the question is that if wild type organisms meet the criteria for HV1, they may be certified...
as HV1. However, I see no need to modify the definition to state this explicitly.

One commentator thought the standards for HV1 should be significantly relaxed and that NIH approval should not be necessary. He proposed that the Guidelines state that “wild type isolates of any bacteriophage or its recombinant DNA molecules introduced into such a host-vector system, are derived from other prokaryotic organisms within Etiologic Agent Class I.” I have rejected this suggestion since I believe it prudent, at least for the present, to have higher standards and to require NIH approval before a system may be called HV1. Some commentators have urged that the requirement for independent confirmation of certain phenotypic traits before certification at the HV3 level should also be applied at the HV2 level. There are two objects of such testing: (1) To determine whether a system already approved has changed its characteristics before a new sample of it is distributed (for example, whether the amber mutations for phage systems are still present), and (2) to repeat independently all the safety tests and confirm that each of these systems would be certified. The first could be done easily and is sufficient to confirm the safety characteristics; the second is cumbersome and difficult. It should be pointed out that the RAC and its working groups that review the data on proposed HV2 systems are, in effect, conducting an independent check and know this area of research well. Further, the Committee may request that additional experimental data be submitted before each of these systems is approved.

The requirement for an independent check at the HV2 level is deemed unnecessary.

For the HV3 level of containment, some objections have been raised to the requirement banning antibiotic-resistance markers. Antibiotic resistance can serve as a valuable marker in experiments with organisms bearing recombinant DNA. The ban at the HV3 level, however, is prudent inasmuch as organisms rendered antibiotic resistant would be less amenable to control should they escape from the laboratory. This requirement also allows only a certain class of certified HV2 systems to qualify for HV3. Therefore, attempts to develop systems that meet these HV3 criteria should simultaneously upgrade the HV2 systems in use, since it is to the experimenter’s advantage to use those HV2 systems with the greatest likelihood of meeting HV3 criteria. Certification of a number of commentators have urged more precise criteria for biological containment systems. They feel that criteria should be as objective as possible and should be framed in terms of performance, as in the case of physical containment (for example, safety cabinets). It should be stressed that specific objective criteria do exist for EK2 host-vector systems. These, however, do not appear in the Guidelines themselves, but rather as information in the Environmental Impact Statement, Appendix H, entitled “Certification of EK2 Host-Vector Systems.” To insure that detailed material on certification of host-vector systems is readily accessible, NIH will publish specific criteria in a standardized format in the Recombinant DNA Technical Bulletin. Specific instructions concerning the type of data to be submitted to NIH for proposed EK2 systems involving either plasmids or bacteriophage lambda in E. coli K-12 are available from the NIH Office of Recombinant DNA Activities, and a statement to this effect is included in the PRG-NIH document. Many problems persist for setting general criteria that could be applied to all organisms for possible certification as HV2 and HV3. For example, with E. subtilis, which forms spores, safety would depend on nonsporulating derivatives. Some commentators have urged that all new systems be certified with deliberate caution, and that criteria and evidence should be a matter of public record before decisions are made. The E. subtilis system was cited as a case in point; extensive public analysis and debate should precede certification.

I agree that prior notification to the public in the Federal Register should be required for significant applications for certification. (It should be noted that all meetings of the RAC are announced in the Federal Register.) I also agree with the suggestion that the RAC should have a more fixed schedule of meetings throughout the year so that the public and scientific communities may know the schedule of events clearly.

The entire section (II-D-2-a) on responsibility for certification of host-vector systems has been rewritten in the PRG-NIH to clarify this process. Distribution of Certified Host-Vectors. Some commentators have suggested that NIH distribute HV1 systems as well as HV2 and HV3 systems. Language has been placed in the PRG-NIH indicating that, where appropriate, HV1 systems other than E. coli K-12 may be sent by NIH to investigators. Concern has been expressed about culture contamination and how this problem would be addressed. The PRG-NIH provides that if NIH propagates any of the host-vector phages, it will not distribute the culture before sending a sample to the investigator who developed the system or to an appropriate contractor for verification that the culture is free from contamination and unchanged in phenotypic properties.” The PRG-NIH also assigns to the investigator the responsibility for “insuring the integrity of physical containment (e.g., biological safety cabinets) and biological containment (e.g., genotypic and phenotypic characteristics, purity, etc.).” Distribution of certified host-vector systems has raised comment relating to the protection of proprietary information and patent rights, for this section of the Guidelines seems to mandate distribution and might conflict with patent protection. NIH has carefully considered such protection. Language has been included in the PRG-NIH (in section IV-D) allowing RAC review for certification at the request of the private sector. The language notes, however, that interested individuals should consider filing for patent protection before submitting information to DHHS. To be consistent with the institutional patent agreement policies of the Department of Health, Education, and Welfare, support is accorded the concept of protection of proprietary and patent rights within the bounds of due process for public review.

III. Containment Guidelines for Covered Experiments

Review of RAC-proposed guidelines

A major concern of all individuals who have participated in establishing guidelines for recombinant DNA research is that any guidelines that are drafted and adopted be reassessed periodically and expeditiously. Although improvements are warranted by new information and/or experimental data. In keeping with this responsibility, the RAC compiled additional information pertaining to risk assessment in recombinant DNA research. This information is in the following forms:

1. Consultations with scientists with expertise in the areas of evolution, plant biology, bacteriology, virology, and human and animal infectious diseases;
2. Reports from scientific meetings dealing with the potential hazards of recombinant DNA research (for example, the Tenth Elisha International Symposium on Recombinant Molecules—Impact on Science and Society, Cambridge, Mass., June 1976; the National Academy of Sciences Forum on Recombinant DNA, Washington, D.C., March 1977; Genetic Engineering for Nitrogen Fixation, Brook-
Results of experiments specifically designed to test (a) the survivability and colonizing ability of E. coli K-12 and EK2 host-vector systems, (b) the transmissibility of plasmids and phage vectors, (c) the potential of E. coli K-12 for pathogenicity, and (d) the potential of genetic exchange between diverse bacteria and between eukaryotic and prokaryotic organisms.

Each category of experiments in part III of the original guidelines was then extensively examined, applying the following criteria to the new information:

- The degree to which the DNA segment has been purified away from other genes and shown to be free of harmful characteristics;
- The potential biohazard associated with the DNA of the cell or microorganism that serves as the DNA source (e.g., genes for toxin production);
- The potential biohazard associated with the vector that serves to transmit the source DNA to a recipient host cell;
- The ability of the vector to survive in natural environments or habitats;
- The kinds and number of different organisms that are susceptible to infection by the vector or recipient;
- The potential biohazard of the recipient host cell that serves to replicate the recombinant DNA molecule;
- The ability of the recipient cell to survive in natural environments of habitats;
- The ability of the recipient cell to transmit the recombinant DNA molecule to other cells capable of surviving in natural environments or habitats;
- The potential of the recipient cell to obtain the source DNA by natural means; and
- The evolutionary relatedness of the DNA source to humans. The potential dangers are considered to increase as the organism providing the source DNA approaches human phylogenetically. Thus, source DNA from primate cells is considered to have greater potential danger than source DNA from prokaryotes.

To present more clearly the changes in containment levels proposed by the PRG-RAC, a table was prepared for use at the December 1977 meeting of the Advisory Committee to the Director, which compared the containment levels in the PRG-RAC with those of the 1976 guidelines. This table has now been expanded with a third column to show the containment levels of the proposed revised guidelines which are now being proposed by NIH (called PRG-NIH). The table appears as appendix A, to the accompanying Environmental Impact Assessment.

The remainder of this section summarizes a number of the proposed changes comparing the 1976 guidelines with those of the PRG-NIH. Under the original guidelines, containment for E. coli K-12 clones containing characterized and harmless portions of viruses and plasmids could not be lowered.

The rationale for these proposed changes is explained in further detail in the Environmental Impact Assessment.

### Rationale

Part III of the guidelines received the most extensive comment in any section during the development of the original guidelines in early 1976. While there was also much discussion of this part in the PRG-RAC, the issues raised did not primarily address the proposed changes in the containment levels but more general topics such as the need for a rationale for each of the changes.

A number of commentators noted that the rationale for the classification of permissible experiments be clearly spelled out. It was pointed out that (1) the part on permissible experiments is especially difficult for a lay person to understand, (2) the whole categorization is dependent upon investigational confidence rather than documented fact, and (3) the quantification of containment levels, the means by which the levels were decided, and the rationale for raising and lowering these levels are not clear.

In general, the classification may appear somewhat arbitrary, because it depends in large part on the scientific judgment of the RAC rather than on demonstrable risk, since there is actually no scientific evidence of hazard to any recombinant DNA experiment.

The rationale for classifying different recombinant DNA experiments at different containment levels was explained in the "Decision of the Director, National Institutes of Health, To Release Guidelines for Research on Recombinant DNA Molecules," which was published along with the current guidelines in the Federal Register on July 7, 1976, as follows:

The guidelines assign different levels of containment for experiments in which DNA from different sources is to be introduced into an E. coli K-12 host-vector system. The variation is based on both facts and circumstantial evidence, and no clear-cut test of containment has been achieved.
fluores, because an exchange experiments have undoubtedly been performed already in nature.

In every instance of artificial recombination, consideration must be given to the possibility that foreign DNA may be translated into protein (expressed), and also to the possibility that the increased efficiency of the host may be expressed and thus change, undesirably, the characteristics of the cell. It is assumed that the more similar the DNA of donor and host, the greater the probability of expression of foreign DNA, or of possible derepression of host genes. In those cases where the donor exchanges DNA with E. coli in nature, it is unlikely that recombination experiments will create new genetic combinations. When prokaryote donors known not to exchange DNA with E. coli in nature are used, however, there is a greater potential for new genetic combinations to be formed and expressed. Therefore, it is required that experiments involving prokaryotic DNA from a donor that is not known to exchange DNA with E. coli in nature be carried out at a higher level of containment. Recombination using prokaryotic DNA from an organism known to be highly pathogenic is prohibited.

There are only limited data available concerning the expression of DNA from higher forms of life (eukaryotes) in E. coli. If any other prokaryote. Therefore, the containment prescriptions for experiments inserting eukaryotic DNA into prokaryotes are based on risks having quite uncertain probabilities.

On the assumption that a prokaryote host might translate eukaryotic DNA, it is further presumed that the product of that foreign gene would be most harmful to man if it were an enzyme, hormone, or other protein that was similar (homologous) to proteins already produced by or active in man. An example is a bacterium that could produce insulin. Such a "rogue" bacterium could be of benefit if contained, a nuisance or possibly dangerous if capable of surviving in nature. This is one reason that the higher the phylogenetic order of the eukaryote, the higher the recommended containment, at least until the efficiency of expression of DNA from higher eukaryotes in prokaryotes can be determined.

There is a second, more concrete reason for scaling containment upward as the eukaryote host becomes similar to man. This is the concern that eukaryotes are better adapted to living in human tissue, and possibly causing diseases, can contaminate DNA, replicate in prokaryote hosts and infect the experimentalist. Susceptible DNA from donor tissue is used in "shotgun" recombinant experiments; it diminishes to much lower levels when pure cloned DNA is used.

The structure of the classification for permissible experiments is based, therefore, on assumptions governing potential risk. It should be emphasized again that although recombinant DNA experiments have now been performed for over five-years in hundreds of laboratories throughout the world with hundreds of thousands of different recombinant DNA molecules produced, no case of hazard has been demonstrated.

Part III of the guidelines assigns to each specified class of experiments a level of physical containment and a level of biological containment at which the experiment shall be performed. As noted before, there is no "zero" level of safety. For biological containment, there is the criterion for HSV systems that "escape of the recombinant DNA either via survival of the organisms or via transmission of recombinant DNA to other organisms should be less than 1/100 under specified conditions." However, that criterion is not relative to the HSV host-vector systems but absolute; thus, this might be a characteristic found for some host-vectors in the HSV system, but it is mandated for all HSV systems. This level was chosen, it was pointed out, because it represents a practical limit which one can measure experimentally.

Use of E. coli K-12

A number of comments were made concerning the use of E. coli host-vector systems. It was observed that because K-12 is currently a "poor" pathogen doesn't mean that it might not be converted to a "good" pathogen with the addition of one or two genes; the efeebled nature of E. coli K-12 is presumably the consequence of mutations introduced during its laboratory passage," but that perhaps different strains of K-12 with different histories may not all be similarly enfeebled.

Further, it was claimed that the failure to convert K-12 to a pathogen by the use of certain plasmids or Salmonella genes is not definitive: to be definitive, we must have the detailed nature of the mutations in K-12 which prevent the expression of pathogenicity." Also, it was noted that there is no way to assess the absolute risk associated with these experiments, and that it is important to assess the potential harm not only to man but to plants, animals, and the environment.

Another commentator urged that this section be supplemented with the evidence from the Falmouth Conference to show that the potential risk is minimal. A commentator cited the potential risk on the basis that "virtually any highly conserved physiologically active eukaryotic protein** or fragment thereof could be highly toxic when introduced out of context by a bacterium which received the appropriate gene in a recombinant experiment." This criticism of the E. coli K-12 system does not detract from the scientific knowledge over the past two years of the great safety of this system. This evidence is presented in detail in the Environmental Impact Assessment. I agree that different strains of K-12 with different histories may not all be similarly enfeebled and that failure to convert K-12 to a pathogen to date does not prove it can never happen. However, the safety of E. coli K-12 has been clearly shown and we need not limit ourselves to particular strains for E. coli.

On the basis of the Falmouth Conference (which is discussed further in the Environmental Impact Assessment), the conclusion can be drawn that it is essentially impossible for E. coli K-12 to be transformed by recombinant DNA into a pathogenic E. coli. An E. coli K-12 containing toxic genes through recombination could theoretically present a risk to a laboratory worker who accidentally ingested it; but it would only be to that laboratory worker. I am evidence to show that harmful genes will have a very low probability of being transferred from E. coli to another organism. The plasmids used at the HSV level are engineered so that they neither can transfer nor transform when another plasmid induces conjugation. Thus, the high degree of safety of this system is clear and explains why it is preferable to any other host-vector system at present.

General Classification

Disagreement was expressed over whether the PRG-RAC was too stringent or too lax. Those advocating a more stringent position maintain that the guidelines should be relaxed even further because all the experimental evidence gathered and analyzed in the past 2 years indicates that the initial fears concerning the potential hazards were extremely exaggerated; moreover, the benefits to be derived from the research are great. Also, it is pointed out that recombinant DNA experiments not allowed under the current NIH guidelines are proceeding with the approval of responsible national committees in a number of European countries. Those opposing this view argue that there is a lack of experimental data for a sound evaluation of the potential risks, and the fact that a recombinant DNA experiment is permitted in Europe is irrelevant to the establishment of standards in the United States.

Recombinant DNA Experiments Involving Viral DNA

FEDERAL REGISTER, VOL. 43, NO. 145-FRIDAY, JULY 22, 1978
Many of the commentators agreed that both the original guidelines and the PRG-RAC were overly stringent with regard to virus experiments. In commenting on the PRG-RAC, the EMBO Standing Committee on Re- combinant DNA Research wrote:

The EMBO Committee believes that the containment categorization of experiments with animal virus DNA's which is proposed by the NIH Animal Virus Committee is too discriminating and excessively stringent considering the proposed classification of experiments with DNA and the longstanding, accepted safety precautions for handling intact virus particles and viral nucleic acid.** The EMBO Committee proposes that it would be more reasonable either to consider experiments with viral DNA on a case-by-case basis or to produce a detailed set of recommended categories for experiments with specific viral DNA's. The EMBO Committee expects in the near future to establish an ad hoc international group of virologists to draw up such proposals.

In response to this suggestion (i.e., for an international group of virologists to consider this issue), a joint U.S.-EMBO Workshop To Assess Risks for Recombinant DNA Experiments Involving the Genomes of Animal, Plant, and Insect Viruses was held in Ascot, England, on January 26-28, 1978. The workshop was attended by 27 distinguished scientists from the United States, the United Kingdom, West Germany, Finland, France, Sweden, and many other countries. One of the goals of the "Ascot" Workshop was published in the FEDERAL REGISTER on March 31, 1978, and appears as appendix A to the accompanying Environmental Impact Assessment. The workshop concluded:

The probability that K-12 organisms carrying viral DNA inserts could represent a significant hazard to the community was so small as to be of no practical consequence.*** The viral genome in the K-12 plasmid vector was not of concern. Consequently, cloning in E. coli K-12 using approved plasmid or phage vectors, pose no more risk than work with the infectious virus or its nucleic acid if not absolutely necessary.

The workshop participants agreed that cloning of viral DNA in E. coli K-12 may provide a unique opportunity to study with greatly reduced risks the biology of extremely pathogenic and virulent viruses.

On April 6-7, 1978 (as announced on March 17 in the FEDERAL REGISTER), a working group sponsored by the RAC, composed of distinguished American microbiologists, met to review the report of the "Ascot" Workshop. The report of this working group appears as appendix F to the accompanying Environmental Impact Assessment. The working group unanimously endorsed the "Ascot" report with certain minor amendments. Their report included recommended new language to be inserted into the PRG-NIH. The working group also commented on the sections dealing with viruses in the PRG-RAC. This report was presented to the RAC at its April 27-28, 1978, meeting, and was unanimously endorsed by the RAC with certain minor recommendations. I have accepted these recommendations of the RAC, with certain additional minor amendments, and these now constitute the sections dealing with viruses in part III of the PRG-NIH.

Recombinant DNA Experiments Involving DNA from Plants and Plant Pathogens

One of the comments made at the December 1977 meeting of the Advisory Committee to the Director, NIH was that "the NIH guidelines do not adequately deal with the use of recombinant DNA in plants.** Other commentators have expressed similar sentiments, and the suggestion has been made that "a subcommittee be formed to deal with plants and plant pathogens and make specific recommendations for revision of the guidelines."

Workshop To Assess Risks for Recombinant DNA Experiments Involving the Genomes of Agricultural Pathogens, composed of distinguished American plant pathologists, was held on March 20-21, 1978 (as announced on March 6 in the FEDERAL REGISTER). Sponsored by the U.S. Department of Agriculture, the National Science Foundation, and the NIH, the report of this workshop appears as appendix G to the accompanying Environmental Impact Assessment. The report was presented to the RAC at its April 27-28, 1978, meeting and was unanimously endorsed by the RAC with certain minor amendments. I have accepted these recommendations of the RAC with certain additional minor amendments; these involve changes in the PRG-NIH in sections dealing with the use of plants and plant pathogens in recombinant DNA research.

On the other hand, in certain other specific cases (e.g., DNA from birds) the PRG-RAC recommended the containment level be P2+EK2, without the option of P3+EK1. Certain commentators urged that in all cases where the containment level of P2+EK2 is given, the option of P3+EK1 be allowed. However, the RAC felt that in view of their increased confidence in the biological containment offered by the EK2 system, P2+EK2 offers more containment than P3+EK1. Therefore, that P2+EK2 without the option of P3+EK1 should be the containment level for certain specified classes of experiments. I accept the view of the RAC and have therefore specified in the PRG-NIH the containment levels of P2+EK2 without the option of

NOTICES

Section III—Opening Paragraphs

As discussed above in part I of this document, the section of the guidelines numbered III-A in both the 1976 guidelines and the PRG-RAC and entitled "Experiments That Are Not To Be Performed" has been moved in the PRG-NIH to become section I-D entitled "Prohibitions." This leads to a renumbering of the remaining subsections of part III of the PRG-NIH as compared to the PRE-RAC.

Two new paragraphs have been inserted at the beginning of part III of the PRG-NIH. The first reminds the reader to consult part I "where listings are given of prohibited and exempt experiments."

The second inserted paragraph is a "flexibility clause." Insertion of such a "clause" was recommended by the RAC at its April 27-28, 1978, meeting. It recognizes that the classification of experiments given in part III will necessarily be imperfect, as investigators in the future devise new ways to conduct recombinant DNA experiments not currently foreseen and therefore not explicitly considered in the guidelines. Also, new data may become available showing that certain particular experiments currently assigned a particular containment level are, indeed, clearly more (or less) safe than envisioned at this time. Therefore, this "clause" states that "changes in these levels for specific experiments (or the assignment of levels to experiments not explicitly considered here) may be expressly approved by the Director, NIH, on the recommendation of the Recombinant DNA Advisory Committee (RAC)."

Section III–A–I–a. Shotgun Experiments into E. coli K-12 with Inserted Eukaryotic DNA

At a number of places in this subsection the principal investigator is allowed to choose between two combinations of containment procedures. For example, in several instances one is permitted to use P2+EK1 or P1+EK2. This was endorsed by some commentators but questioned by others. This concept of flexibility was addressed in part II of this document. I also wish to point out that the concept is not a new one—it was allowed under the original guidelines. Based upon events of the past 2 years, the RAC merely proposed that this principle be extended to certain specified additional cases where they believe it appropriate. I agree with their proposed additions and therefore included in the PRG-NIH all such specific cases of flexibility recommended in the PRG-RAC.
In the 1976 guidelines, the section (III-B-2-a)-(iii) dealt with shotgun experiments into E. coli K-12 with inserted prokaryotic DNA was subdivided into two sections, i.e., "Prokaryotes That Exchange Genetic Information With E. coli" and "Prokaryotes That Do Not Exchange Genetic Information With E. coli." In the PRG-RAC it was assumed that all prokaryotes that exchange genetic information with E. coli would be exempt from the guidelines by appearing on the "list of nonnovel exchangers." Therefore, in the PRG-RAC the section (III-B-1-a)-(2) dealing with shotgun experiments into E. coli K-12 with inserted prokaryotic DNA actual- ly considered only prokaryotes that did not exchange genetic information with E. coli. The problem with this approach was discussed by commentators, focusing especially on the case of Agrobacterium tumefaciens. It meant that a prokaryote which exchanges genetic information with E. coli, and was therefore properly assigned a low containment level under the 1976 Guidelines, would under the PRG-RAC in this category appear on the list, this section in the PRG-NIH (III-A-1-b-(11)) reads:

"Prokaryotes That Exchange Genetic Information [35] with E. coli. It is expected that many of the prokaryotes that exchange genetic information with E. coli be PI+EK1 vectors. For these not on the list, the containment levels are PI+EK2, or EK2. Physical containment + an EK2 host-vector, or PI+EK2, except for DNA from class 2 agents, (1) which require P3+EK2.

The EMBO Standing Advisory Committee on Recombinant DNA Research recommends that the containment level for all non pathogen- ically prokaryotic DNA into E. coli K-12 be PI+EK1. It is my opinion that it is prudent to retain the levels of P2+EK1 or P1+EK2 for nonpatho- genic prokaryotes that do not ex- change genetic information with E. coli.

The PRG RAC received substantial criticisms for identifying all agents classified as class 2 in the CDC's publication "Classification of Etiologic Agents and Their Products," (Fourth edition, July 1974) as being pathogenic for the purpose of assigning containment levels. Many comments- tors stated that many of the or- ganisms so classified were harmless and other were of such low pathogen- icity that severe safety precautions were unwarranted. It was also pointed out that the pathogenicity of an intact micro-organism and the conjunctural hazard of a piece of DNA from such an organism within E. coli K-12 were quite different matters. It should be noted that the difficulties in ap- plication of the CDC classification for the purposes of these guidelines was recognized in the original guidelines. For example, all species of Salmonella are classified as class 2 organisms by CDC. The original guidelines, however, dis- tinguish between the pathogenicity of S. typhimurium and S. typhi for the ascertainment of containing levels. I have therefore accepted the sugges- tion of these commentators and have added footnote 1 to the PRG-NIH. This gives NIH the authority, upon the recommendation of the RAC, to designate certain agents which are listed as class 2 by CDC as class 1 agents for the purpose of these guidelines.

Section III-A-2-a. DNA from Viruses of Eukaryotes Into E. coli K-12

Discussed earlier within part III of this document under the heading "Recombinant DNA Experiments Involving Viral DNA" was the history of the "Ascot" workshop report (App. E to the accompanying environmental impact assessment) and the report of the working group which met on April 6-7, 1978 (App. F to the accompanying environmental impact assessment) and the report of the working group which met on April 6-7, 1978 (App. F to the accompanying environmental impact assessement) and the report of the working group which met on April 6-7, 1978 (App. F to the accompanying environmental impact assessment). The working group with minor modifica-
tion. It is based on a reassessment made by these experts in the field of virology of the potential hazards of inserting pieces of viral DNA into E. coli. I believe the argument presented in the "Ascot" report and the working group report are well founded, specifically that "the probability that K-12 organisms carrying DNA inserted could represent a significant hazard to the community was so small as to be of no practical consequence". Viral genomes or fragments thereof, cloned in E. coli K-12 using approved plasmid or phage vectors pose no more risk than work with the infectious virus or its nucleic acid and in most, if not all, cases clearly present less risk." Accordingly, section III-A-2-a of the PRG-NIH has been completely rewritten.

Section III-A-2-b. Eukaryotic Organellar DNA into E. coli K-12

To be consistent with the one step lowering of physical containment described earlier for shotgun experiments with primate DNA, the levels for mitochondrial DNA from primates has been similarly lowered by one step in physical containment in the PRG-NIH as compared to PRG-RAC.

Section III-A-3. Lowering of containment for characterization or purified DNA preparations and clones

Concern was expressed by several commentators regarding the revisions in the PRG-RAC which would allow the local IBC (with notification to be sent to NIH) to reduce either the biological or physical containment level by one step if (1) the DNA is 99-per cent purified and shown to be free of harmful genes prior to its insertion into a recombinant molecule, or (2) if subsequent to insertion the clone is rigorously characterized and shown to be free of harmful genes. In the original guidelines lowering in case (2) could only be done with NIH prior approval.

There was support from several commentators for the changes in this subsection. The rationale is explained in new language added into this section of the PRG-RAC, which is retained in the PRG-NIH; i.e.: Many of the risks which might conceivably arise from some types of recombinant DNA experiments, particularly shotgun experiments, would result from the inadvertent cloning of a harmful sequence. Therefore, in cases where the risk of inadvertent cloning the "wrong" DNA is reduced by prior enrichment for the desired piece, or in which a clone, made from a random assortment of DNAs, has been purified and the absence of harmful sequences established, the containment conditions for further work may be reduced.

Some commentators noted the ambiguity and difficulty attendant in the phrase "free of harmful genes." The EMBO Standing Advisory Committee on Recombinant DNA Research reports that "several national guidelines for recombinant DNA research state that containment measures may be relaxed once a cloned DNA fragment has been biochemically characterized and shown to be free of harmful genes (NIH guidelines) or devoid of any known pathogenic characteristics (French guidelines). The EMBO committee believes the latter to be a more feasible requirement, but neither can readily be met, and the committee finds it difficult to suggest what sorts of experimental tests might be devised to meet these requirements."

I agree that "the terms 'characterized' and 'free of harmful genes' are unavoidably vague." However, footnote 2 of the PRG-NIH goes on to list five types of data which should be considered in making this determination.

Some commentators were also concerned that this grant of additional authority to the local IBC's for single step lowering of containment levels might introduce variability in the application of the guidelines. I have considered this possibility and have decided that the principle of promoting local involvement in the implementation of the guidelines outweighs the difficulties which may be encountered in this process. In an attempt to minimize these problems, I have (1) attempted to make all parts of the guidelines as clear, specific, and unambiguous as possible, and (2) expanded the "Roles and Responsibilities" section to outline functions and responsibilities in greater detail. Also, the guidelines require that the Office of Recombinant DNA Activities at the NIH be notified in writing of such an action. A mechanism is therefore in place to ensure that such actions proceed with an acceptable degree of uniformity.

The question was raised whether a clone, the containment level of which was lowered by the IBC at Institution X, may after shipment to Institution Y still be used at the lower level without review by the IBC at Institution Y. It clearly has been, and remains, the intention of both the IBC and myself that the IBC at the receiving institution must approve the reduction in containment for the handling of the clone in such a situation. The investigator at the receiving institution must handle the clone at the higher level until such permission is granted.

One commentator urged that prior cloning be accepted as a "feasible" technique for the purification of DNA molecules prior to their reinsertion in a new recombinant DNA molecule. The PRG-RAC specified that purification must be achieved by physical or chemical techniques. The characteristic single step reduction in containment levels in this situation is that the DNA preparation be 99 percent pure; I see no reason to so restrict the means by which such purification is obtained. I have accepted this suggestion as a means of better serving the needs of the investigator without reducing the margin of safety to the public and the environment, and therefore have replaced the phrase "by physical and chemical techniques" with the words "by physical or chemical techniques" following the work "purified."

One commentator noted that the PRG-NIH might be interpreted as allowing a single step reduction in containment levels for purification of the DNA prior to its insertion into a recombinant DNA molecule, and then a subsequent further step reduction in containment level once the same molecule was cloned. This was not intended. Therefore, clarifying language has been added in the PRG-NIH stating that an IBC "may give approval for a single step reduction in physical or biological containment on receipt of evidence of characterization of a clone derived from a shotgun experiment and its."*

Finally, as noted above in this document under "Section III-A-1-a—Shotgun Experiments into E. coli K-12 with Inserted Eukaryotic DNA, the RAC recommended at its April 27-28, 1978, meeting (and I have accepted the recommendation and inserted it in the PRG-NIH), that the containment levels for shotgun of primate DNA into E. coli K-12 be lowered to P2+EK2. However, on the recommendation of the RAC, a stipulation added in section III-A-1-a of the PRG-NIH is that for primate shotgun "any lowering of containment below these levels (i.e., for purified DNA or characterized clones) cannot be made solely by an institutional biosafety committee but requires NIH approval."

Language stating this limitation in authority of the IBC with regard to primate DNA has been inserted into subsection III-A-3 of the PRG-NIH, as has language indicating that any lowering of containment under this section to levels below P1+EK1 requires prior NIH approval.

Section III-B. Experiments with Other Prokaryotic Host-Vectors

Some commentators felt that the PRG-RAC unnecessarily emphasized the use of E. coli K-12 and would not allow important recombinant DNA experiments to be done in other prokaryotic hosts. Section III-B describes the use of prokaryotic host-vector systems other than E. coli K-12 which have been approved as HVI hosts. It should be remembered that "self-cloning experiments with prokaryotic hosts are exempt from the guidelines under exemption I-E-2 and I-E-3 that other experiments involving DNA segments from species that exchange
DNA by known physiological processes are exempt from the Guidelines under exemption I-E-4.

The RAC at its April 27-28, 1978, meeting pointed out that there are certain scientifically important experiments which are very safe but which neither fit the criteria to be exempt from the guidelines, nor the criteria for HVI certification. A new section III-B-2 has been added to the PRG-NIH to cover these cases and assign appropriate containment levels. In these experiments DNA from a prokaryotic host (Host X) is cloned into E. coli K-12 (this situation is already covered in sec. III-A-1- b(2) of the guidelines); in the second part of the experiment the recombinant DNA (consisting of DNA sequences from Host X linked to an E. coli plasmid or bacteriophage) is returned to Host X and propagated there.

Section III-C. Experiments with eu- karyotic host-vectors

A number of commentators felt that the stringent containment conditions required both in the original guidelines and in the PRG-RAC for introduction of recombinant DNA into tissue culture cells, using viruses as vectors were unwarranted. The EMBO Standing Advisory Committee on Recombinant DNA Research wrote:

In experiments involving the introduction of foreign DNA into cultured cells of animals using DNA viruses as vectors, biological containment is assumed by the very restricted permissive conditions for the host cells; the only routes by which the recombinant molecule might escape are by chance infection of a contaminating microorganism or within a viral capsid and the size of the recombinant molecule may well preclude its encapsidation **. For example, cloning of mouse DNA using polyoma virus as a vector and mouse cells as host should not require precautions more stringent than those routinely used for many years in laboratories studying polyoma virus infection of mouse cells and mice. The EMBO Committee finds the proposals for this class of experiments in the revised NIH Guidelines not sufficiently discriminating because they would impose unnecessarily high levels of physical containment on experiments with many eu- karyotic DNA's.

Discussed earlier within Part III of this document under the heading "Recombinant DNA Experiments Involving Viral DNA" was the history of the "Ascot" workshop report (See App. E to the accompanying environmental impact assessment, and the report of the working group which met on April 6-7, 1978 (App. F to the accompanying environmental impact assessment). I have accepted the recommendations of the work group and incorporated their suggested revision of this section which now becomes section III-C of the PRG-NIH. The result of this change is that section III-B-3 of the PRG-RAC "Experiments with Eukaryotic Host-Vectors," subparts (a) "Vetebrate Host-Vector Systems," and (b) "Invertebrate Host-Vector Systems," are eliminated; substituted for it in the PRG-NIH is new language derived from the working group report which became the "Recommendations on Experiments With Eukaryotic Host-Vectors," subparts (1) "Vertebrate Host-Vector System;" (2) "Invertebrate Host-Vector Systems in which Insect Viruses Are Used To Propagate Other DNA Segments," and (3) "Plant Viral Host-Vector Systems."

Section III-C-4. Plant Host-Vector Sys- tems Other Than Viruses

Discussed earlier within Part III of this document under the heading "Recombinant DNA Experiments Involving DNA From Plants and Plant Pathogens" was the Workshop on Risk Asses- sment of Agricultural Pathogens, held on March 20-21, 1978, sponsored by USDA, NSF and NIH. Based on the Workshop report (See Appendix G to the accompanying Environmental Impact Assessment), section III-D of the PRG-NIH has been rewritten.

Section III-C-5. Fungal or Similar Lower Eukaryotic Host-Vector Sys- tems

Both the 1976 Guidelines and the PRG-RAC used the same short paragraph for this section, giving little detail, because they noted "the development of these host-vector is presently in the speculative stage." Since that time a specific host-vector system of this class has been developed, i.e., Saccharomyces cerevisiae (baker's yeast), and other similar systems may also soon be proposed. Accordingly, this section (III-C-5) of the PRG-NIH has been expanded to give more specific instructions on appropriate containment levels.

Section III-D. Complementary DNAs

Since specific containment levels for the use of purified cDNA of viral mRNA are now given in section III-A-2-a of the PRG-NIH, a sentence has been added noting this at the beginning of section III-D of the PRG-NIH. Otherwise, the rest of this evolved no comments and remains identical in the PRG-NIH to the PRG-RAC.

Section III-E. Synthetic DNA

Because synthetic DNA is now explicitly included in the PRG-NIH (as discussed in section I of this document), it was necessary to add language to Part III of the PRG-NIH de- tailing the appropriate containment levels for these experiments. The RAC at its meeting on April 27-28, 1978, approved such language, and it has been inserted in the PRG-NIH as section III-E.
a particular host-vector system be certified; and (2) certification of the system by the Director, NIH. The PRG-RAC clarifies the fact that a two-step procedure is followed. The rationale for the two-step procedure is that it allows the Director, NIH, to reflect the opinions of additional experts prior to making a final decision on certification.

The RAC’s authority to recommend exceptions from the prohibitions was also clarified. The 1976 version of the Guidelines envisioned the possibility of the RAC’s recommending an exception to the 10-liter limit on culture volume for recombinant DNA’s known to make harmful products. The proposed revision would extend the possibility of an exception to the five other classes of currently prohibited experiments. The general rationale for this addition is the RAC’s inability to foresee all possible future circumstances, and the RAC’s desire to specify, within the limits of strict safeguards, the possibility of an exception for compelling social or scientific reasons. A more immediate and specific justification for the paragraph on exceptions from the prohibitions is that the risk-assessment studies necessary for a clearer understanding of the potential biohazards of recombinant DNA research may not be able to be carried out without the involvement of the RAC. Therefore, it is important that these responsibilities be stated in an unambiguous manner. For this reason, and in response to a number of commentators’ requests, appendix D of the original guidelines was modified to give additional advice on safety matters (see “Laboratory Safety Monograph—A Supplement to the NIH Guidelines for Recombinant DNA Research”). The revised guidelines also retain requirements for emergency plans to cover accidents as well as strengthening the requirement for training of all recombinant DNA researchers in safe laboratory procedures.

The intent of this section, as before, is to integrate safety practice into the conduct of recombinant DNA research and to assign responsibilities for this to the principal investigator, institutions, and biological safety officer. Therefore, it is important that these responsibilities be stated in an unambiguous manner. For this reason, and in response to many commentators, appendix IV has been retained to distinguish in greater detail and more clearly align some of these functions. The appendices contain additional complementary information on roles and responsibilities, including information for IBC’s and biological safety officers.

In response to several comments, the scope of review of research has been broadened to cover all recombinant DNA research at an institution receiving funds from NIH for recombinant DNA research, whether or not the specific recombinant DNA project is being funded by NIH. While this increases the responsibility of the institution and the IBC’s, it is believed that this revision will enhance the overall safety of the conduct of this research. Furthermore, at the suggestion of one commentator, I have decided to change the name of the biohazards committees to biosafety committees to reflect the spirit of the guidelines more closely.

Several generic comments deserve to be highlighted as they represent significant increased authority to be delegated to the Institution. In 1976, the RAC did not accept commentators’ suggestions for requiring local committees to make an independent evaluation of the containment levels required by the guidelines for individual research projects. I therefore stated in the 1976 decision that NIH would not require local institutions to have their committees perform this function, although they would not be prohibited from doing so. Commentators have now noted that in order for an IBC to accomplish its mandated responsibilities under the 1976 guidelines, including reviewing and approving recombinant DNA research projects, it has been necessary for the committee to determine containment. Therefore, in order to better clarify its role, the assessment of appropriate containment levels is now made an explicit responsibility of the IBC.

In addition, institutions through their IBC’s will be given increased responsibility for primary oversight of this research as they have now been delegated the authority from NIH to approve or disapprove proposed recombinant DNA projects. NIH through ORDA will conduct a review of institutional actions, upon registration of the projects, to ensure compliance with the NIH guidelines, thereby maintaining a national standard for the research. This action has been in response to several comments calling for increased local responsibility and a more simplified administrative process with regard to gaining approval for this research to proceed. In view of the possibility of Federal assistance to enforce these standards externally, I feel it is essential to increase the authority and responsibility of the local institution. It was also requested that IBC’s have a role if legislation in this area is adopted, and this concept is endorsed in the bill report of March 24, 1978, on the Recombinant DNA Act, by the House Committee on Interstate and Foreign Commerce, which says, “It is the view of the committee that the appropriate portions of the administrative requirements of section IV of the NIH guidelines are a reasonable model upon which the Secretary could base administrative regulations. In particular, the current practice of the NIH guidelines of delegating to local biohazards committees most of the responsibility for the inspection of facilities and the approval of the specific safety requirements appropriate to each project or activity is an effec-
As in the 1976 decision, a number of recommendations were received regarding the membership of IBCs. In 1976, suggestions were made for enhancing IBC representation to include members not only from various disciplines related to recombinant DNA molecule technology, biological safety, and engineering but also to include those from legal, social sciences, and community relations.

Consequently, at that time I recommended in my decision that these diverse points be made available to the committees. The language in the PRG-RAC requires a diversity of membership, but does not mandate noninstitutional members. In response to several requests, and in view of increased responsibility at the local level, I now propose that new guidelines be made available to the committees. The language in the PRG-RAC requires a diversity of membership, but does not mandate noninstitutional members. In response to several requests, and in view of increased responsibility at the local level, I now propose that new guidelines be made available to the committees.

The possibility of conflict between IBCs and local community oversight committees was raised. With noninstitutional membership on IBCs I believe there is no need to have additional community committees.

A number of other recommendations were received from public commentators relating to more specific issues; they are considered below under the appropriate headings.

**Responsibilities of the Institution (specific)**

**Institution.** A number of points were raised by commentators concerning health monitoring by institutions. NIH was requested to develop a model for institutional medical surveillance, including recombinant DNA research workers. The issue of medical monitoring is one of considerable importance to the NIH. This is a general problem not unique to recombinant DNA research. As one commentator noted, instituting routine health monitoring and reporting program for personnel engaged in areas of research besides recombinant DNA, such as tumor viruses and pathogenic organisms, is important. However, the state-of-the-art is primitive in terms of what can be done.

The PRG-RAC recommends that, in general, but particularly in the area of recombinant DNA research where there is no known hazard, at my request, an NIH committee reviewed this area and has made recommendations as to what recommendations were received from public comment. This recommendation, which calls for monitoring illness, collecting serum samples, and keeping a register of agents handled, is responsive to several suggestions regarding the membership of IBCs. It has, therefore, been adopted in the PRG-NIH. Additionally, appendix D will include more detailed information on medical surveillance.

**Grievance procedures for workers and management.** Suggestions were made for broadening the representation to include individuals from disciplines relevant to recombinant DNA, biological safety, and engineering; that it is recommended that at least one member be a nonmedical individual from a laboratory technical staff; and that the members be knowledgeable about such matters as applicable law, standards of professional conduct and practice, community attitudes, and the environment.

The question was raised concerning the area of biosafety committees and possible jurisdictional disputes between them and institutional biosafety committees. This has been further clarified in the definitions in Part I. It was suggested that biosafety committee meetings be open to the public. The guidelines currently require only that the minutes be available to the public. In view of possible discussion of proprietary and patentable information, IBC meetings cannot always be open. I urge, however, that local committees, when possible, have open meetings and suggest that all meetings be announced.

**Biological Safety Officer.** Because increased authority and responsibility have been given the IBCs, it is appropriate that institutions conducting F3 or F4 level research have someone designated to handle biological safety questions generally.

I have accepted the suggestion that the biological safety officer shall be a member of the IBC because his or her responsibilities are so closely allied to the function of the IBC. Another commentator noted that too much emphasis was placed in the PRG-RAC on the regulatory role of the biosafety officer rather than on his or her role as a technical consultant; this is also true. However, indicating this latter role has been inserted in the PRG-NIH.

**In response to questions on the qualifications of biological safety officers.** It has been noted that for the purpose of the IBC, the banding of the biological safety officer rather than on his or her role as a technical consultant; this is also true. However, indicating this latter role has been inserted in the PRG-NIH.

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the local and national levels have been delineated in Appendix C to the guidelines which contains documentation of NIH administrative procedures for recombinant DNA research projects.

Consideration has been given to the issue of training. Several commentators urged that training standards be set by the NIH, preferably in the guidelines. Other commentators wanted the guidelines to direct the institution or IBC to set standards for training; however, some opposed this view. Still others wanted investigator competency evaluated or certified after training had been undertaken. It should be noted that the PRG-RAC represented a strengthening of training requirements, compared to those in the 1976 guidelines. Commentators remain concerned regarding the quality and uniformity of such training. The NIH is responding to this by placing a high priority on the development of standards and courses. Currently, NIH is supporting a Working Panel of the American Society for Microbiology (ASM) which is considering standards of training in microbiological techniques for recombinant DNA research. When a report is submitted to NIH, it will be shared with institutions, IBC's, and principal investigators for their use. At this time, however, national certification should not be attempted until the ASM/NIH criteria for training have been formulated and subsequently evaluated. It should be noted that, aside from Nuclear Regulatory Commission standards for training for radioscopework, there are apparently no other formal training criteria presently required for biomedical research. Thus, the work of the ASM Panel will be establishing a precedent. It is for these reasons that I feel NIH should proceed carefully and in stages, at the same time safety training for researchers. Accordingly, NIH will develop courses based on these standards of training and make them widely available.

Responsibilities of the NIH (General)

Due Process Considerations. A focus of public comment at the December hearing was on "procedural due process," to assure public participation in the development of NIH recombinant DNA policies. Much of the public testimony and comment in letters thereafter focused on public representation on committees. Also stressed was the need for public notice of all meetings, and for public participation in the exercise of responsibilities by the RAC, the Office of the Director, NIH, and the Advisory Committee to the Director, NIH.

Several commentators specifically urged that the guidelines spell out the procedures to be used for the following:

- To develop and amend the list of "non-novel experiments";
- To permit the Director, on the advice of the IBC and the Director, to establish special safety procedures to deal with infractions of the guidelines. Specifically, one commentator suggested that procedures outline in detail:
  - How charges of non-compliance would be brought;
  - How charges of non-compliance would be evaluated;
  - What opportunities would be provided for the principal investigator and his institution to defend themselves against charges; and
  - What appeals procedures would be available before the termination of funding or the invoking of other penalties.

Because of the key role of the RAC in the development and monitoring on NIH recombinant DNA policies, a number of comments were directed to its composition and functions. Many commentators focused on the RAC's membership, urging that the guidelines define procedures for nomination and selection of members. Suggestions for potential membership on the RAC included more representation for certain scientific disciplines, such as virology and microbiology; greater representation of individuals skilled in occupational and environmental health and safety; and more public representation, including perhaps a "dissenter" from current NIH policies.

A number of comments concerned Committee operations. The RAC was urged to formalize schedules so that all would know when it would meet over the next 2 to 3 years. Further, it was urged that notices and complete agendas be placed in the Federal Register for each meeting; that all documents for Committee consideration be made available to the public; and that the NIH pay for public witnesses to attend meetings of the RAC.

In response to these comments, Part IV of the guidelines has been reorganized extensively. The responsibilities of the local to national level have been outlined and defined more clearly. Further, for NIH responsibilities, procedures suggested by commentators have been specified to afford opportunity for public comment. A special appendix to the guidelines includes relevant implementing recommendations from ORDA that explain the hierarchy of the NIH guidelines at the local and national levels.

From the beginning, the NIH has gone to great lengths to insure procedural due process for the public and scientific communities. The RAC conducts all meetings in the open, and files notice of each meeting in the Federal Register. All the documents and minutes of meetings have been available to the public. Additionally, the Advisory Committee to the Director, NIH, has provided a public forum on the 1976 guidelines and now on the proposed revisions. The public hearing of the RAC, July 1976, and comments on the originally proposed guidelines resulted in extensive revision of that proposal. The PRG-RAC was published in the Federal Register on September 27, 1977, for public comment, and the meeting of the Director's Advisory Committee held in December 1977 was announced in the Federal Register. In addition to a general invitation for public testimony, the NIH provided funds for major public participation through the mail, the public, private, and scientific sectors to attend and present their views.

The proposed reorganization of Part IV has more clearly defined a structure for responsibilities at the local and national level, with opportunity for public and scientific participation. It makes more formal a process that has been occurring informally. Flexibility, however, remains essential to avoid unnecessary and protracted delays in decisionmaking. Clearly, a full panoply of review, including a public hearing, is not essential for most of the functions under the guidelines. For many functions, the need for public review can be met through publication in the Federal Register. For certain responsibilities comment may be solicited. Because procedures by which policies will be developed at the national and local levels are of key importance, notice for major policy initiatives is required. I believe the reorganization of Part IV achieves that goal.

Application to the Private Sector. Several commentators spoke on the application of the NIH guidelines to the private sector. Specifically, the NIH was urged to provide, voluntarily, to the private sector, the following:

- Advice on interpretation of the guidelines;
- Registration of projects;
- Certification of host-vector systems;
- Advice on the operation of institutional biosafety committees; and
- Protection for patent and proprietary information.

Prior to the release of the guidelines in June 1976, representatives of private industry were invited to NIH to be briefed on the agenda of the RAC meetings. At the time of the release of the guidelines, several other meetings with representatives from the private sector have been held. Commerce Department representatives on the Interagency Committee...
played a key role in working with private industry leading to the agreement. Relevant industry was abide by the safety standards of the NIH guidelines.

Many of the services provided by the NIH to its grantees and contractors had not been extended to the private sector. After careful consideration of comments at the public hearing and in correspondence received, I now believe the NIH should extend certain services to the private sector in several of the areas suggested by the commentators. A new section has been added to Part IV that provides the opportunity for private industry participation in a voluntary fashion. If legislation is enacted, the NIH Guidelines will serve as the basis for regulations that will encompass the private sector.

Occupational and Environmental Safety. A key concern of all commentators was the need for programs in occupational and environmental safety, that would allow the NIH to take a lead role for laboratory personnel and the community. As I stated in my Decision in November, the NIH has a special responsibility for national leadership in programs for laboratory safety. This responsibility is a critical one and we must accept it. Recombinant DNA research policies have stimulated a broad NIH commitment and interest in laboratory safety. The P3G-NIH reflects that commitment. As previously described, there are several training programs that the NIH has undertaken and supported. Several NIH committees are involved in development of policies in this area. The newly updated and a revised supplement to the P3G-NIH, entitled “Laboratory Safety Monograph,” reflects the growing experience in this area.

A collaborative effort has been initiated between NIH and the Center for Disease Control (CDC) to establish a mechanism for providing advice, consultation, and necessary assistance regarding major accidents in laboratories involved in recombinant DNA research. It was not considered necessary to have a standing “strike force” as suggested by one commentator; however, in the event of an emergency, a team of experts from NIH and CDC could be formed to respond, depending on the nature of the problem.

Several commentators suggested that the NIH examine laboratory work involving genetic techniques other than recombinant DNA research. Indeed, it was recommended that another advisory committee similar to the RAC be established to propose standards for work involving biosafety. Generally, I appreciate and understand this concern. The NIH over the past year and a half has engaged several internal committees that are critically examining different areas where laboratory work is conducted with potential biohazards. These committees are considering recommendations for safety standards.

Another commentator also urged the NIH to consider a forum for dealing with social issues related to “genetic engineering.” The NIH responsibilities to address the pressing policy questions involving safety of recombinant DNA research in single cells in the laboratory. I recognize the importance of the potential future application of this and other genetic research to the altering of the genetic character of higher forms of life including man. However, the application of this research to the “genetic engineering” of man is clearly far from imminent. In light of public concern, a study is warranted of the ethical, legal, and social implications of these techniques. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research considered, but was unable to initiate, a study because of its pressing workload. Such a study should be a key priority for the Commission currently being considered by Congress as part of the legislation to regulate recombinant DNA research.

It has also been suggested that the NIH work closely with other relevant research and regulatory agencies, particularly the Environmental Protection Agency and the Occupational Safety and Health Administration. Indeed, the NIH, from the inception of the Guidelines, has worked to foster cooperation among the Federal agencies. Prior to the release of the Guidelines, representatives from several agencies met at the NIH for a briefing on the Guidelines. After the release of the Guidelines, the question of their extension to the rest of the Federal Government and the private sector prompted the creation of an Interagency Committee. This Federal Interagency Committee on Recombinant DNA Research on which I have served as Chairman, was created by the Secretary of HEW at the request of the President in October 1976. It is composed of all relevant Federal research and regulatory agencies and has provided coordination of Federal policies concerning recombinant DNA research. In March 1977, the committee developed recommendations for legislation.

It was suggested by a commentator that the NIH address the international implications of control of recombinant DNA research. Indeed, the Federal Interagency Committee issued in November 1977 a thorough and comprehensive review of all guidelines for such research internationally with recommendations for continued cooperation. This report is available from the Office of Recombinant DNA Activities, NIH, Bethesda, Md. 20201.

Responsibilities of NIH (Specific)

Office of the Director. As suggested by the commentators, for purposes of clarity, the responsibilities of the NIH Director mentioned in Parts I, II, and III of the P3G-NIH, and are repeated again in Part IV, include the Interim Implementation of the Guidelines; rerevision and amendment of the Guidelines; certification of new host-vector systems; promulgating and amending a list of classes of recombinant DNA molecules permitting specific exceptions to the Prohibitions in the Guidelines; approving changes in containment levels for specific experiments; designating certain agents for the purpose of the Guidelines; and overseeing the implementation of the Guidelines. For many of the responsibilities, appropriate notice and opportunity for public comment are provided.

Recombinant Advisory Committee. At the hearing in 1976, many commentators made suggestions concerning the structure, function, and scope of responsibility of the RAC. Comments on the P3G-NIH were grouped under a specific heading entitled “Office of the Director, NIH.” These responsibilities (many of which are mentioned in Parts I, II, and III of the P3G-NIH, and are repeated again in Part IV) include the Interim Implementation of the Guidelines; rerevision and amendment of the Guidelines; certification of new host-vector systems; promulgating and amending a list of classes of recombinant DNA molecules permitting specific exceptions to the Prohibitions in the Guidelines; approving changes in containment levels for specific experiments; designating certain agents for the purpose of the Guidelines; and overseeing the implementation of the Guidelines. For many of the responsibilities, appropriate notice and opportunity for public comment are provided.

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Recombinant Advisory Committee. At the hearing in 1976, many commentators made suggestions concerning the structure, function, and scope of responsibility of the RAC. Comments on the P3G-NIH were grouped under a specific heading entitled “Office of the Director, NIH.” These responsibilities (many of which are mentioned in Parts I, II, and III of the P3G-NIH, and are repeated again in Part IV) include the Interim Implementation of the Guidelines; rerevision and amendment of the Guidelines; certification of new host-vector systems; promulgating and amending a list of classes of recombinant DNA molecules permitting specific exceptions to the Prohibitions in the Guidelines; approving changes in containment levels for specific experiments; designating certain agents for the purpose of the Guidelines; and overseeing the implementation of the Guidelines. For many of the responsibilities, appropriate notice and opportunity for public comment are provided.
between the scientific and the public policy implications, public members now serve on the RAC and additional public members may be added. Current public members are Dr. Emmette S. Redford, Ashbel Smith Professor of Government and Public Affairs, Lyndon B. Johnson School of Public Affairs, University of Texas at Austin; and Dr. LeRoy Walters, Director, Center for Bioethics, Kennedy Institute, Georgetown University. Both have served the public interest well and have done a superb job as have all members of the committee. The task for all RAC members has been enormous and their work and spirit of cooperation have been exemplary.

In order to ensure fairness, and sensitivity to the public commentators, solicitation of nominations for openings on the RAC will be in accord with the recommendations of the NIH Grants Peer Review Study Team concerning announcements of vacancies on committees. Thus, NIH will publish, periodically, an announcement of upcoming vacancies on the RAC with instructions on how to submit nominations. By this means I will be able to consider carefully a wide spectrum of nominations and assure appropriate representation suited to the needs of this committee.

One commentator suggested that representatives from Federal agencies serve on the RAC. Several agencies, including the National Science Foundation, the Department of Energy, and the Department of Agriculture, have liaison representatives who come regularly to the RAC meetings and, of course, the Federal Interagency Committee is kept fully informed of the activities of this committee.

It was also recommended by a commentator that the NIH finance the cost of attendance at RAC meetings by interest members of the public. For the present I do not believe such a policy is necessary, especially in light of the responsibilities of the RAC for public oversight where public witnesses may be invited and their expenses paid (as they were at the December 1977 hearing). All RAC meetings are announced in the Federal Register and are open to the public.

In sum, the operations of the RAC have been more clearly detailed in the PRG-NIH. The procedures for the selection of members and the operations of the committee have been, or are in the process of being, formalized for the benefit of the scientific community and the public.

**NIH Components.** A new section now describes all other functions of the NIH including the responsibilities of the Office of Recombinant DNA Activities (ORDA). Several commentators at the public hearing in 1976 urged that the NIH create an office to coordinate recombinant DNA activities. On the basis of these suggestions, ORDA was created and Dr. William Gartland was named Director. Since its creation, ORDA has done a splendid job in fulfilling very difficult tasks in the implementation of the NIH Guidelines. It now also serves as Executive Secretary to the RAC, has provided a focus for coordination of activities within the NIH and with institutional biosafety committees.

It is important to note that the responsibility of the NIH peer review groups (e.g., study sections) for an independent assessment of the recombinant DNA research protocols has been eliminated. This responsibility will now solely be that of ORDA in conjunction with the institutional biosafety committee. In the 1½ years of our experience, such review by NIH peer review groups has been found to be unnecessary and an additional burden on these groups.

Several commentators urged new responsibilities for ORDA and additional personnel to fulfill them. Several urged that ORDA be responsible for inspecting and certifying laboratories at the P3 level. At the present time P4 facilities are operating at the Frederick Cancer Research Center in Frederick, Md; and at the NIH in Bethesda, Md; no other P4 facilities for recombinant DNA research are in operation nationally. The NIH has the responsibility under the Guidelines to certify P4 facilities because of their special nature. However, a P3 facility does not require special expertise at a national level; and there is no need for national certification of P3 facilities. As specified, the local institution has responsibility for monitoring and certifying facilities from the P1 to the P3 level and that, indeed, should be a local responsibility.

Several commentators urged greater dissemination of information to the public and scientific community alike. ORDA has a key responsibility for the dissemination of information through the "Recombinant DNA Technical Bulletin." The Bulletin is a new publication that attempts to link investigators involved in recombinant DNA research, both in the United States and abroad, with the advisory groups and organizations active in this area. In light of comments received, the Bulletin will include more information for institutional biosafety committees, as well as for the advisory groups at the national and local levels. It was suggested that ORDA provide advice to state and local governments, and to the media. In 1977, ORDA will be available to state and local government for technical advice. In large part, ORDA serves as a clearinghouse for information related to recombinant DNA activities internationally, nationally, and locally.

**Registration and Compliance (General)**

Over the past 2 years in the administration of the NIH Guidelines, it has been clear that a new section should be added on the general requirements for registration of activities with the NIH, not only for NIH grantees or contractors, but also, on a voluntary basis, for the private sector.

Further, in light of the review of HEW policies on the patenting of recombinant DNA research inventions, a section on disclosure of information was also necessary. And finally, as suggested, a section on compliance with the Guidelines was needed. Thus, new sections C and D have been added under "Roles and Responsibilities" covering Registration (including disclosure of information) and Compliance. Many comments on the Guidelines over the past 1½ years and at the public hearing in December 1977 urged that these provisions be added, and in my view, they are necessary in the absence of legislation. Further, if legislation were to pass, these provisions could serve as a model for the regulations to be promulgated on the basis of the legislation. As in 1976, I believe the Guidelines should not become regulations without new legislation specifically mandating this.

**Registration and Compliance (Specific)**

Section IV-C has been added providing the elements for registration. Other requirements may need to be added; notice will be given of any change in the requirements. All projects subject to the Guidelines must be registered with ORDA. A mechanism for voluntary registration by the private sector has been provided in response to suggestions by private sector representatives. A requirement for registration is that the registrant must agree to abide by the standards of the Guidelines.

Many comments were directed to the protection of proprietary information. A new section outlining the elements for protection of proprietary data has been included in response to these suggestions.

One commentator urged that no patents be granted for recombinant DNA research inventions. Shortly after the release of the Guidelines in 1976, NIH received a letter requesting a review of HEW policies relating to the patenting of recombinant DNA research inventions. The letter prompted NIH to respond to suggestions by private sector representatives. A requirement for registration is that the registrant must agree to abide by the standards of the Guidelines.

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IV. Roles and Responsibilities.

IV-A. Responsibilities of the Institution.

IV-A-1. Institution.


IV-A-4. Principal Investigator.

IV-B. Responsibilities of the NIH.

IV-B-1. Office of the Director, NIH.

IV-B-2. NIH Recombinant DNA Advisory Committee.

IV-B-3. NIH Components.

IV-C. Registration.

IV-C-2. Voluntary Registration and Certification.

IV-C-3. Disclosure of Information.

IV-B. Compliance.

IV-D. Policy on Noncompliance.

V. Footnotes and References.

I. Scope of the Guidelines

I-A. Purpose.

The purpose of these guidelines is to specify practices for constructing and handling (i) recombinant DNA molecules and (ii) organisms and viruses containing recombinant DNA molecules.

I-B. Definition of Recombinant DNA Molecules.

In the context of these guidelines, recombinant DNA molecules are defined as either (i) molecules which are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or (ii) DNA molecules that result from the replication of those described in (i) above.

I-C. General Applicability.

The guidelines are applicable to all recombinant DNA research within the United States or its territories conducted at or sponsored by an institution that receives any support for recombinant DNA research from NIH. This includes research performed directly by NIH.

Any individual receiving support must be associated with or sponsored by an institution which can and does assume responsibilities described in these guidelines.

Once approved at the local level, research may proceed but shall be modified in accordance with the recommendations of the NIH if found not to
comport with requirements of the NIH guidelines.

The guidelines are also applicable to projects done abroad if they are supported by NIH funds. If the host country has established rules for the conduct of recombinant DNA projects, then a certificate of compliance with these guidelines, and no registration with NIH is necessary.

I-E. Exemptions. It must be emphasized that the following exemptions(4) are not meant to apply to experiments described in the section I-D as being prohibited.

The following recombinant DNA molecules are exempt from these guidelines, and no registration with NIH is necessary:
I-E-1. Those that are not in organisms or viruses.(5)
I-E-2. Those that consist entirely of DNA segments from a single nonchromosomal or viral DNA sources, though one or more of the segments may be a synthetic equivalent.
I-E-3. Those that consist entirely of DNA from a prokaryotic host, including its indigenous plasmids or viruses, when propagated only in that host (or closely related strain of the same species); also those that consist entirely of DNA from a eukaryotic host, including its chloroplasts, mitochondria, or plasmids (but excluding viruses), when propagated only in that host (or a closely related strain of the same species).
I-E-4. Certain specified recombinant DNA molecules that consist entirely of DNA segments from different species that exchange DNA by known physiologic processes, though one or more of the segments may be a synthetic equivalent. A list of such exchangers will be prepared and periodically revised by the Director, NIH, on the recommendation of the Recombinant DNA Advisory Committee, after appropriate notice and opportunity for public comment. Certain classes are exempt as of publication of these revised guidelines. The list in appendix A. An updated list may be obtained from the Office of Recombinant DNA Activities, National Institutes of Health, Bethesda, Md. 20014.
I-E-5. Other classes of recombinant DNA molecules if the Director, NIH, on the recommendation of the Recombinant DNA Advisory Committee, after appropriate notice and opportunity for public comment, finds that they do not present a significant risk to health or the environment.
I-F. General Definitions. The following terms, which are used throughout these guidelines, are defined as follows:
I-F-1. "DNA" means deoxyribonucleic acid.
I-F-2. "Recombinant DNA molecule" means either (i) molecules which are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or (ii) DNA molecules which result from the replication of a molecule described in (i) above.
I-F-3. "Director" means the Director of the National Institutes of Health (NIH) and any other officer or employee of NIH to whom authority has been delegated.
I-F-4. "Institution" means any public or private entity (including Federal, State, and local government agencies).
I-F-5. "Memorandum of Understanding and Agreement" or "MUA" means an institution's certification to NIH that the project will comply with the guidelines. See appendix C regarding the form and contents of an MUA.
I-F-6. "Institutional Biosafety Committee" or "IBC" is discussed in detail in section IV-A-2.
I-F-7. "Area Biosafety Committee" or "ABC" means that in special circumstances, in consultation with the NIH Office of Recombinant DNA Activities, an Area Biosafety Committee may be formed, composed of members from the institution and other organizations beyond its own staff, as an alternative to an IBC when additional expertise outside the host institution is needed for the indicated reviews.
I-F-8. "Recombinant DNA Advisory Committee" or "RAC" means the public advisory committee that shall advise the Secretary, Assistant Secretary for Health, and the Director of the National Institutes of Health, concerning recombinant DNA research. The RAC shall consist of members who shall be selected from persons knowledgeable in the fields of recombinant DNA technology, biological safety, and community interests. Nominations for the RAC may be submitted to ORDA and will be considered in accordance with established nomination procedures for NIH peer review groups.
I-F-9. "NIH Office of Recombinant DNA Activities" or "ORDA" means the office within NIH with responsibility to (i) review and coordinate all activities of NIH related to the guidelines; (ii) foster the interrelationships between NIH and other Government agencies, private foundations, professional societies, and industry, in order to assure coordination of activities; (iii) promote international cooperation; (iv) review the composition of Institutional Biosafety Committees; (v) review MUAs; (vi) develop registries of activities related to recombinant DNA research (laboratories, projects, new containment facilities, etc.); and (vii) prepare regular reports.

II. CONTAINMENT

Effective biological safety programs have been operative in a variety of laboratories for many years. Considerable information therefore already exists for the design of physical containment facilities and the selection of laboratory procedures applicable to organisms carrying recombinant DNA's. (6-7)

The existing programs rely upon mechanisms that, for convenience, can

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be divided into two categories: (1) a set of standard practices that are generally used in microbiological laboratories, and (2) special procedures, equipment, and laboratory installations that provide physical barriers which are applied in varying degrees according to the estimated biohazard.

Experiments on recombinant DNA's, by their very nature, allow themselves to a third containment mechanism—namely, the application of highly specific biological barriers. In fact, natural barriers do exist which limit either (i) the infectivity of a vector, or vehicle, (plasmid, bacteriophage, or virus) to specific hosts or (ii) its dissemination and survival in the environment. The vectors that provide the means for replication of the recombinant DNA's and/or the host cells in which they replicate can be genetically designed to decrease by many orders of magnitude the probability of dissemination of recombinant DNA's outside the laboratory. As listed, three means of containment are complimentary, different levels of containment appropriate for experiments with different recombinants can be established by applying various combinations of the physical and biological barriers along with a constant use of the standard practices. We consider these categories of containment separately here in order that such combinations can be conveniently expressed in the guidelines.

In constructing these guidelines, it was necessary to define boundary conditions for the different levels of physical and biological containment and for the classes of experiments to which they apply. We recognize that these definitions do not take into account all existing and anticipated information on special procedures that will allow particular experiments to be carried out under conditions of risk. Indeed, we urge that individual investigators devise simple and more effective containment procedures and that investigators and institutional biosafety committees recommend changes in the guidelines to permit their use.

II-A. Standard Practices and Training. The first principle of containment is a strict adherence to good microbiological practices. (6-15) Consequently, all personnel directly or indirectly involved in experiments on recombinant DNA's must receive adequate instruction. This should as a minimum include instruction in aseptic techniques and in the biology of the organisms used in the experiments, so that the potential biohazards can be understood and appreciated.

Any research group working with agents with a known or potential biohazard should have an emergency plan which describes the procedures to be followed if an accident contaminates personnel or the environment. The principal investigator must ensure that everyone in the laboratory is familiar with both the potential hazards of the work and the emergency plan. If a research group is working with a known pathogen for which an effective vaccine is available, all workers should be immunized. Serological monitoring, where appropriate, should be provided.

II-B. Physical Containment Levels. The objective of physical containment is to confine organisms containing novel recombinant DNA molecules, and thus to reduce the potential for exposure of the laboratory worker, persons outside of the laboratory, and the environment to organisms outside the laboratory or to the environment. Special laboratory design is used primarily in facilities in which experiments of moderate to high potential hazard are performed.

Combinations of laboratory practices, containment equipment, and special laboratory design can be made to achieve different levels of physical containment. Four levels of physical containment, which are designated as P1, P2, P3, and P4, are described. It should be emphasized that the descriptions and assignments of physical containment detailed below are based on existing approaches, to containment of pathogens organisms. For example, the "Classification of Etiologic Agents on the Basis of Hazard." (7) prepared by the Center for Disease Control, describes four general levels which roughly correspond to our designations for P1, P2, P3, and P4; and the National Cancer Institute describes three levels for research on oncogenic viruses which roughly correspond to our P2, P3, and P4 levels. (8) It is recognized that several different combinations of laboratory practices, containment equipment, and special laboratory design may be appropriate for containment of specific research activities. The guidelines, therefore, allow alternative selections of primary containment equipment within facilities that have been designed to provide P3 and P4 levels of physical containment. The selection of alternative methods of primary containment may, however, be based on the level of biological containment provided by the host-vector system used in the experiment. Consideration will also be given by the Recombinant DNA Advisory Committee to other combinations which achieve an equivalent level of containment. Additional material on physical containment for plant host-vector systems is found in sections III-C-3 and III-C-4.

II-B-1. Laboratory Practices. Laboratory doors shall be kept closed while experiments are in progress.

II-B-1-a. (2). Work surfaces shall be decontaminated daily, and immediately following spills of organisms containing recombinant DNA molecules.

II-B-1-a-(3). All biological wastes shall be decontaminated before disposal. Other contaminated materials such as glassware, animal cages, and laboratory equipment shall be decontaminated before washing, reuse, or disposal.

II-B-1-a-(4). Mechanical pipetting devices shall be used; pipetting by mouth is prohibited.

II-B-1-a-(5). Eating, drinking, smoking, and storage of foods are not permitted in the working area.

II-B-1-a-(6). Persons shall wash their hands after handling organisms containing recombinant DNA molecules and when they leave the laboratory.

II-B-1-a-(7). Care shall be taken in the conduct of all procedures to minimize the creation of aerosols.

II-B-1-a-(8). Contaminated materials that are to be decontaminated at a site away from the laboratory shall be placed in a durable leak-proof container which is closed before removal from the laboratory.

II-B-1-a-(9). An insect and rodent control program shall be instituted.

II-B-1-a-(10). The use of laboratory gowns, coats, or uniforms is discretionary with the laboratory supervisor.

II-B-1-a-(11). Use of the hypodermic needle and syringes shall be avoided when alternative methods are available.

II-B-1-b. Containment Equipment. Special containment equipment is not required at the P1 level.

II-B-1-c. Special Laboratory Design. Special laboratory design is not required at the P1 level.

II-B-2. P2 Level.

II-B-2-a. Laboratory Practices.

II-B-2-a-(1). Laboratory doors shall be kept closed while experiments are in progress.

II-B-2-a-(2). Work surfaces shall be decontaminated daily, and immediately following spills of organisms containing recombinant DNA molecules.

II-B-2-a-(3). All biological wastes shall be decontaminated before disposal. Other contaminated materials such as glassware, animal cages, and labora-
II-B-2-a-(4). Mechanical pipetting devices shall be used; pipetting by mouth is prohibited.

II-B-2-a-(5). Eating, drinking, smoking, and storage of food are not permitted in the laboratory.

II-B-2-a-(6). Persons shall wash their hands after handling organisms containing recombinant DNA molecules and when they leave the laboratory.

II-B-2-a-(7). Care shall be exercised to minimize the creation of aerosols. For example, manipulations such as inserting a hot inoculating loop or needle into a culture, flaming an inoculation loop or needle so that it splatters, and forceful ejection of fluids from pipettes or syringes shall be avoided.

II-B-2-a-(8). Contaminated materials that are to be decontaminated at a site away from the laboratory shall be placed in a durable leak-proof container which is closed before removal from the laboratory.

II-B-2-a-(9). Only persons who have been advised of the nature of the research being conducted shall enter the laboratory.

II-B-2-a-(10). Children under 12 years of age shall not enter the laboratory.

II-B-2-a-(11). The universal biohazard sign shall be posted on all laboratory access doors when experiments requiring P2 containment are in progress. Freezers and refrigerators used to store organisms containing recombinant DNA molecules shall also be posted with the universal biohazard sign.

II-B-2-a-(12). An insect and rodent control program shall be instituted.

II-B-2-a-(13). The use of laboratory gowns, coats, or uniforms is required. Laboratory clothing shall not be worn to the lunch room or outside of the building in which the laboratory is located.

II-B-2-a-(14). Animals not related to the experiment shall not be permitted in the laboratory.

II-B-2-a-(15). Use of the hypodermic needle and syringe shall be avoided when alternative methods are available.

II-B-2-a-(16). The laboratory shall be kept neat and clean.

II-B-2-a-(17). Experiments of lesser biohazard potential can be carried out concurrently in carefully demarcated areas of the same laboratory.

II-B-2-b. Containment Equipment.

*Biological safety cabinets (20) shall be used to contain aerosol-producing equipment such as blenders, lyophilizers, sonicators, and centrifuges when used to process organisms containing recombinant DNA molecules, except where equipment design provides for containment of the potential aerosol. For example, a centrifuge may be operated in the open if a sealed head or safety centrifuge cups are used.

II-B-2-c. Special Laboratory Design.

*An autoclave for sterilization of wastes and contaminated materials shall be available in the same building in which organisms containing recombinant DNA molecules are used.

II-B-3. P3 Level.

II-B-3-a. Laboratory Practices.

II-B-3-a-(1). Laboratory doors shall be kept closed while experiments are in progress.

II-B-3-a-(2). Work surfaces shall be decontaminated following the completion of the experimental activity, and immediately following spills of organisms containing recombinant DNA molecules.

II-B-3-a-(3). All biological wastes shall be decontaminated before disposal. Other contaminated materials such as glassware, animal cages, and laboratory equipment shall be decontaminated before washing, reuse, or disposal.

II-B-3-a-(4). Mechanical pipetting devices shall be used; pipetting by mouth is prohibited.

II-B-3-a-(5). Eating, drinking, smoking, and storage of food are not permitted in the laboratory.

II-B-3-a-(6). Persons shall wash their hands after handling organisms containing recombinant DNA molecules and when they leave the laboratory.

II-B-3-a-(7). Care shall be exercised to minimize the creation of aerosols. For example, manipulations such as inserting a hot inoculating loop or needle into a culture, flaming an inoculation loop or needle so that it splatters, and forceful ejection of fluids from pipettes or syringes shall be avoided.

II-B-3-a-(8). Contaminated materials that are to be decontaminated at a site away from the laboratory shall be placed in a durable leak-proof container which is closed before removal from the laboratory.

II-B-3-a-(9). Entry into the laboratory shall be through a controlled access area. Only persons who have been advised of the nature of the research being conducted shall enter the controlled access area. Only persons required on the basis of program or support needs shall be authorized to enter the laboratory. Such persons shall be advised of the nature of the research being conducted before entry, and shall comply with all required entry and exit procedures.

II-B-3-a-(10). Children under 12 years of age shall not enter the laboratory.

II-B-3-a-(11). The universal biohazard sign shall be posted on the controlled access area door and on all laboratory doors when experiments requiring P3-level containment are in progress. Freezers and refrigerators used to store organisms containing recombinant DNA molecules shall also be posted with the universal biohazard sign.

II-B-3-a-(12). An insect and rodent control program shall be instituted.

II-B-3-a-(13). Laboratory clothing that protects street clothing (i.e., long-sleeve solid-front or wrap-around gowns, no-button or slipover jackets, etc.) shall be worn in the laboratory. Front-button laboratory coats are unsuitable. Laboratory clothing shall not be worn outside the laboratory and shall be decontaminated before it is sent to the laundry.

II-B-3-a-(14). Raincoats, overcoats, topcoats, coats, hats, caps, and such street outer-wear shall not be kept in the laboratory.

II-B-3-a-(15). Gloves shall be worn when handling materials requiring P3 containment. They shall be removed aseptically immediately after the handling procedure and decontaminated.

II-B-3-a-(16). *Animals and plants not related to the experiment shall not be permitted in the laboratory.

II-B-3-a-(17). Vacuum outlets shall be protected by filter and liquid disinfectant traps.

II-B-3-a-(18). Use of hypodermic needle and syringe shall be avoided when alternative methods are available.

II-B-3-a-(19). The laboratory shall be kept neat and clean.

II-B-3-a-(20). * If experiments involving other organisms which require lower levels of containment are to be conducted in the same laboratory concurrently with experiments requiring P3-level physical containment, they shall be conducted in accordance with all P3-level laboratory practices.

II-B-3-b. Containment Equipment.

II-B-3-b-(1). *Biological safety cabinets 20 shall be used for all equipment and manipulations that produce aerosols—e.g., pipetting, dilutions, transfer operations, plating, flaming, grinding, blending, drying, sonication, shaking, centrifuging—where these procedures involve organisms containing recombinant DNA molecules, except where equipment design provides for containment of the potential aerosol.

II-B-3-b-(2). *Laboratory animals held in a P3 area shall be housed in partial containment caging systems such as Horsfall units, open cages placed in ventilated enclosures, solid-wall-and-bottom cages covered by filter bonnets, or solid-wall-and-bottom cages covered by filter bonnets. For example, manipulations such as inserting a hot inoculating loop or needle into a culture, flaming an inoculation loop or needle so that it splatters, and forceful ejection of fluids from pipettes or syringes shall be avoided.


II-B-3-c. Special Laboratory Design. 
II-B-3-c-(1). *The laboratory shall be separated from areas which are open to unrestricted traffic flow by a controlled access area. A controlled access area is an anteroom, a change room, an air lock or any other double-door arrangement which separates the laboratory from areas which are open to unrestricted traffic flow.

II-B-3-c-(2). *The surfaces of walls, floors, and ceilings shall be readily cleanable. Penetrations through these surfaces shall be sealed or capable of being sealed to facilitate space decontamination.

II-B-3-c-(3). *A foot, elbow, or automatically operated handwashing facility shall be provided near each primary laboratory exit area.

II-B-3-c-(4). *Windows in the laboratory shall be sealed.

II-B-3-c-(5). *Laboratory doors shall be self-closing.

II-B-3-c-(6). *An autoclave for sterilization of wastes and contaminated materials shall be available in the same building (and preferably within the controlled laboratory area) in which organisms containing recombinant DNA molecules are used.

II-B-3-c-(7). *An exhaust air ventilation system shall be provided. This system shall be balanced so that the direction of airflow is from the controlled access area into the laboratory environment. The exhaust air shall not be recirculated to any other areas of the building. Recirculation of air within the laboratory room, however, may be provided. The exhaust air from the laboratory shall be discharged to the outdoors so that it is dispersed clear of occupied buildings and air intakes. The exhaust air from the laboratory can be discharged to the outdoors without filtration or other treatment.

II-B-3-c-(8). *The treated exhaust air from class I and class II biological safety cabinets (22) may be discharged either directly to the laboratory or to the outdoors. The treated exhaust air from a class III cabinet shall be discharged directly to the outdoors. If the treated exhaust air from these cabinets is to be discharged to the outdoors through a building exhaust air system, it shall be connected to this system so as to avoid any interference with the airflow of the cabinet or building exhaust air system.

II-B-4. P4 Level.

II-B-4-a. Laboratory Practices.
II-B-4-a-(1). Laboratory doors shall be kept closed while experiments are in progress.

II-B-4-a-(2). Work surfaces shall be decontaminated following the completion of the experimental activity and immediately following spills of organisms containing recombinant DNA molecules.

II-B-4-a-(3). All biological wastes shall be decontaminated before disposal. Other contaminated materials such as glassware, animal cages, and laboratory equipment shall be decontaminated before washing, reuse, or disposal.

II-B-4-a-(4). Mechanical pipetting devices shall be used; pipetting by mouth is prohibited.

II-B-4-a-(5). *Eating, drinking, smoking, and storage of food are not permitted in the P4 facility.

II-B-4-a-(6). Persons shall wash their hands after handling organisms containing recombinant DNA molecules and when they leave the laboratory.

II-B-4-a-(7). Care shall be exercised to minimize the creation of aerosols. For example, manipulations such as inserting a hot inoculating loop or needle into a culture, flaming an inoculation loop or needle so that is splatters, and forceful ejection of fluids from pipettes or syringes shall be avoided.

II-B-4-a-(8). *Biological materials to be removed from the P4 facility in a viable or intact state, shall be transferred to a nonbreakable sealed container which is then removed from the P4 facility through a pass-through disinfectant dunk tank or fumigation chamber.

II-B-4-a-(9). *No materials, except for biological materials that are to remain in a viable or intact state, shall be removed from the P4 facility unless they have been sterilized or decontaminated as they pass out of the P4 facility. All wastes and other materials as well as equipment not damaged by high temperature or steam shall be sterilized in the double-door autoclave of the P4 facility. Other materials which may be damaged by temperature or steam shall be removed from the P4 facility through a pass-through fumigation chamber.

II-B-4-a-(10). *Materials within the class III cabinets shall be removed from the cabinet system only after being sterilized in an attached double-door autoclave or after being contained in a nonbreakable sealed container which is then passed through a disinfectant dunk tank or fumigation chamber.
II-B-4-a-(11). *Only persons whose entry into the P4 facility is required to meet program or support needs shall be authorized to enter. Before entering, such persons shall be advised of the nature of the research being conducted and shall be instructed as to the appropriate safeguards to insure their safety. They shall comply with instructions and all other required procedures.

II-B-4-a-(12). *Persons under 18 years of age shall not enter the P4 facility.

II-B-4-a-(13). *Personnel shall enter into and exit from the P4 facility only through the clothing change and shower rooms. Personnel shall shower at each egress from the P4 facility. Air locks shall not be used for personnel entry or exit except for emergencies.

II-B-4-a-(14). *Street clothing shall be removed in the outer side of the P4 facility clothing change area and kept there. Complete laboratory clothing including undergarments, head cover, shoes, and either pants and shirts or jumpsuits shall be provided and used by all persons who enter the P4 facility. Upon exit, personnel shall store this clothing in lockers provided for this purpose or discard it into collection hampers before entering the shower area.

II-B-4-a-(15). *The universal biohazard sign is required on the P4 facility access doors and all interior doors to individual laboratory rooms where experiments are conducted.

II-B-4-a-(16). An insect and rodent control program shall be instituted.

II-B-4-a-(17). *Animals and plants not related to the experiment shall not be permitted in the laboratory in which the experiment is being conducted.

II-B-4-a-(18). Use of the hypodermic needle and syringe shall be avoided when alternate methods are available.

II-B-4-a-(19). The laboratory shall be kept neat and clean.

II-B-4-a-(20). *If experiments involving other organisms which require lower levels of containment are to be conducted in the P4 facility concurrently with experiments requiring P4-level containment, they shall be conducted in accordance with all P4-level laboratory practices specified in this section.

II-B-4-b. Container Equipment

II-B-4-b-(1). *Experimental procedures involving organisms which require P4-level physical containment shall be conducted either in (i) a class III cabinet system or in (ii) class I or class II cabinets that are located in a specially designed area in which all personnel are required to wear one-piece positive-pressure isolation suits.

II-B-4-b-(2). Laboratory animals involved in experiments requiring P4-level physical containment shall be housed either in cages contained in class III cabinets or in partial containment caging systems (such as Horsfall units, open cages placed in ventilated enclosures, or solid wall and bottom cages covered by filter bonnets, or solid wall and bottom cages placed on holding racks equipped with ultraviolet irradiation lamps and reflectors) that are located in a specially designed area in which all personnel are required to wear one-piece positive-pressure suits.

II-B-4-b-(3). *Alternative Selection of Containment Equipment. Experimental procedures involving a host-vector system which provides a one-step higher level of biological containment than that specified in Part III can be conducted in the P4 facility using containment equipment requirements specified for the P3 level of physical containment. Alternative combinations of containment safeguards are shown in table II.

Table II

<table>
<thead>
<tr>
<th>Classification of experiment</th>
<th>Alternate combinations of physical and biological containment</th>
<th>Physical containment</th>
<th>Biological containment</th>
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<tr>
<td></td>
<td></td>
<td>Laboratory design</td>
<td>Laboratory containment</td>
</tr>
<tr>
<td>Physical*</td>
<td>Biological*</td>
<td>practices</td>
<td>Containment equipment</td>
</tr>
<tr>
<td>P4</td>
<td>HV1</td>
<td>P4</td>
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<td>P4</td>
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<tr>
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<td>HV1</td>
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</tr>
<tr>
<td>P4</td>
<td>HV1</td>
<td>P4</td>
<td>P4</td>
</tr>
</tbody>
</table>

* See Section II-D for description of biological containment.

II-B-4-c. Special Laboratory Design

II-B-4-c-(1). *The laboratory shall be located in a restricted access facility which is either a separate building or a clearly demarcated and isolated zone within a building. Clothing change areas and shower rooms shall be provided for personnel entry and egress. These rooms shall be arranged so that personnel egress is through the shower area to the change room. A double-door ventilated vestibule or ultraviolet air lock shall be provided for passage of materials, supplies, and equipment which are not brought into the P4 facility through the change room area.

II-B-4-c-(2). *Walls, floors, and ceilings of the P4 facility are constructed to form an internal shell which readily allows vapor-phase decontamination and is animal- and insect-proof. All penetrations through these structures and surfaces are sealed. The integrity of the walls, floors, ceilings, and penetration seals should insure adequate containment of a vapor-phase decontaminant under static pressure conditions. This requirement does not imply that these surfaces must be watertight.

II-B-4-c-(3). *A foot elbow, or automatically-operated hand-washing facility shall be provided near the door within each laboratory in which experiments involving recombinant DNA are conducted in open-face biological safety cabinets.

II-B-4-c-(4). *Where a central vacuum system is provided, it shall not serve areas outside the P4 facility. The vacuum system shall include in-line HEPA filters as near as practicable to each use point or service cock. The filters shall be installed so as to permit in-place decontamination and replacement. Water supply and liquid and gaseous services provided to the P4 facility shall be protected by devices that prevent backflow.

II-B-4-c-(5). *Foot-operated water fountains are permitted in the corridors of the P4 facility. The water service provided to the fountain shall be protected from the water services to the laboratory areas of the P4 facility.

II-B-4-c-(6). Laboratory doors shall be self-closing.

II-B-4-c-(7). *A double-door autoclave shall be provided for sterilization of material passing out of the P4 facility. The autoclave doors shall be interlocked so that both doors will not be open at the same time.

II-B-4-c-(8). *A passthrough dunk tank or fumigation chamber shall be provided for removal of material and equipment that cannot be heat-sterilized from the P4 facility.

II-B-4-c-(9). *All liquid effluents from the P4 facility shall be collected and decontaminated before disposal. Liquid effluents from biological safety cabinets and laboratory sinks shall be
stereilized by heat. Liquid effluents from the shower and hand washing facilities may be destroyed by chemical treatment. HEPA filters shall be installed in all effluent drain vent lines.

II-4-c-(10). An individual supply and exhaust-air ventilation system shall be provided for the P4 facility. The system shall maintain pressure differentials and directional airflow as required to assure inflow from areas outside the P4 facility toward areas of highest potential risk within the facility. The system shall be designed to prevent the reversal of airflow. The system shall sound an alarm in the event of system malfunction.

II-4-c-(11). Recirculation of air within individual laboratories of the P4 facility is permissible if this air is filtered by a HEPA filter.

II-4-c-(12). The exhaust air from the P4 facility shall be filtered and discharged to the outdoors so that it is dispersed clear of occupied buildings and a filter chamber shall be designed to allow in situ decontamination before removal and to facilitate certification testing after replacement.

II-4-c-(13). The treated exhaust air from Class I and Class II biological safety cabinets(20) may be discharged directly to the laboratory room environment or to the outdoors. The treated exhaust air from Class III cabinets shall be discharged to the outdoors. If the treated exhaust air from these cabinets is to be discharged to the outdoors through the P4 facility exhaust air system, it shall be connected to this system so as to avoid any interference with the cabinets or the facility exhaust air system.

II-4-c-(14). A specially designed suit area may be provided in the facility. Personnel who enter this area shall wear a white-piece positive-pressure suit that includes a life-support system. The life-support system shall be provided with alarms and emergency backup air. Entry to this area is through an air-lock fitted with air-tight doors. A chemical shower area shall be provided to decontaminate the surfaces of the suit before removal. The exhaust air from the suit area shall be filtered by two sets of HEPA filters installed in series, and a duplicate filtration unit and exhaust fan shall be provided. The air pressure within the suit area shall be less than that in any adjacent area. An emergency lighting system, communication systems, and power source shall be provided.

The internal shell of the suit area shall be airtight. A doubledoor autoclave shall be provided for sterilization of all waste materials to be removed from the facility.

II-C. Shipment. Recombinant DNA when contained in an organism or virus shall be shipped in compliance with the requirements issued by the U.S. Public Health Service (section 72.25 of Part 72, Title 42, Code of Federal Regulations), Department of Transportation (section 173.387(b) of Part 173, Title 49, Code of Federal Regulations), and the Civil Aeronautics Board (C.A.B. No. 82, Official Air Transport Restricted Articles Tariff No. 6-D) for shipment of etiologic agents.

The packaging and shipment of organisms and viruses containing recombinant DNA molecules shall be in compliance with all requirements specified in subparagraphs (1)-(5) of paragraph (c), "Transportation; etiologic agents subject to additional requirements," of Part 72, Title 42, Code of Federal Regulations. Subparagraph (6) of paragraph (c) of section 72.25 of Part 72, Title 42, Code of Federal Regulations shall apply to the shipment of all viable host and vector organisms which require P4 physical containment.

Additional information on packaging and shipment is given in "Laboratory Safety Monograph-A Supplement to the NIH Guidelines for Recombinant DNA Research."

II-D. Biological containment. II-D-1. Levels of biological containment. In consideration of biological containment, the vector (plasmid, organelle, or virus) for the recombinant DNA and the host (bacterial, plant, or animal cell) in which the vector is propagated in the laboratory will be considered together. Any combination of vector and host which are to provide biological containment must be constructed so that the following types of "escape" are minimized: (i) Survival of the vector in its host outside the laboratory, and (ii) transmission of the vector from the propagating host or other nonlaboratory hosts.

The following levels of biological containment (HV, or Host-Vector, systems) for prokaryotes will be established; specific criteria will depend on the organisms to be used. Eukaryotic host-vector systems are considered in Part III.

II-D-1-a. HV1. A host-vector system which provides a moderate level of containment. Specific systems:

II-D-1-a-(1). EK1. The host is always E. coli K-12 or a derivative thereof, and the vectors include non-conjugative plasmids (e.g., pSC101, ColE, or derivatives thereof (21-27) and variants of bacteria phage, such as 028-33). The E. coli K-12 hosts should not contain conjugation-proficient plasmids, whether autonomous or integrated, or generalized transducing phages.

II-D-1-a-(2). Other Prokaryotes. Hosts and vectors should be, at a minimum, comparable in containment to E. coli K-12 with a nonconjugative plasmid or virus vector. The data to be considered and a mechanism for approval of such HV1 systems are described below (section II-D-2).

II-D-1-b. HV2. These are host-vector systems shown to provide a high level of biological containment as demonstrated by data from suitable tests performed in the laboratory. Escape of the recombinant DNA either via survival of the organisms or via transmission of recombinant DNA to other organisms should be less than 10^-6 under specified conditions. Specific systems:

II-D-1-b-(1). For EK2 host-vector systems in which the vector is a plasmid, no more than one in 10^8 host cells should be able to perpetuate a cloned DNA fragment under the specified nonpermissive laboratory conditions designed to represent the natural environment, either by survival of the original host or as a consequence of transmission of the cloned DNA fragment.

II-D-1-b-(2). For EK2 host-vector systems in which the vector is a phage, no more than one in 10^8 phage particles should be able to perpetuate a cloned DNA fragment under the specified nonpermissive laboratory conditions designed to represent the natural environment either (i) as a prophage or plasmid in the laboratory host used for phage propagation or (ii) by surviving in natural environments and transferring a cloned DNA fragment to other hosts (or their resident phages).

II-D-1-c. HV3. These are host-vector systems which:

II-D-1-c-(1). All HV2 criteria are met.

II-D-1-c-(2). The vector is dependent on its propagation host or is highly defective in mobilization. Relevant genotypic criteria are:

II-D-1-c-(3). No markers conferring resistance to antibiotics commonly used clinically or in agriculture are carried by the vector, unless expression of such markers is dependent on the propagating host or on unique laboratory controlled conditions or is blocked by the inserted DNA.

II-D-1-c-(4). The specified containment shown by laboratory tests has been independently confirmed by specified tests in animals, including primates, and in other relevant environments.

II-D-1-c-(5). The relevant genotypic and phenotypic traits have been independently confirmed.

II-D-2. Certification of host-vector systems.

II-D-2-a. Responsibility. HV1 systems other than E. coli K-12, and HV2 and HV3 host-vector systems may not

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be used unless they have been certified by the NIH. Application for certification of a host-vector system is made by written application to the Office of Recombinant DNA Activities (ORDA), National Institutes of Health, Bethesda, MD 20892.

When appropriate, the proposed host-vector system will be reviewed by the NIH Recombinant DNA Advisory Committee (RAC). This may first involve review of the data on construction, properties, and testing of the proposed host-vector system by a subcommittee composed of one or more members of the RAC and other individuals chosen because of their expertise in evaluating such data. The committee will then evaluate the report of the subcommittee and any other available information at a regular meeting.

When new host-vector systems are certified, notice of the certification will be sent to the applicant and to all IBCs and will be published in the Recombinant DNA Technical Bulletin. Copies of a list of all currently certified host-vector systems may be obtained from ORDA at any time.

NIH may at any time rescind the certification of any host-vector system. If certification of a host-vector system is rescinded, investigators may be asked to transfer cloned DNA into a different system.

Certification of a given system does not extend to modifications of either the host or vector component of that system. Such modified systems must be independently certified by NIH. If modifications are minor, it may only be necessary for the investigator to submit data showing that the modifications have either improved or not impaired the major phenotypic traits on which the containment of the system depends. More substantial modifications of a certified system may necessitate the submission of complete testing data.

II-D-2-b. Data to be Submitted for Certification

II-D-2-b-(1). HV1 Systems Other than E. coli K-12. The following types of data should be submitted, modified as appropriate for the particular system, under consideration: (i) A description of the organism and vector; the strain's natural habitat and growth requirements; the range of organisms with which this organism normally exchanges genetic information and what sort of information is exchanged; any relevant information on its pathogenicity or toxicity. (ii) A description of the history of the particular strains and vectors to be used, including data on any mutations which render this organism less able to survive or transmit genetic information. (iii) A general description of the range of experiments contemplated, with emphasis on the need for developing such an HV1 system.

II-D-2-b-(2). HV2 Systems. Investigators planning to request HV2 certification for host-vector systems can obtain instructions for preparing and submitting data to be submitted. In general, the following types of data are required: (i) Description of construction steps, with indication of source, properties, and manner of introduction of genetic traits. (ii) Data on the stability of genetic traits that contribute to the containment of the system. (iii) Data on the survival of the host-vector system under non-permissive laboratory conditions designed to represent the relevant natural environment. (iv) Data on transmissibility of the vector and/or a cloned DNA fragment under both permissive and non-permissive conditions. (v) Data on all other traits of HV2 systems prior to consideration of the system for certification, be certified as HV2 systems. Systems which meet the criteria for certification, be certified as HV2 systems. Systems which meet the criteria for certification will be distributed as small-volume ly- sates.

Data must be submitted in writing to ORDA. Ten to twelve weeks are normally required for review and circulation of the data prior to the meeting at which such data can be considered.

II-D-2-b-(3). HV3 Systems. Putative HV3 systems must, as the first step in certification, be certified as HV2 systems. Systems which meet the criteria given above under II-D-1-(c)-(1), II-D-1-(c)-(2), and II-D-1-(c)-(3) will then be recommended for HV3 testing. Tests to evaluate various HV2 host-vector systems for HV3 certification will be performed by contractors selected by NIH. These contractors will repeat tests performed by individuals proposing the HV2 system and, in addition, will conduct more extensive tests on conditions likely to be encountered in nature. The genotypic and phenotypic traits of HV2 systems will be evaluated. Tests on survival and transmissibility in and on animals, including primates, will be performed, as well as tests on survival in certain specified natural environments.

II-D-2-c. Distribution of Certified Host-Vectors. Certified HV2 and HV3 host-vector systems (plus appropriate host strains) are recommended for certification by NIH. NIH may also distribute certified HV1 host-vector systems.

III. CONTAINMENT GUIDELINES FOR COVERED EXPERIMENTS

Part III discusses experiments covered by the guidelines. The reader must first consult Part I, where listings are given of prohibited and exempt experiments.

Containment guidelines for permissible experiments are given in Part III. Changes in these levels for specific experiments (or the assignment of levels to experiments not explicitly considered here) may be expressly approved by the Director, NIH, on the recommendation of the Committee for Recombinant DNA Advisory Committee (RAC).

III-A. Classification of Experiments Using the E. coli K-12 Host-Vector Systems. Most recombinant DNA experiments currently being done employ E. coli K-12 host-vector systems. These are the systems for which we have the most experience and knowledge (i) regarding the effectiveness of biological containment provided by existing hosts and vectors, and (ii) necessary for the construction of more effective biological barriers. We therefore consider DNA recombinants in E. coli K-12 before proceeding to other host-vector systems. The levels of biological containment for E. coli K-12 systems...
are designated EK1, EK2, and EK3 in ascending order.

It has been necessary, throughout this section, to use words and phrases such as "purified" or "rigorously characterized." In the text such terms are marked with footnote reference numbers. These footnotes (part V) define more fully what these terms denote.

In the following classification of containment levels, for different classes of eukaryotic DNA, the states of physical and biological containment are minimal for the experiments designated. The use of higher levels of biological containment (EK3 > EK2 > EK1) is encouraged if they are available and equally appropriate for the purposes of the experiment.


These experiments involve the production of recombinant DNA's between the vector and portions of the specified cell source, preferably a partially purified fraction. Care should be taken either to preclude or eliminate contaminating microorganisms before isolating the DNA.


III-A.-a-(1). Primates. P2 physical containment + and EK2 host-vector. Any lowering of containment below these levels (i.e., for purified DNA or characterized clones) cannot be made solely by an institutional biosafety committee but requires NIH approval.


III-A.-a-(4). Cold-Blooded Vertebrates. P2 physical containment + an EK1 host-vector or P1 + EK2. If the eukaryote is known to produce a potent polypeptide toxin,[34] the containment shall be increased to P3 + EK2.

III-A.-a-(5). Other Cold-Blooded Animals and Lower Eukaryotes. This large class of eukaryotes is divided into two groups:

III-A.-a-(5)-(a). Species that are known to produce a potent polypeptide toxin[35] that acts in vertebrates, or are known pathogens listed in Class 2,(1) or are known to carry such pathogens must use P3 physical containment + an EK2 host-vector. When the potent toxin is not a polypeptide and is likely not to be the product of closely linked eukaryote genes, containment may be reduced to P3 + EK1 or P2 + EK2. Species that produce potent toxins that affect invertebrates of plants but not vertebrates require P2 + EK2 or P3 + EK1. Any species that has a demonstrated capacity for carrying particular pathogenic microorganisms is included in this group, unless the organisms used as the source of DNA have been shown not to contain those agents, in which case they may be placed in the following group.

III-A.-a-(5)-(b). The remainder of the species in this class including plant pathogens or symbiotic fungi that do not produce potent toxins: P2 + EK1 or P1 + EK2. However, any insect in this group must be either (i) grown under laboratory conditions for at least 10 generations prior to its use as a source of DNA, or (ii) if caught in the wild, must be shown to be free of disease-causing microorganisms or must belong to a species that does not carry microorganisms causing disease to vertebrates or plants. If these conditions cannot be met, experiments must be done under P3 + EK1 or P2 + EK2 containment.

III-A.-a-(6). Plants. P2 physical containment + an EK1 host-vector or P1 + EK2. If the plant source makes a potent polypeptide toxin,[34] the containment shall be raised to P3 physical containment + an EK2 host-vector. When the potent toxin is not a polypeptide and is likely not to be the product of closely linked plant genes, containment may be reduced to P3 + EK1 or P2 + EK2.


III-A.-b.-a-(1). Prokaryotes That Exchange Genetic Information with E. Coli. It is expected that many of the prokaryotes that exchange genetic information with E. coli by known physiological processes will be exempted from these Guidelines by appearing on the list of exchangers (see Section I-E-4).

For those not on the list, the containment levels are P1 physical containment + an EK1 host-vector or P2 physical containment + an EK1 host-vector. In fact, experiments in this category may be performed with any E. coli K-12 vector (e.g., conjugative plasmids). However, for prokaryotes that are classified[1] as Class 2 the containment levels are P2 + EK1.


III-A.-2. Plasmids, Bacteriophages, and Other Viruses. Recombinants formed between a vector and some other plasmid or virus DNA have in common the potential for acting as double vectors because of the replication functions in these DNA's. The containment conditions given below apply only to propagation of the DNA recombinants in E. coli K-12 hosts. They may apply to other hosts in which the recombinants may be able to replicate as a result of functions provided by the DNA inserted into the EK vectors. These are considered under other host-vector systems.


III-A.-2-a-(1)-(a)-(1). Adeno-Associated Viruses, Minute Virus of Mice, Mouse Adenovirus (strain FL), and Plant Viruses. P1 physical containment + and EK1 host-vector shall be used for DNA recombinants produced with (i) the whole viral genome, (ii) subgenomic DNA segments, or (iii) purified cDNA copies of viral mRNA.[37]

III-A.-2-a-(1)-(a)-(2). Hepatitis B.

III-A.-2-a-(1)-(b)-(2)-(a). P1 physical containment + an EK2 host-vector shall be used for purified subgenomic DNA segments.

III-A.-2-a-(1)-(a)-(2)-(b). P2 physical containment + an EK2 host-vector or P3 + EK1 shall be used for DNA for recombinants produced with the whole viral genome.

III-A.-2-a-(1)-(a)-(2)-(c). P2 physical containment + an EK1 shall be used for DNA recombinants derived from purified cDNA copies of viral mRNA.

III-A.-2-a-(1)-(a)-(3). Other Nontransforming Members of Presently Classified Viral Families.[36]

III-A.-2-a-(1)-(a)-(3)-(a). P1 physical containment + an EK1 host-vector shall be used for DNA recombinants produced with purified subgenomic DNA segments or (ii) purified cDNA copies of viral mRNA.[37]

III-A.-2-a-(1)-(a)-(3)-(b). P1 physical containment + an EK1 host and a vector certified for use in an EK2 system shall be used for DNA recombinants produced with the whole viral genome.

III-A.-2-a-(1)-(b)-(1). Transforming Viruses.

III-A.-2-a-(1)-(b)-(1)-(1). Herpes Similis, Herpes Atelis, and Epstein Barr Virus.[39]

III-A.-2-a-(1)-(b)-(1)-(2). P1 physical containment + an EK1 host-vector shall be used for DNA recombinants produced with purified nontransforming subgenomic DNA segments.[38]

III-A.-2-a-(1)-(b)-(1)-(2)-(b). P2 physical containment + an EK1 host-vector or P3 + EK1 shall be used for (i) DNA recombinants produced with purified subgenomic DNA segments containing an entire transforming gene or (ii) purified cDNA copies of viral mRNA.[37]

III-A.-2-a-(1)-(b)-(1)-(c). P3 physical containment + an EK1 host-vector or P2 + EK2 shall be used for DNA recombinants produced with the whole viral genome.

III-A.-2-a-(1)-(b)-(2). Other Transforming Members of Presently Classified Viral Families.[36]
shall be used for DNA recombinants produced with purified nontrans-
forming subgenomic DNA segments.(38)

III-A-2-a-(1)-(b)-(2)-(b). P2 physical containment + an EK1 host and a
vector certified for use in an EK2 system or F3 + EK1 shall be used for
(i) DNA recombinants produced with the whole viral genome, (ii) purified
subgenomic DNA segments containing an entire transforming gene, or (iii)
purified cDNA copies of viral mRNA.(37)

III-A-2-a-(2). DNA Transcripts of
RNA Viruses.


III-A-2-a-(2)-(a)-(1). Gibbon Ape,
Woolly Monkey, Feline Leukemia and
Feline Sarcoma Viruses.(39)

III-A-2-a-(2)-(a)-(1). P1 physical
containment + an EK1 host-vector shall be used for DNA recombinants
produced with purified nontrans-
forming subgenomic DNA seg-
ments.(38)

III-A-2-a-(2)-(2). P2 physical
containment + an EK1 host and a
vector certified for use in an EK2
system, or F3 + EK1, shall be used for
DNA recombinants produced with pu-
rified subgenomic DNA segments(39)
containing an entire transforming
gene.

III-A-2-a-(2)-(7)-(c). P2 physical
containment + an EK1 host-vector or
F3 + EK1 shall be used for DNA re-
combinants produced with (i) the
whole viral genome or (ii) purified
cDNA copies of viral mRNA.(37)

III-A-2-a-(2)-(a)-(2). Other Members
of the Family Retroviridae.(36)

III-A-2-a-(2)-(a)-(2)-(a). P1 physical
containment + an EK1 host-vector shall be used for DNA recombinants
produced with purified nontrans-
forming subgenomic DNA seg-
ments.(38)

III-A-2-a-(2)-(a)-(2)-(b). P2 physical
containment + an EK1 host and a
vector certified for use in an EK2
system or F3 + EK1 shall be used for
DNA recombinants produced with (i)
purified subgenomic DNA segments
containing an entire transforming
gene, (ii) the whole viral genome, or
(iii) purified cDNA copies of viral
mRNA.(37)

III-A-2-a-(2)-(b). Negative Strand
RNA Viruses. P1 physical containment
+ an EK1 host-vector shall be used for
DNA recombinants produced with (i)
cDNA copies of the whole genome, (ii)
subgenomic cDNA segments, or (iii)
purified cDNA copies of viral
mRNA.(37)

III-A-2-a-(2)-(c). Plus-Strand RNA
Viruses.

III-A-2-a-(2)-(c)-(1). Types 1 and 2
Sabin Poliovirus Vaccine Strains and
Strain 17D (Thiel) of Yellow Fever
Virus. P1 physical containment + and
EK1 host-vector shall be used for DNA re-
combinants produced with (i) cDNA
copies of the whole viral genome, (ii)
subgenomic cDNA segments, or (iii)
purified cDNA copies of viral
mRNA.(37)

III-A-2-a-(2)-(c)-(2). Other Plus-
Strand RNA Viruses Belonging to Pre-
viously Classified Viral Families.(36)
<table>
<thead>
<tr>
<th>Virus class</th>
<th>Subgenomic[38]</th>
<th>Genomic</th>
<th>cDNA from viral mRNA[37]</th>
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<tr>
<td>DNA</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Nontransforming viruses</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AAV, HWM, House Adeno (Strain FL)</td>
<td>PL + EL</td>
<td>P2 + EL</td>
<td>PL + EL</td>
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<tr>
<td>Plant Viruses</td>
<td>PL + EL</td>
<td>P2 + EL</td>
<td>PL + EL</td>
</tr>
<tr>
<td>Hepatitis B</td>
<td>PL + EL</td>
<td>P2 + EL</td>
<td>P2 + EL</td>
</tr>
<tr>
<td>Other</td>
<td>PL + EL</td>
<td>P1 + ELCV1401 or P3 + EL</td>
<td>P1 + EL</td>
</tr>
<tr>
<td>Transforming Viruses</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Herpes Saimiri, H. Ateles and EBV[39]</td>
<td>PL + EL</td>
<td>P2 + ELCV1401 or P3 + EL</td>
<td>P2 + ELCV1401 or P3 + EL</td>
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<tr>
<td>Other</td>
<td>PL + EL</td>
<td>P2 + ELCV1401 or P3 + EL</td>
<td>P2 + ELCV1401 or P3 + EL</td>
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<tr>
<td>RNA</td>
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<tr>
<td>Retroviruses</td>
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<tr>
<td>Gibbon Ape, Woolly Monkey, FeLV and FeSV[39]</td>
<td>PL + EL</td>
<td>P2 + ELCV1401 or P3 + EL</td>
<td>P2 + ELCV1401 or P3 + EL</td>
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<tr>
<td>Other</td>
<td>PL + EL</td>
<td>P2 + ELCV1401 or P3 + EL</td>
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</table>

**Table III**
Recommended Containment for Cloning of Viral DNA or cDNA in E. coli K-12 Host-Vector Systems
(See text for full details)

<table>
<thead>
<tr>
<th>Virus class</th>
<th>Subgenomic[38]</th>
<th>Genomic</th>
<th>cDNA from viral mRNA[37]</th>
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<tr>
<td>Negative Strand RNA</td>
<td>PL + EL</td>
<td>P1 + EL</td>
<td>P1 + EL</td>
</tr>
<tr>
<td>Plus Strand RNA</td>
<td>PL + EL</td>
<td>P2 + ELCV1401 or P3 + EL</td>
<td>P2 + ELCV1401 or P3 + EL</td>
</tr>
<tr>
<td>Types 1 and 2 Sabin Polio, 17D Yellow Fever Vaccine Strains</td>
<td>PL + EL</td>
<td>P1 + EL</td>
<td>P1 + EL</td>
</tr>
<tr>
<td>Other</td>
<td>PL + EL</td>
<td>P2 + ELCV1401 or P3 + EL</td>
<td>P2 + ELCV1401 or P3 + EL</td>
</tr>
<tr>
<td>Double Stranded DNA</td>
<td>PL + EL</td>
<td>P1 + EL</td>
<td>P1 + EL</td>
</tr>
<tr>
<td>Plant Viruses + Viroids</td>
<td>PL + EL</td>
<td>P1 + EL</td>
<td>P1 + EL</td>
</tr>
<tr>
<td>Intracellular Viral DNA</td>
<td>See text</td>
<td>See text</td>
<td>See text</td>
</tr>
</tbody>
</table>

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III-A-2-a-(2)-(c)-(2)-(a). Ph1 physical containment + an EK1 host-vector shall be used for DNA recombinants produced with purified subgenomic cDNA segments.(37)

III-A-2-a-(2)-(c)-(2)-(b). P2 physical containment + an EK1 host and a vector certified for use in an EK2 system of P3+EK1 shall be used for DNA recombinants produced with (i) cDNA copies of the whole genome, or (ii) purified cDNA copies of viral mRNA.(37)

III-A-2-a-(2)-(d). Double-Stranded Segmented RNA Viruses. Ph1 physical containment + an EK1 host-vector shall be used for RNA recombinants produced with (i) mixtures of subgenomic cDNA segments, (ii) a specific subgenomic cDNA segment, or (iii) purified cDNA copies of viral mRNA.(37)

III-A-2-a-(2)-(e). RNA Plant Viruses and Plant Viroids. Ph1 physical containment + an EK1 host-vector shall be used for DNA recombinants produced with (i) cDNA copies of the whole viral genome, (ii) subgenomic cDNA segments, or (iii) purified cDNA copies of viral mRNA.(37)

III-A-2-a-(3). Intracellular Viral DNA. Physical and biological containment specified for shotgun experiments with eukaryotic cellular DNA (see section III-A-1-a-(1) or (ii) any lowering of containment under section III-A-3-a to levels below P1+EK1, which also requires prior NIH approval.

III-A-2-b. Eukaryotic Organelle DNA's. P2 physical containment + an EK1 host-vector shall be used for eukaryotic DNA contained in plasmids or viruses) will generally require prior NIH approval. Experiments with phages, plasmids, and viruses, except for those that produce potent polypeptide toxins, shall be carried out under P1 conditions. Host-vectors shall be used for shotgun experiments with phages, plasmids, and DNA from nonpathogenic prokaryotes which do not produce polypeptide toxins. (33)

Other classes of recombinant DNA experiments with these HV1 systems will require prior approval and classification by NIH. Experiments with DNA's from eukaryotes (and their plasmids or viruses) will generally follow the criteria for the corresponding experiments with E. coli K-12 host-vectors if the major habitats of the given host-vector overlap those of E. coli. The habitats of other host-vectors may be considered in relation to containment.

III-B-2. Return of DNA Segments to Non-HVI Host of Origin. Many of the prokaryotes that exchange genetic information with E. coli by known physical processes are expected to be exempt from these Guidelines by appearing on the "list of exchangers" (see Section I-E-4). For a prokaryote which can exchange genetic information (35) with E. coli under laboratory conditions but which is not on the list (Host A), the following type of experiment may be carried out under P1 conditions without Host A having been approved as an HV1 host: DNA from Host A may be inserted into a vector and propagated in E. coli K-12 under P1 conditions. Subsequently, this recombinant DNA may be returned to Host A by mobilization, transformation, or transduction and may then be propagated in Host A in any desired vector under P1 conditions.

For a prokaryote which does not exchange genetic information with E. coli (Host B), the following type of experiment may be carried out without Host B having been approved as an HV1 host: DNA from Host B may be inserted into a vector and propagated in E. coli K-12 under P1 conditions. Subsequently, this recombinant DNA may be returned to Host B and propagated in Host B under P1 conditions. (33)

III-C. Experiments with Eukaryotic Host-Vectors.

III-C-1. Vertebrate Host-Vector Systems. (44) (Summary Given in Table III-C-1-a.)


III-C-1-a-(1)-(a). Detective polyoma virus genomes, with appropriate helper, if necessary, can be used in P2 conditions to propagate DNA sequences: III-C-1-a-(1)-(a)-(1). From bacteria of class 1 or class 2 (11) or their phages or plasmids, except for those that produce potent polypeptide toxins; (30)

III-C-1-a-(1)-(a)-(2). From mice;

III-C-1-a-(1)-(a)-(3). From eukaryotic organisms that do not produce potent polypeptide toxins, (30) provided the DNA segment is > 99 percent pure.

III-C-1-a-(1)-(b). Defective polyoma genomes, with appropriate helper, if necessary, can be used in P2 conditions for shotgun experiments to propagate DNA sequences from eukaryotic or-
III-C-1-a-(1)-(c). Defective or intact virus genomes with appropriate helper, if necessary, can be used in P2 conditions for extended experiments to propagate DNA sequences from eukaryotic viruses. In the latter case, such experiments will be evaluated by NIH on a case-by-case basis.(45)

III-C-1-a-(1)-(d). Experiments involving the use of defective polynucleotic virus genomes to propagate DNA sequences from eukaryotic viruses will be evaluated by NIH on a case-by-case basis (45) and will be conducted under the recommended physical containment conditions.

III-C-1-a-(2). Nonproductive Virus-Cell Interactions. Defective or intact polynucleotic virus genomes can be used as vectors in P2 conditions to transform nonpermissive cells in culture, provided the inserted DNA sequences are not derived from eukaryotic viruses. In the latter case, such experiments will be evaluated by NIH on a case-by-case basis.(45)

III-C-1-b. Simian Virus 40.

III-C-1-b-(1). Productive Virus-Cell Interactions.

III-C-1-b-(1)-(a). SV40 DNA, rendered unconditionally defective by a deletion in an essential gene, with appropriate helper, can be used in P2 conditions to propagate DNA sequences from eukaryotic organisms that do not produce potent polypeptide toxins.(34) Uninfected African green monkey kidney cell cultures.

III-C-1-b-(1)-(b). SV40 DNA, rendered unconditionally defective by a deletion in an essential gene, with an appropriate helper, can be used in P2 conditions to propagate DNA sequences from eukaryotic organisms. In the latter case, such experiments will be conducted under the recommended physical containment conditions.

III-C-1-b-(2). Nonproductive Virus-Cell Interactions. Defective or intact polynucleotic virus genomes can be used as vectors in P2 conditions to transform nonpermissive cells in culture, provided the inserted DNA sequences are not derived from eukaryotic viruses. In the latter case, such experiments will be evaluated by NIH on a case-by-case basis,(45)

III-C-1-c. Human Adenoviruses 2 and 5.

III-C-1-c-(1). Productive Virus-Cell Interactions.

III-C-1-c-(1)-(a). Human adenoviruses 2 and 5, rendered unconditionally defective by at least two complete genes, with appropriate helper, can be used in P2 conditions to propagate DNA sequences from eukaryotic organisms that produce potent polypeptide toxins; (34)

III-C-1-c-(1)-(a)-(2). Eukaryotic or prokaryotic or eukaryotic organisms that do not produce potent polypeptide toxins (34) (shotgun experiments or purified DNA).

III-C-1-c-(1)-(b). Experiments involving the use of unconditionally defective human adenovirus 2 and 5 genomes to propagate DNA sequences from eukaryotic viruses will be evaluated by NIH on a case-by-case basis (45) and will be conducted under the recommended physical containment conditions.

III-C-1-c-(2). Nonproductive virus-cell interactions. Defective or intact human adenovirus 2 and 5 genomes can be used as vectors in P2 conditions to transform nonpermissive cells in culture, provided the inserted DNA sequences are not derived from eukaryotic viruses. In the latter case, such experiments will be evaluated by NIH on a case-by-case basis (45).

III-C-1-d. Murine Adenovirus Strain FL.

III-C-1-d-(1). Productive Virus-Cell Interactions.

III-C-1-d-(1)-(a). Unconditionally defective murine adenovirus strain FL genomes, with appropriate helper, can be used in P2 conditions to propagate DNA sequences from eukaryotic organisms. In the latter case, such experiments will be conducted under the recommended physical containment conditions.

III-C-1-d-(1)-(b). Experiments involving the use of intact murine adenovirus strain FL genomes to propagate DNA sequences from prokaryotic or eukaryotic organisms will be evaluated by NIH on a case-by-case basis (45) and will be conducted under the recommended physical containment conditions.

III-C-1-d-(1)-(c). Experiments involving the use of unconditionally defective murine adenovirus strain FL genomes to propagate DNA sequences from eukaryotic viruses will be evaluated by NIH on a case-by-case basis (45) and will be conducted under the recommended physical containment conditions.

III-C-1-d-(2). Non-productive Virus-Cell Interactions. Defective or intact murine adenovirus strain FL genomes can be used as vectors in P2 conditions to transform nonpermissive cells in culture, provided the inserted DNA sequences are not derived from eukaryotic viruses. In the latter case, such experiments will be evaluated by NIH on a case-by-case basis (45) and will be conducted under the recommended physical containment conditions.

HIV will also review all experiments involving the use of virus vectors in animals and the physical containment conditions appropriate for such studies.

III-C-2. Invertebrate Host-Vector Systems in Which Insect Viruses Are Used to Propagate Other DNA Segments. As soon as information becomes available on the host range restrictions and on the infectivity, persistence, and integration of the viral DNA in vertebrate and invertebrate cells, experiments involving the use of insect viruses to propagate DNA sequences will be evaluated by NIH on a case-by-case basis and will be conducted under the recommended physical containment conditions. Experiments should be done in established invertebrate cell lines and should follow, where appropriate, criteria recommended for vertebrate viral DNA vectors (see Section III-C).

III-C-3. Plant Viral Host-Vector Systems. The DNA plan viruses which could currently serve as vectors for cloning genes in plants and plant cell protoplasts are Cauliflower Mosaic Virus (CaMV) and its close relatives, which have relaxed circular double-stranded DNA genomes with a molecular weight of 4.5 x 10^6, and Bean Golden Mosaic Virus (BGMV) and re-
lated viruses with small (<10^6 daltons) single-stranded DNA genomes. These viruses are not known to integrate into host chromosomes or to incorporate cellular genes into their genomes. CaMV is spread in nature by aphids, in which it survives for a few hours. Spontaneous mutants of CaMV which lack a factor essential for aphid transmission arise frequently. BGMV is spread in nature by whiteflies, and certain other single-stranded DNA plant viruses are transmitted by leafhoppers. These single-stranded plant viruses persist for days or weeks in their insect vectors, but are thought not to replicate there.

The DNA plant viruses have narrow host ranges and are relatively difficult to transmit mechanically to plants. For this reason, they are most unlikely to be accidentally transmitted from spillage of purified virus preparations. When these viruses are used as vectors in intact plants, or propagative plant parts, the plants should be grown under P1 conditions—that is, in either a limited access greenhouse or plant growth cabinet which is insect-proof, preferably with positive air pressure, and in which an insect fumigation regime is maintained. Soil, plant pots, and unwanted infected plant materials should be removed from the greenhouse or cabinet in sealed insect-proof containers and sterilized. It is not necessary to sterilize run-off water from the infected plants, as this is not a plausible route for secondary infection. When the viruses are used as vectors in tissue cultures or in small plants in axenic cultures, no special containment is recommended. Infected plant materials which have to be removed from the greenhouse or cabinet for further research, should be maintained under insect-proof conditions. These measures provide an entirely adequate degree of containment. They are similar to those required in many countries for licensed handling of "exotic" plant viruses.

The CaMV strain used as a cloning vector should be a mutant that lacks the aphid transmission factor.

The viruses or their DNA may also be useful as vectors to introduce genes into plant protoplasts. The fragility of plant protoplasts combined with the properties of the viruses mentioned above provide adequate safety. Since no risk to the environment from the use of the DNA plant virus/protoplast system is envisaged, no special containment is recommended, except as described in the following paragraph.

Experiments involving the use of plant virus genomes to propagate DNA sequences from eukaryotic viruses will be evaluated on a case-by-case basis and will be conducted under the recommended containment conditions.
### Table IV

Recommended Containment for Recombinant DNA Research Using Eukaryotic Viral Vectors
(See text for full details)

<table>
<thead>
<tr>
<th>Vector DNA</th>
<th>Productive virus-cell interactions</th>
<th>Nonproductive virus-cell interactions[46]</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Prokaryotic</td>
<td>Eukaryotic</td>
</tr>
<tr>
<td></td>
<td>Type of DNA insert</td>
<td>Shotgun</td>
</tr>
<tr>
<td></td>
<td>Natural host</td>
<td>P2</td>
</tr>
<tr>
<td>1. Polyoma</td>
<td></td>
<td>P2</td>
</tr>
<tr>
<td></td>
<td>Intact Genome</td>
<td>P2</td>
</tr>
<tr>
<td></td>
<td>Deleted Genome</td>
<td>P2</td>
</tr>
<tr>
<td>2. SV40</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Intact Genome</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Deleted Genome</td>
<td>P2</td>
</tr>
<tr>
<td>3. Human Ad2+Ad5</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Deleted Genoma</td>
<td></td>
</tr>
<tr>
<td>4. Mouse Adenovirus (Strain FL)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Intact Genome</td>
<td>CBC*</td>
</tr>
<tr>
<td></td>
<td>Deleted Genoma</td>
<td>P2</td>
</tr>
<tr>
<td>5. Insect Viruses</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>CBC*</td>
<td>CBC*</td>
</tr>
<tr>
<td>6. Plant Viruses (CaMV and BGMV)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>**</td>
<td>**</td>
</tr>
<tr>
<td>7. All other potential Viral Vectors</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*CBC = Case-by-case[45]
**See text
III-C-4. Plant Host-Vector Systems Other Than Viruses. Organellar, plasmid, and chromosomal DNA's may be used as vectors. DNA recombinants formed between such vectors and host DNA, when propagated only in that host (or a closely related strain of the same species), are exempt from the containment criteria for plants described above. The other sections of the Guidelines (see section III-E) and the containment criteria for shotgun experiments with these host-vector systems will require prior approval on a case-by-case basis. Such DNA may be returned to Host and propagated there under P1 conditions.

III-D. Complementary DNA's. Specific containment levels are given in Section III-A-2-a (see also last column of Table III) for complementary DNA (cDNA) of viral RNA. For the other sections, the containment conditions must be as stringent as would be used for propagating the natural DNA counterpart.

If the synthetic DNA sequence codes for a harmless product, it may be propagated at the same containment level as its purified natural DNA counterpart. For example, a synthetic DNA segment (e.g., a toxin or a pharmacologically active agent), the containment conditions must be as stringent as would be used for propagating the natural DNA counterpart.

If the synthetic DNA segment is not expressed in vivo as a polynucleotide or polypeptide product, the organisms containing the recombinant DNA molecules are exempt from the containment criteria.

IV. ROLES AND RESPONSIBILITIES

Safety involving recombinant DNA molecules depends primarily on the individuals conducting the research activities. The guidelines cannot anticipate every possible situation. Motivation and good judgment are the keys to protection of health and the environment.

The guidelines are designed to help the principal investigator determine the safeguards that should be implemented. They will never be complete and final, since all conceivable experiments involving recombinant DNA cannot be foreseen. Therefore, it is the principal investigator's responsibility to assure that the purpose of the guidelines is fulfilled.

The institution, and the Institutional Biosafety Committee (IBC) acting on its behalf, are given responsibility for seeing that recombinant DNA activities comply with the guidelines. This delegation of authority will serve the scientific process and at the same time properly focus accountability for safe conduct of the research. The following roles and responsibilities constitute an administrative framework in which safety is an essential and integral part of research involving recombinant DNA molecules. Detailed administrative procedures designed to implement this framework are provided in Appendix C. Further clarifications and interpretations of roles and responsibilities will be issued by NIH as necessary.

IV-A. Responsibilities of the Institution

IV-A-1. Institution. The institution bears primary responsibility for establishing and implementing policies for the safe conduct of research involving recombinant DNA molecules. These shall be policies that assure compliance with the NIH Guidelines. In carrying out its responsibilities, the institution shall:

IV-A-1-a. establish an Institutional Biosafety Committee (IBC) and insure that it is fulfilling its responsibilities;

IV-A-1-b. report to the NIH Office of Recombinant DNA Activities (ORDA) the names of members of its IBC and relevant information on them;

IV-A-1-c. submit to NIH for regulatory purposes a Memorandum of Understanding and Agreement (MUA) or equivalent information (in the case of non/NIH supported recombinant DNA projects), approved by the IBC, for all recombinant DNA research at an institution receiving any NIH funds for recombinant DNA research (see section IV-C and Appendix C for NIH policies on MUs and other required documentation);

IV-A-1-d. Assume responsibility for insuring compliance of recombinant DNA projects with the procedures and standards of the NIH Guidelines. If, upon registration and review, NIH (ORDA) finds that IBC approved protocols do not conform with standards, NIH shall be policies for NIH activities on MUAs and other required documentation;
IV-A-1-f. Establish rules as necessary to implement the Guidelines.

IV-A-2. Institutional Biosafety Committee. The principal functions of the IBC shall be to review and oversee all recombinant DNA projects and to advise the institution and ORDA whether the proposals and the research comply with the NIH Guidelines.

The IBC shall be a committee of not less than five members so selected that the committee has the experience and expertise to assess the safety of proposed recombinant DNA research projects and any potential risks to public health or the environment. Its membership shall include individuals from disciplines relevant to recombinant DNA technology, biological safety, and engineering. It is recommended that the IBC also include members knowledgeable about such matters as applicable law, standards of professional conduct and practice, community attitudes, and the environment. It is recommended that at least one member be a non-doctoral person from a laboratory technical staff. No member of an IBC may be involved (except to provide information requested by the IBC) in the review or approval of a project in which he or she has been, or excepts to be engaged, or has a direct financial interest. At least one member shall not be affiliated with the institution, i.e., no IBC may consist entirely of persons who are officers, employees, or agents of the institution, or are otherwise associated with it apart from their membership on the IBC.

On behalf of the institution, the IBC shall:

IV-A-2-a. Review and, if in compliance with the NIH Guidelines, approved the initiation of all proposed recombinant DNA research conducted at or sponsored by the institution receiving NIH funds for any recombinant DNA research. (All P4 research must receive prior approval by NIH before its initiation.) This review shall include (i) an independent assessment of the containment levels required by these guidelines for the proposed research, and (ii) review and approval of facilities, procedures, practices, and the training and expertise of recombinant DNA personnel.

IV-A-2-b. Consider requests for approval of single-step reductions in containment levels for experiments with purified DNA and characterized clones and report to ORDA those actions in which approval is given (see section III-A-3).

IV-A-2-c. Review periodically recombinant DNA research being conducted at the institution;

IV-A-2-d. Review and approve emergency plans covering accidental spills and personnel contamination resulting from this research;

IV-A-2-f. Keep minutes of meetings and, upon request, make them available to the public;

IV-A-2-g. Otherwise advise the institution and ORDA on policy matters relating to recombinant DNA research.

Appendix C and “Laboratory Safety Monograph—A Supplement to the NIH Guidelines for Recombinant DNA Research” shall be provided to the IBC. The principal investigator is responsible for ensuring the institution's copies of the guidelines are distributed to the IBC members. The principal investigator is responsible for:

IV-A-3-a. Insuring through periodic inspections that laboratory safety standards are rigorously followed;

IV-A-3-b. Developing emergency plans for dealing with accidental spills and personnel contamination, and investigating laboratory accidents;

IV-A-3-c. Providing advice on laboratory security;

IV-A-3-d. Providing technical advice to the principal investigator and IBC on research safety protocols and procedures.

See “Laboratory Safety Monograph—A Supplement to the NIH Guidelines for Recombinant DNA Research” for instructions on shipping and distributing organisms and viruses containing recombinant DNA;

IV-A-3-m. After ORDA approval and before initiating the research, the principal investigator is responsible for:

IV-A-4-a. Complying fully with the guidelines in carrying out the research;

IV-A-4-b. Making the initial determination of the required levels of physical and biological containment in accordance with the guidelines;

IV-A-4-c. Selecting appropriate microbiological practices and laboratory techniques to be used in the research;

IV-A-4-d. Being adequately trained in good microbiological techniques;

IV-A-4-e. Submitting the proposed research (including subsequent changes in the protocol—e.g., changes in the source of DNA or host-vector system to be used) to the IBC for review and approval or disapproval, and remaining in communication with the IBC throughout the conduct of the project;

IV-A-4-f. Initiating no recombinant DNA research subject to the guidelines until it has been approved by the IBC and has met all other requirements of the guidelines, and agreeing to make changes to conform if ORDA's review so requires;

IV-A-4-g. Petitioning NIH, after notifying the IBC, for exceptions or exemptions (4) to these guidelines—e.g., for an exception to a prohibition (see section I-D) or an exemption from the guidelines (see section I-E-4 and I-E-5). Each request for such an exception or exemption must be accompanied by adequate documentation (see appendix C for additional information on procedures);

IV-A-4-h. Reporting promptly to the IBC and NIH (ORDA) any problems with or violations of the guidelines;

IV-A-4-l. Complying with shipping requirements for recombinant DNA molecules (see section II-C, appendix C, and “Laboratory Safety Monograph—A Supplement to the NIH Guidelines for Recombinant DNA Research” for instructions on shipping and distributing organisms and viruses containing recombinant DNA);

IV-A-4-k. Adhering to IBC-approved emergency plans for dealing with accidental spills and personnel contamination;

IV-A-4-l. Making available to the laboratory staff copies of the approved protocols that describe the potential biohazards and the precautions to be taken;

IV-A-4-m. Instructing and training the staff in the practices and techniques required to insure safety in the procedures for dealing with accidents;

IV-A-4-r. Informing the staff of the reasons and provisions for any adverse disposal of recombinant DNA or the source of the recombinant DNA.

IV-A-4-s. Before initiating the research, the principal investigator is responsible for:

IV-A-4-t. During the conduct of the research, the principal investigator is responsible for:

IV-A-4-u. Supervising the safety performance of the staff to insure compliance with the NIH Guidelines.
that the required safety practices and techniques are employed;

IV-A-4-n-(2). Investigating and reporting in writing to ORDA and the IBC any serious or extended illnesses of a worker or any accident that results in (i) inoculation of recombinant DNA materials through cutaneous penetration, (ii) ingestion of recombinant DNA materials, (iii) probable inhalation of recombinant DNA materials following gross aerosolization, or (iv) any incident causing serious exposure to personnel or danger of environmental contamination;

IV-A-4-n-(3). Investigating and reporting in writing to ORDA, the biological safety officer (where applicable), and the IBC any significant problems pertaining to operation and implementation of biological and physical containment practices and procedures;

IV-A-4-n-(4). Correcting work errors and conditions that may result in the release of recombinant DNA materials;

IV-A-4-n-(5). Insuring the integrity of the physical containment (e.g., biological safety cabinets) and the biological containment (e.g., genotypic and phenotypic characteristics, purity, etc.).

See "Laboratory Safety Monograph—A Supplement to NIH Guidelines for Recombinant DNA Research" for additional information on training and laboratory and accident procedures.

IV-A-4-o. While not a requirement, it is urged that all publications dealing with recombinant DNA research include a description of the physical and biological containment procedures employed, to aid others who might consider repeating the work.

IV-B. Responsibilities of NIH.

IV-B-1. Office of the Director, NIH. The Office of the Director shall be responsible for:

IV-B-1-a. Final interpretation of the guidelines;

IV-B-1-b. Revision and amendment of the guidelines after appropriate notice and opportunity for public comment;

IV-B-1-c. Certification of new host-vector systems and decertification of existing host-vector systems after appropriate notice and opportunity for public comment (see Section II-D-2-a); and

IV-B-1-d. Promulgating and amending a list of classes of recombinant DNA molecules to be exempt(4) from these guidelines after appropriate notice and opportunity for public comment, if it is found that they consist entirely of DNA segments from different species that exchange DNA by known physiological processes or otherwise do not present a significant risk to health or environment (see section I-E-3-a and I-E-5); and

IV-B-1-e. Permitting, after appropriate notice and opportunity for public comment, exceptions(d) to the Prohibitions in the guidelines for experiments—e.g., risk-assessment studies. In making such decisions on exceptions, weight will be given both to scientific and societal benefits and to potential risks (see section I-D). Also, approving changes in containment levels for specific experiments, or the assignment of levels to experiments not explicitly considered in the guidelines (see part III-A), or designating as class 1 for purposes of these guidelines certain agents which are listed as class 2 (see footnote 1);

IV-B-1-f. Overseeing the implementation of the guidelines;

IV-B-1-g. Requesting, when appropriate, the advice of the Advisory Committee to the Director, NIH, on matters relevant to recombinant DNA polices;

IV-B-1-h. Promulgating rules as necessary to implement the guidelines.

IV-B-2. NIH Recombinant DNA Advisory Committee. The duties of the Recombinant DNA Advisory Committee (RAC) shall include:

IV-B-2-a. Recommending to the Director, NIH, revisions of these guidelines periodically and any amendments to the guidelines as necessary;

IV-B-2-b. Advising the Director, NIH, and ORDA on questions of interpretation of the guidelines;

IV-B-2-c. Recommending to the Director, NIH, whether vector-host systems qualify for certification (see section II-D-2-a);

IV-B-2-d. Recommending to the Director, NIH, whether currently certified host-vector systems should be decertified;

IV-B-2-e. Recommending to the Director, NIH, whether experiments should be granted an exception (d) from the prohibitions in the guidelines—for example, in order to allow risk-assessment studies—and at the same time recommending appropriate levels of physical and biological containment for these experiments. In making such recommendations, weight shall be given both to scientific and societal benefits and to potential risks (see sections II-D-2-a and II-D-10);

IV-B-2-f. Recommending to the Director, NIH, changes in containment levels for specific experiments, or the assignment of levels to experiments not explicitly considered in the guidelines (see part III-A); and

IV-B-2-g. Recommending to the Director, NIH, designation as class 1 for purposes of these guidelines certain agents that are listed as class 2 (see footnote 1);

IV-B-2-h. Recommending to NIH whether a cloned recombinant DNA segment has been rigorously characterized and whether there is sufficient evidence that it is free of harmful genetic elements that escaped original containment; and for cases involving primate DNA, or for levels below Pl+EK1 (see section III-A-3). In most cases this will involve prior review by the RAC;

IV-B-2-i. Recommending to NIH whether experiments involving it have been received; and

IV-B-3. NIH Components. Various NIH components shall perform the following:

IV-B-3-a. ORDA. ORDA shall serve as a focal point for information on recombinant DNA activities and provide advice to all within and outside NIH, including institutions, biosafety committees, principal investigators, and State and local governments. In addition, ORDA shall:

IV-B-3-a-(1). Make an independent evaluation of the containment levels required for the research covered by these guidelines;

IV-B-3-a-(2). Determine whether the physical and biological containment levels approved by the IBC are in accord with the requirements of the guidelines;

IV-B-3-a-(3). Make interpretations of these guidelines to allow reduction of containment levels of more than one step for characterized clones, or for cases involving primate DNA, or to levels below Pl+EK1 (see section III-A-3). In most cases this will involve prior review by the RAC;

IV-B-3-a-(4). Provide timely notice to local institutions when protocols, including modifications to ongoing projects, do not conform to the standards in the NIH guidelines;

IV-B-3-a-(5). Maintain a register of recombinant DNA projects;

IV-B-3-a-(6). Serve as executive secretary for the RAC;

IV-B-3-a-(7). Publish the Recombinant DNA Technical Bulletin;

IV-B-3-a-(8). Review membership of IBC's.

IV-B-3-b. Other NIH Components. Other NIH components shall be responsible for:

IV-B-3-b-(1). Awarding no grants or contracts unless properly executed MUsas have been received;

IV-B-3-b-(2). Certifying P4 facilities and inspecting them periodically, and inspecting other recombinant DNA facilities as deemed necessary;

IV-B-3-b-(3). Announcing and distributing certified HY2 and HY3 host-vector systems (see section I-E-3-a); and

IV-B-3-b-(4). Reviewing NIH financial information on the administrative procedures of ORDA and other NIH components.
NOTICES

IV-C. Registration.
IV-C-1. Required Registration. All institutions receiving NIH funds for recombinant DNA projects shall inform NIH of all recombinant DNA projects at the institution. A non-NIH project shall be registered with NIH if it has been approved by the IBC and involved recombinant DNA projects must be accompanied by an MUA.

For information on MAUs or equivalent documents, which must be submitted for registration of recombinant DNA projects, see section IV of appendix C.

IV-C-2. Voluntary Registration and Certification. Any institution which is not required to comply with the guidelines must yet comply with the guidelines, must apply to the NIH to be registered as a recombinant DNA facility. The NIH will accept requests for certification of host-vector systems proposed by the institution, must include:

1. A description of the physical and biological containment standards of the NIH guidelines.

IV-C-3. Disclosure of Information

IV-C-3-a. Disclosure of Information by the institution, in carrying out their responsibilities under the guidelines, shall not release confidential or proprietary information submitted pursuant to the guidelines, except to the extent:

IV-C-3-a-1. Required by law;

IV-C-3-a-2. Necessary to certify host-vector systems;

IV-C-3-a-3. Necessary to determine whether or not to allow exemptions from the guidelines;

IV-C-3-a-4. Necessity, in the judgment of the Secretary or his designee, to protect the public or the environment against an unreasonable risk of injury to health or the environment.

IV-C-3-b. Potentially Hazardous Material. Institutions are reminded that whenever they regard information as potentially proprietary, they should consider applying for a patent before submitting information to DHHS.

IV-D. Compliance

IV-D-1. As a condition for NIH funding of recombinant DNA research, institutions must ensure that recombinant DNA research conducted at or sponsored by that institution shall comply with the guidelines irrespective of the source of funding.

IV-D-1-a. Policy on Noncompliance

IV-D-1-b. All NIH-funded projects involving recombinant DNA technology must comply with the NIH guidelines. Noncompliance may result in suspension, limitation, or termination of financial assistance for such projects, and for other recombinant DNA research at the institution.

IV-D-1-c. All non-NIH funded projects involving recombinant DNA techniques conducted at or sponsored by an institution that receives NIH funds for projects involving recombinant DNA techniques must comply with the NIH guidelines. Noncompliance may result in suspension, limitation, or termination of NIH funds for recombinant DNA research.

IV-D-1-d. Information concerning noncompliance with the guidelines may be communicated to any person. It should be delivered to both ORDA and the relevant institution.

The institution, generally through the IBC, shall take such action as appropriate. It shall forward a complete report of the incident to ORDA and, if appropriate, shall include recommendations for further action.

IV-D-1-e. In cases where NIH proposes to suspend, limit, or terminate financial assistance because of a non-NIH sponsored project at the institution, the IBC, shall take such action as appropriate. It shall forward a complete report of the incident to ORDA and, if appropriate, shall include recommendations for further action.

IV-D-1-f. In cases where NIH proposes to suspend, limit, or terminate financial assistance because of a non-NIH sponsored project at the institution, the IBC, shall take such action as appropriate. It shall forward a complete report of the incident to ORDA and, if appropriate, shall include recommendations for further action.

5. See "Laboratory Safety Monograph—A Supplement to the NIH Guidelines for Recombinant DNA Research" for information on inactivating DNA.


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31. We are specifically concerned with potential toxins which could be produced by acquiring a single gene or cluster of genes.

32. Defined as observable under optimal laboratory conditions by transformation, transduction, plaque formation, and/or conjugation with transfer of phase, plasmid, and/or chromosomal genetic information. Note that this definition of exchange may be less stringent than that applied to existing organisms under section 1-E-4.

33. As defined in the Second Report of the International Committee on Taxonomy of Viruses: Classification and Nomenclature of Viruses, Frank Fenner. Ed. Intervirology 7 (11-15) 1976. (As noted in the Prohibition Section, the use of viruses classified 11 as class 3, 4, or 5, other than VSV, is prohibited).

34. The cDNA copy of the viral mRNA must be >99 percent pure; otherwise as for shotgun experiments with eukaryotic cellular DNA.

35. The viruses have been classified by NCI as “moderate risk oncoviruses.” See “Laboratory Safety Monograph—A Sup- plement to the NIH Guidelines for Recom- binant DNA Research” for recommendations on handling the viruses themselves.

36. EKICV means the use of an EK1 host and vector certified for use in an EK2 system.

37. The DNA preparation is defined as “purified, DNA,” which represents at least 99 percent (w/w) of the total DNA in the preparation, provided that it was verified by more than one procedure.

38. The insertion of the containment level when this degree of purification has been obtained is based on the fact that the total number of clones that must be examined to obtain this degree of purity was greatly re- duced. Thus, the probability of cloning a harmful gene could, for example, be re- duced by more than 106-fold when a nonre- cipient vector is used. This reduction was sought. Furthermore, the level of purity specified here makes it easier to establish that the desired DNA does not contain harmful genes.

43. This is not permitted, of course, if it falls under any of the Prohibitions of sec- tion 1-D. Of particular concern here is the provi- sion to limit the use of a drug to control disease agents in human or veteri- nary medicine or agriculture.

44. Because this work will be done almost exclusively in vertebrate cell cultures, which have no capacity for propagation outside the laboratory, the primary focus for con- tainment is the vector. It should be pointed out that risk of laboratory-acquired infec- tion as a consequence of tissue culture manipulation is very low. Given good microbio- logical practices, the most likely mode of escape of recombinant DNA's from a physically contained laboratory is carriage by an infected human. Thus the vector with an in- serted DNA segment that replicates to a limited extent in human cells in tissue culture, if the recombinant molecule is used to trans- form nonpermissive cells (i.e., cells which do not do so when exposed to viral particles), this is not a requirement.

45. It should be derived from a virus whose epidemiological behavior and host range are well-documented.
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1. Bacterial agents:
   - *Actinobacillus*—all species except *A. malic* which is in Class 3
   - *Arkeia hinzihai*—all serotypes
   - *Bacillus anthracis*
   - *Bordetella*—all species
   - *Borrelia recurrentis*, *B. vincenti*
   - *Clostridium botulinum*, *C. chauvoei*, *C. haemolyticum*, *C. histolyticum*, *C. novyi*, *C. septicum*, *C. tetani*
   - *Corynebacterium diphtheriae*, *C. equi*, *C. haemolyticum*, *C. pseudotuberculosis*, *C. pyogenes*, *C. renale*
   - *Diplococcus (Streptococcus) pneumoniae*
   - *Erysipelothrix insidiosa*
   - *Escherichia coli*—all enteropathogenic serotypes
   - *Haemophilus ducreyi*, *H. influenzae*
   - *Herellea vaginicola*
   - *Klebsiella*—all species and all serotypes
   - *Leptospira interrogans*—all serotypes
   - *Listeria*—all species
   - *Mimia polymorpha*
   - *Moraxella*—all species
   - *Mycoplasma*—all species except those listed in Class 3
   - *Mycoplasma pneumoniae*
   - *Neisseria gonorrhoeae*, *N. meningitidis*
   - *Pasteurella*—all species except those listed in Class 3
   - *Salmonella*—all species and all serotypes
   - *Shigella*—all species and all serotypes
   - *Sphaerophorus necrophorusr*
   - *Staphylococcus aurus*
   - *Streptobacillus moniliformis*
   - *Streptococcus pyogenes*
   - *Treponema pallidum*, *T. pertens*
   - *Borrelia fallus*, *V. comma*, including biotype *El Tor*, and *V. parahemolyticus*
   - *2. Fungal agents:
   - *Actynomycetes (Including *Nocardia* species and *Actinomyces* species and *Arachnia propionica*):*
   - *Blastomyces dermatitidis*
   - *Cryptococcus neoformans*
   - *Paracoccidioides brasiliensis*
   - *3. Parasitic agents:
   - *Endameba histolytica*
   - *Leishmania sp.*
   - *Naegleria gruberi*
   - *Toxoplasma gondii*
   - *Toxocara canis*
   - *Trichinella spiralis*
   - *Trypanosoma cruzi*
   - *V. cholerae*—all types
   - *3. Fungal agents:*
   - *Coccidioides immitis*
   - *Histoplasma capsulatum*
   - *Histoplasma capsulatum var. duboisii*
   - *4. Viral, Rickettsial, and Chlamydial agents:*
   - *Adenoviruses*—human—all types
   - *Cache Valley virus*
   - *Coxsackie A and B viruses*
   - *Cytomegaloviruses*
II. Classification of Oncogenic Viruses

A. LOW-RISK ONCOGENIC VIRUSES

<table>
<thead>
<tr>
<th>Virus Type</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hamster Leukemia</td>
<td>Bovine Leukemia</td>
</tr>
<tr>
<td>Dog Sarcoma</td>
<td>Mason-Pfizer Monkey Virus</td>
</tr>
<tr>
<td>Marek's</td>
<td>Guinea Pig Herpes</td>
</tr>
<tr>
<td>Lucke (Frog)</td>
<td>Adenovirus</td>
</tr>
<tr>
<td>Shope Fibroma</td>
<td>Shope Papilloma</td>
</tr>
</tbody>
</table>

B. MODERATE RISK ONCOGENIC VIRUSES

<table>
<thead>
<tr>
<th>Virus Type</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ad2-SV40</td>
<td>FeLV</td>
</tr>
<tr>
<td>HV Saimiri</td>
<td>EBV</td>
</tr>
<tr>
<td>SSV-1</td>
<td>GaLV</td>
</tr>
<tr>
<td>Yaba</td>
<td>FeSV</td>
</tr>
</tbody>
</table>

III. Animal Pathogens (3)

A. ANIMAL DISEASE ORGANISMS WHICH ARE FORBIDDEN ENTRY INTO THE UNITED STATES BY LAW (CDC CLASS 5 AGENTS)

1. Foot and mouth disease virus

B. ANIMAL DISEASE ORGANISMS AND VECTORS WHICH ARE FORBIDDEN ENTRY INTO THE UNITED STATES BY USDA POLICY (CDC CLASS 5 AGENTS)

African horse sickness virus
African swine fever virus
Besnoitia besnoiti
Borna disease virus
Bovine infectious petechial fever
Canal pox virus
Ephemeral fever virus
Fowl plague virus
Goat pox virus
Hog cholera virus
Loping ill virus
Lumpy skin disease virus
Nairobi sheep disease virus
Newcastle disease virus (Asiatic strains)
Mycoplasma mycoides (contagious bovine pleuropneumonia)
Mycoplasma agalactiae (contagious agalactia of sheep)
Rickettsia ruminantium (heart water)
Rift valley fever virus
Rinderpest virus
Sheep pox virus
Swine vesicular disease virus
Tschen disease virus
Trypanosoma cruzi (Nagana)
Trypanosoma evansi
Thelazia parva (East Coast fever)
Thelazia annulata
Thelazia laurentii
Thelazia bovis
Thelazia hirici
Vesicular exanthema virus
Wesslestron disease virus
Zyozena farciminosum (pseudofarcy)

REFERENCES


APPENDIX C—TABLE OF CONTENTS

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I-B. Approval and Registration of Projects.

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II-A-1. Contents of an MUA.


II-A-1-g. Date of MUA.

II-A-2. MUA's for Recombinant DNA Research at Multiple Sites.

II-A-3. MUA's Associated with Individual Fellowship Applicants, Research Career Development Award Candidates (RCDA), Research Career Awards (RCA), and Institutional National Research Service Fellowship Applications.

II-B. Submission of Memorandum of Understanding and Agreement (MUA).

II-B-1. Competing Applications.


II-C. Notation on Applications for Research and Training Grants.

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II-F. Shipping Requirements.

III. Policies and Procedures for Recombinant DNA Research Supported by NIH and Conducted in Foreign Countries.
discusses the roles and responsibilities of principal investigators and institutions. A roster of the members of the Institutional Biosafety Committee (IBC) must be submitted to NIH.

The minimum information must include the names, addresses, occupations, qualifications, and curricula vitae of the chairperson and members of the committee. Information must be submitted to: Office of Recombinant DNA Activities, National Institutes of Health, Room 4A52, Building 31, Bethesda, Md. 20014.

The membership of IBC's is subject to review by ORDA for compliance with recommendations stated in the guidelines. It is the responsibility of each institution to update this information at least annually. As stipulated in the guidelines, ORDA will assist in the formation of an Area Biosafety Committee (ABC) when appropriate. Such a committee will be necessary when additional expertise from outside a given institution is necessary for the IBC to fulfill its functions.

B. Approval and Registration of Projects. Central to the implementation of the guidelines is the review of proposed projects by the IBC. When the IBC has approved the project, the experiments may be initiated (except for experiments requiring F4 physical containment, which require prior NIH approval; special procedures cover NIH awards, see sec. II-D below). The institution is responsible for registering approved projects with NIH. ORDA will review approved projects and notify investigators and institutions of the results of such review. (See sec. II-B for requirements for competing and noncompeting NIH applications. See sec. II-E for changes in ongoing projects, and Pt. IV for information on registration.)

II. Requirements and Procedures for NIH-Supported Projects. This section describes policies and procedures for projects supported by NIH.

A. Memorandum of Understanding and Agreement (MUA). Each application to the National Institutes of Health for a project which involves experiments subject to the NIH guidelines for recombinant DNA research (see sec. I-E of the guidelines) must be accompanied by an MUA prepared in the format shown in the attached illustration. Applicants are urged to follow the sequence and format of the illustration as closely as possible.

An application submitted to NIH without an attached MUA is incomplete and will not be reviewed until a properly executed MUA is provided.

1. Contents of an MUA. An MUA must contain the following sections:

   a. Description. A description of each series of experiments subject to the NIH guidelines. The descriptions must be sufficient to provide information about the experiments and to allow the IBC to attest to the accuracy of the information. Each perform-
1. **Signatures.** The signatures of the principal investigator, the IBC chairperson, and the institutional official(s) are required.

2. **Date of MUA.** The date of the MUA for future reference will be the date of the institutional official's signature.

3. **MUA's for Recombinant DNA Research at Multiple Sites.** When research at multiple sites is proposed, the MUA must specify where each part of the project will be carried out. When research is proposed at sites governed by other than the applicant institution, signatures of the appropriate officials at both the applicant institution and the institution(s) where the recombinant DNA research is to be conducted are required. The signatures shall indicate that the IBC(s) of each of the institution(s) where the research is to be performed have given the certification and/or assurance required in item d of the MUA.

4. **MUA's for Individual Fellowship Applications, Research Career Development Award Candidates (RCDA), Research Career Awardees (RCA), and Institutional National Research Service Fellowship Applications.** When projects involving recombinant DNA technology subject to the Guidelines are involved, fellowship applicants, RCDA candidates, RCA's, or Program Directors for Institutional National Research Service Fellowship Applications should attach to the application either a copy of MUA(s) already submitted to the NIH, or submit a new MUA(s) as indicated below. If a copy is submitted, the fellowship applicant, RCDA candidate, RCA, or Program Director (if other than the principal investigator) must sign the MUA copy under the signature of the principal investigator.

5. **MUA's for Recombinant DNA Work.** If any recombinant DNA work is proposed other than that indicated in an existing MUA(s), a new or amended MUA must be submitted to NIH in accordance with procedures in II-B and II-E of this Appendix. These procedures also apply to experiments using recombinant DNA technology in courses supported by an institutional fellowship.

6. **Submission of Memorandum of Understanding and Approval (MUA).**

   a. **Competing Applications.** For competing applications involving recombinant DNA research subject to the Guidelines, an MUA must be submitted to the Division of Research Grants, NIH, with the application.

   b. **Noncompeting Applications.** Each noncompeting continuation application involving recombinant DNA research subject to the Guidelines must be accompanied by an updated MUA that indicates that the IBC has reviewed the project prior to submission of the application, and has found it still in compliance with NHIGuidelines. IMPORTANT NOTE: If an investigator wishes immediately to initiate a project after IBC approval, after submitting a new competing application to NIH, the procedures for registration of non-NIH projects, described in section IV of this Appendix, must also be followed. If an investigator wishes immediately to initiate new experiments in an ongoing project, an MUA must be filed with NIH within 30 days of IBC approval, even if the proposed experiments are described in an MUA submitted with a noncompeting or a competing renewal application. In the latter cases, see procedures in section II-E of this Appendix, dealing with changes in ongoing projects, which must also be followed.

   c. **Notice on Applications for Research and Training Grants.** NIH application forms will be revised to include a block to be checked indicating whether the research subject to the Guidelines is involved. Until such time as revised forms are available, applicants should specify in capital letters at the bottom of the first page of the application the following statement:

   **APPLICATION INVOLVES EXPERIMENTS SUBJECT TO GUIDELINES FOR RECOMBINANT DNA RESEARCH.**

   D. **Award Procedures.** Prior to award, MUA's will be reviewed by ORDA for compliance with the requirements of the Guidelines. Notification of the status of NIH review of the MUA will be accomplished by one of the following 3 footnotes on the Notice of Grant Award:

   - **Footnote 1.** "Protocols in MUA dated —/—/— conform to standards of NIH Guidelines."

   - **Footnote 2.** "Protocols in MUA dated —/—/— modified, conform to standards of NIH Guidelines."

   - **Footnote 3.** "Protocols in MUA dated —/—/— do not conform to standards of NIH Guidelines."

   Footnote 1 will be used to indicate that the MUA has been reviewed by ORDA, and the protocols have been found to conform to the standards set forth in the Guidelines.

   Footnote 2 will be used to indicate that the MUA has been reviewed by ORDA and that certain aspects of the MUA do not conform to standards set forth in the Guidelines. Use of this footnote indicates that NIH has notified the institution that appropriate action must be taken to bring the protocols in question into compliance with NIH standards, or that the protocols in question must not be carried on IV of this Appendix, must also be followed.

   Footnote 3 will be used to indicate that the MUA has been reviewed by ORDA and the protocols have been found not to conform to standards set forth in the Guidelines. This footnote indicates that the proposed experiments are not to be carried out until they have been brought into compliance with NIH standards, and a revised MUA has been submitted to the NIH.

E. **Changes in Ongoing Projects.** Changes in a project subject to the Guidelines must be reported to the IBC by the principal investigator.

   a. **Major Changes.** A new or revised MUA is required for introduction of recombinant DNA research subject to the guidelines in an ongoing project, or for significant changes in the recombinant DNA aspects of an ongoing project. Examples of changes in an ongoing recombinant DNA project which would require the filing of a new or amended MUA would include (1) significant changes in hosts or vectors, (ii) significant changes in the donor species or the nature of the DNA segment being selected, (iii) major changes in the physical location of the experiments, or (iv) a change of the investigator responsible for the conduct of the experiments.

   For such changes in an ongoing project, a new or revised MUA must be submitted to the IBC. If approval has been obtained for other than projects requiring P4 containment, the experiments may be initiated. The institution must then forward the MUA directly to the program administrator of the awarding NIH Bureau, Institute, or Division within 30 days of approval by the IBC. The MUA must identify the project by grant number. The principal investigator will be notified by letter regarding the NIH review of the new or revised MUA. If review by ORDA finds that an MUA, or certain aspects of an MUA, do not conform to standards set forth in the guidelines, the principal investigator and the IBC will be notified. In such cases, immediate action must be undertaken to bring the protocols into compliance with NIH standards or the experiments in question must be suspended.

   b. **Minor Changes.** Principal investigators should submit information or
minor changes in research protocols to the IBC. Minor changes need not be reported to NIH until an updated MUA is requested (see section II-B of this appendix).

2. Protocols for Which Containment Levels Are Not Explicitly Specified by the NIH Guidelines. Investigators who wish to initiate recombinant DNA experiments for which containment levels are not explicitly stated in the guidelines or in announcements from ORDA must obtain approval from the NIH prior to initiating the proposed experiments.

Because it is anticipated that the setting of containment levels for this class of experiments will require review by the Recombinant DNA Advisory Committee, investigators are strongly urged to provide to ORDA in writing full information on the proposed experiments prior to submission of a formal MUA.

F. Shipping Requirements.

Note.—Requirements regarding shipment and transfer of recombinant DNA materials may be incorporated by reference into the MUA (see illustration in this appendix).

All MUA's must indicate that the principal investigator (program director, fellow, or candidate) agrees to comply with the following provisions pertaining to shipment or transfer of recombinant DNA materials:

1. Prior to shipment or transfer of recombinant DNA materials within the United States, the sending laboratory shall obtain a written statement from the requesting laboratory that:
   a. Research involving recombinant DNA molecules shall be conducted in compliance with NIH guidelines, this appendix, and other NIH instructions, and
   b. The project proposed by the requesting laboratory has been reviewed and approved by the IBC of the requesting laboratory.

2. Prior to shipment of recombinant DNA materials to a country other than the United States, the sending laboratory shall obtain a statement from the requesting laboratory stating that research involving recombinant DNA molecules shall be conducted in accordance with the containment levels specified by the NIH guidelines, or applicable national guidelines if such have been adopted by the country in which the research is to be conducted.

3. The sending investigator shall maintain a record of all shipments of recombinant DNA materials.

Note.—See section II-D-3 of the guidelines for restrictions on distribution of certified host-vector systems.

III. Policy and Procedures for Recombinant DNA Research Supported by NIH and Conducted in Foreign Countries.

A. Policy. Many countries in which NIH-supported recombinant DNA research may be conducted have adopted guidelines similar to those of the NIH guidelines for recombinant DNA research. Also, many countries have established regulations and procedures to review and register recombinant DNA research, and require documentation similar to that of NIH. If such guidelines and procedures exist and are comparable to the NIH guidelines, review and approval by the appropriate national body in the country in which the research is to be conducted, in general, will be accepted as assurance that the research will be conducted in a responsible manner and in accord with national guidelines. However, NIH reserves the right to withhold funding if the safety practices to be employed are not reasonably consistent with the NIH guidelines.

B. Requirements and Procedures for NIH-Supported Research in Countries with Guidelines. The following procedures apply both to NIH awards in foreign countries and to U.S. investigators intending to conduct recombinant DNA research with NIH support in foreign countries which have adopted guidelines. For applications for NIH awards in foreign countries, the required documentation may be included with the application, or may be submitted at a later date, but must be submitted prior to the time of award. For U.S. investigators intending to conduct recombinant DNA research abroad, if a, a responsible and in accord with national guidelines. However, NIH reserves the right to withhold funding if the safety practices to be employed are not reasonably consistent with the NIH guidelines.

1. A description of each proposed project and the individual investigator responsible for the research, if other than the principal investigator. Descriptions should indicate the sources of DNA, nature of inserted DNA sequences, hosts and vectors to be used, and must be of sufficient detail to provide information about the research without need for reference to other documentation. Ordinarily, no more than two pages of description for each series of experiments are necessary.

2. An assessment of the level(s) of physical and biological containment required by the guidelines of the country in which the research is to be conducted.

3. Documentation that the research project is in compliance with the applicable national guidelines and, where required, has been registered with the appropriate national body in the country in which the research is to be conducted. If approval of the national body is required prior to initiation of research, the documentation must indicate that such approval has been received.

4. The signatures of both a responsible official and the principal investigator.

5. The date of signature of the responsible official. This will become the date of the document for future reference.

C. Requirements Regarding Countries Which Have Not Adopted Guidelines. NIH funds may not be used for the conduct of recombinant DNA research in a country which has not adopted national guidelines, unless the research is in full compliance with NIH Guidelines and the procedures required for U.S. grant applications have been fulfilled—i.e., establishment of an institutional biosafety committee, filing of an MUA, etc.

IV. Registration of Recombinant DNA Projects.

A. NIH-Supported Projects. An NIH-approved MUA will constitute registration of projects awarded by NIH. For immediate initiation of projects pending with NIH see "Important Notice" under section II-B of this appendix.

B. Required Registration of Non-NIH Projects. The guidelines require that institutions receiving NIH funds for recombinant DNA research shall inform NIH of all initiated recombinant DNA projects subject to the guidelines (see section IV-C-1 of the guidelines). For these projects, the required information must be submitted within 30 days of initiation. NIH guidelines (see section IV-C-2 of the guidelines).

C. Voluntary Registration of Non-NIH Projects. The guidelines stipulate that any institution which is not required to comply with the guidelines may nevertheless register with the NIH guidelines those recombinant DNA research subjects to the guidelines (see section IV-C-2 of the guidelines).

D. Procedures for Registration. The procedures in this section apply to registration of projects in B and C above. Because non-NIH projects filed with the NIH will immediately be added to the register of ongoing recombinant DNA research, institutions may register only those projects which are ongoing or about to be initiated. Institutions should not submit pending projects to this register.

Institutions must register these projects directly with ORDA. It is the responsibility of the institution to ensure that this information is accurate and up-to-date by submitting any necessary revised information on a timely basis. Institutions are responsible for notifying ORDA when a project is completed or terminated so that it may be removed from the register.
NOTICES

For registration of projects described in B and C above, the following information must be submitted:

1. A short title for the project.
2. Registry number of project.
3. Start and end dates of the project.
4. The name of the principal investigator and the name and address of the institution, including the department in which the research is being conducted and the location of the project.
5. The source of support for the project.
6. A description of each project and the name of the investigator responsible for the research. Descriptions should indicate information on the sources of DNA, nature of inserted DNA sequences, and the host-vector systems being used. Ordinarily, no more than two pages of description for each series of experiments are necessary.
7. An assessment of the level(s) of physical and biological containment required by the Guidelines for each series of experiments.
8. A statement that an Institutional Biosafety Committee has reviewed the project and found it to be in compliance with the NIH Guidelines.
9. The signatures of the principal investigator, the chairperson of the IBC, and the institutional official.
10. The date of signature by the institutional official. This date will be used for reference purposes.

E. Review. Institutions will be notified in writing of ORDA's review of the information submitted for registration of recombinant DNA projects not supported by NIH. If review by ORDA finds that the protocols do not conform to standards set forth in the Guidelines, the institution is expected to take appropriate action to bring the protocols into compliance with NIH standards.

V. Lowering of Containment Levels for Purified DNA and Characterized Clones.

A. Purified DNA Other Than Plasmids, Bacteriophages, and Other Viruses.

The Guidelines stipulate that the formation of DNA recombinants from cellular DNA's that have been purified and which are free of harmful genes can be carried out under lower containment conditions than those required for the corresponding shotgun experiment. IBC approval is sufficient for such a reduction of containment level, except for (i) primate DNA, which also requires prior NIH approval, or (ii) any lowering of containment to levels below P1+EK1, which also requires prior NIH approval (see sec. III-A-3-a of the Guidelines).

The IBC must notify ORDA in writing of such actions. Many of these actions will be in the context of submission of a new or revised MUA.

B. Characterized Clones of DNA Recombinants. The Guidelines permit IBC's to give approval for a single-step reduction in physical or biological containment on receipt of evidence of characterization of a clone derived from a shotgun experiment and its probable freedom from harmful genes (see sec. III-A-3-b of the Guidelines). IBC approval is sufficient for such a reduction except for (i) primate DNA which requires prior NIH approval, or (ii) any lowering of containment to levels below P1+EK1, which also requires prior NIH approval. The IBC must notify ORDA in writing of all such actions. Such notification must clearly indicate the name of the principal investigator and the project supporting the work.

Reduction of containment levels by more than one step, use of primate DNA, or cases involving lowering of containment to levels below P1+EK1 require prior approval by NIH. In the latter cases, complete information must be submitted to ORDA. Many of these cases are expected to require review by the RAC at its next scheduled meeting.

VI. Exceptions and Exemptions to the Guidelines.

A. Exceptions. Exceptions to prohibited experiments require express approval by the Director, NIH, on recommendation of the RAC after appropriate notice and opportunity for public comment (see sec. I-D of the Guidelines).

B. Exemptions. Classes of exempt experiments, which are not covered by the Guidelines, are cited in section I-E of the Guidelines. It is anticipated that additional exemptions for specific experiments which fall into the categories cited in sections I-E-4 and I-E-5 of the Guidelines may be granted by the Director, NIH, on the recommendation of the RAC and after appropriate notice and opportunity for public comment.

C. Requests for Exceptions and Exemptions. Requests for an exception to a prohibition or an exemption from the Guidelines must be submitted to ORDA accompanied by adequate documentation. Because the handling of requests for exceptions and exemptions will probably be a time-consuming process, investigators are strongly urged to discuss the proposed request with the staff of ORDA by telephone in advance of submission of a formal request. Decisions or requests for exceptions or exemptions will be published in the Recombinant DNA Technical Bulletin.
NOTICES
Summary


Type of Action: (X) Administrative. ( ) Legislative.

Description of Action: Publication for public comment of proposed revised guidelines for research involving recombinant DNA molecules.

Organisation of Material: Background information is presented on the recombinant DNA process and on the presumed risks and demonstrable benefits of this basic research technique. Next, the proposed revised guidelines are analyzed according to their four main parts: scope, principles of containment of possibly hazardous agents, proposed changes in the containment for experiments to be covered by the revised guidelines, and roles and responsibilities of investigators and institutions.

Analysis of Alternatives: For each of these four main parts, the assessment is presented under four sections: analysis of the current guidelines (in effect since June 23, 1976); alternatives (revisions) proposed by the NIH Recombinant DNA Advisory Committee (RAC) (Federal Register, September 27, 1977); alternatives proposed by the Director, NIH, after full consideration of scientific evidence, public comments, and the testimony in a 2-day meeting of the Director's Advisory Committee (DAC) at which scientists of various disciplines, representatives of environmental groups, and other witnesses discussed the RAC proposals; and finally, the projected environmental impact of research to be conducted under the NIH Director's proposed guidelines. Appendix A will aid in comparing the containment levels under the current guidelines with those under the two alternatives. Appendix B shows how those alternatives would have affected all NIH-funded recombinant DNA experiments active in December 1977.

Environmental Impact of the Proposed Action: As can best be determined from all evidence compiled to date and analyzed in numerous scientific and public forums, there will be no adverse environmental impact from recombinant DNA research conducted under the Director's proposed revisions. The Environmental Impact Statement on NIH Guidelines for Research Involving Recombinant DNA Molecules, issued in October 1977, predicted that the environmental impact of research conducted under the 1976 NIH Guidelines would be the continued protection of the laboratory worker, the general public, and the environment from conjectural hazards. So far, this prediction has been confirmed: We know of no scientists conducting recombinant DNA research in the United States or other countries who are not following the NIH or comparable guidelines, and no untoward effect of the research has been reported. Meanwhile, new scientific evidence as well as extensive experience in operating under the NIH Guidelines indicate that revisions are in order. The predictable effect of continued use of recombinant DNA techniques under the Director's proposed revisions would be a greater realization of the benefits of this valuable tool without compromise of safety.

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Foreword

In June 1976 the National Institutes of Health, with the concurrence of the Secretary of Health, Education, and Welfare and the Assistant Secretary for Health, issued guidelines to govern the conduct of NIH-supported research involving recombinant DNA molecules. These guidelines stated that they would be "subjected to periodic review (at least annually) and modified to reflect improvements in our knowledge of the potential biological hazards and of the available safeguards." Since that time, a number of scientific, administrative, and legislative events have occurred that should be summarized at the outset, for they are reflected in the revisions of the NIH guidelines as proposed, first by the Recombinant DNA Advisory Committee and currently by the Director, NIH.

Recombinant DNA experiments have proceeded in hundreds of laboratories throughout the world. The subject has been discussed and debated in countless meetings, and the public has been consulted as well as the scientific community. NIH has taken into account public comments in preparing the original guidelines, an environmental impact statement (EIS), and the proposed Director's revision.

One of the most important recent developments has been the careful scrutiny, from a very broad point of view, of the premises upon which the original guidelines were based. Thus, the molecular biologists, who first raised questions about the safety of recombinant research, have now had greater opportunity to consider their concerns in the company of many experts on infectious disease, epidemiology, viruses, plants, laboratory safety practices, ecology, and other relevant disciplines.

From all of these activities have emerged certain important facts. For one, no evidence has come to light that any of the thousands of individual recombinant DNA clones construct-
ed over the last 5 years have yielded a product harmful to man or the environment. On the other hand, many examples of useful knowledge obtained through recombinant techniques continue to accumulate rapidly.

Scientific developments

No scientific evidence not considered in the promulgation of the guidelines has emerged to support the fears that the use of these techniques will create a harmful product. On the contrary, scientific information has been developed over the past 2 years that lessens concern over the possible environmental hazard. Dr. David Court, professor of microbiology at the University of Alabama School of Medicine in Birmingham, and others have demonstrated that biological containment measures—methods developed to weaken or destroy the experiments—do prevent these bacteria from surviving in a natural environment, and would do so if they escaped from the laboratory.

While the probability of doing harm with laboratory recombination of genes has not been, and never will be, reduced to zero, we have reached a point where the burden of proof is shifting toward those who would restrict such activities. The careful interpretation of evidence obtained before and after June 1976 has reduced to inconsequential levels the probabilities that E. coli K-12, the host most used in recombinant DNA experiments, would escape as an epidemic pathogen. Much of the relevant data and their discussion by experts are now available in the published proceedings of an NIH-sponsored meeting in Falmouth, Mass., on June 26-28, 1978 (Journal of Infectious Diseases, May 1978).

The Falmouth conference brought out evidence that the risk of transforming E. coli K-12 into a pathogen is minimal, either for laboratory personnel or the public at large. Dr. Sherwood Gorbach, chairman of the conference, has reported that there was scientific consensus on this matter among all in attendance, including microbiologists who work with disease-producing bacteria.

Much of the concern expressed about recombinant DNA experiments relates to the creation of novel organisms in the laboratory. Additional evidence, however, suggests that the recombinations of DNA produced in the laboratory may be very similar to many that occur in nature. If further work confirms and extends this evidence, then the concern about creating novel forms of life will be put into a new perspective.

Administrative developments

Implementation of the NIH guidelines

The current NIH guidelines provide not only explicit instructions about the conduct of experiments, but also an administrative framework for their implementation. This is set out in the respective responsibilities of the principal investigator, the institution where the work is conducted (including the institutional biohazard committee), the NIH Recombinant DNA Advisory Committee (“RAC”) or “Recombinant DNA Advisory Committee” or “RAC,” the technical body responsible for proposing the guidelines), and the NIH staff.

The NIH Office of Recombinant DNA Activities (ORDA) was established to coordinate the administration of NIH policies and procedures for safe utilization of recombinant DNA technology in research. Dr. William Gartland is Director of ORDA. Over the 2 years the implementation of the guidelines has proceeded well. Approximately 130 institutions where NIH-supported research is taking place have established institutional biohazard committees, and approximately 300 projects are involved.

Over the past 2 years administrative practices have evolved to deal with requirements of the guidelines. One of the requirements is a means for interpretation. The standards in the guidelines are very explicit about the conduct of permissible experiments. Still, questions of interpretation continue to arise and must be dealt with. Our determination to assure that the experiments conducted under the guidelines has necessitated a number of administrative delays in acting on research protocols.

Another area of difficult administration has been certification of new host-vector systems. These represent microorganisms weakened by various methods to prevent their survival were they to escape from their specially contained environment in the laboratory. Under the current guidelines, the Recombinant DNA Advisory Committee must review all applications for new host-vector systems and recommend for certification those that meet the relevant criteria.

Undoubtedly the presence of the guidelines and their implementation have caused some experiments to be postponed and some scientific work to be delayed. At the same time, NIH, having embarked upon this conservative course, believes it must guarantee the integrity of the administrative safeguards and see that due process is observed in implementation.

Policy issues

Three key policy issues concerning recombinant DNA research have dominated NIH attention during the administration of the NIH Guidelines. They are the determination of the environmental impact, if any, of the NIH Guidelines and the research conducted thereunder; the patenting of recombinant DNA research inventions developed under Federal support; and the extension of the NIH Guidelines nation-wide through existing regulation or new legislation. Discussions of these policy issues follow:

National Environmental Policy Act (NEPA). In accordance with the National Environmental Policy Act of 1969 (NEPA), NIH undertook an environmental impact assessment of environmental effects, if any, of the original NIH Guidelines. A draft environmental impact statement was published in the Federal Register in September 1978 for public review and comments. On the basis of the comments received, NIH published a final EIS in October 1977.

During the development of the EIS, two suits under NEPA were brought against the Department. One suit, in the Federal District Court in New York, alleged that NIH failed to comply with NEPA and sought an EIS before supporting recombinant DNA research and before releasing the original guidelines. The Government has answered the allegations, and the case is pending in New York.

The second suit filed in the Federal District Court in Washington, D.C., by a resident of Frederick, Md., sought an injunction to prevent NIH from conducting a risk-assessment experiment at the Frederick Cancer Research Center without first filing an environmental impact statement. On February 23, 1978, a decision was rendered by the U.S. District Court against the issuance of an injunction, and this decision was affirmed by the U.S. Court of Appeals on March 8, 1978. It was the decision of the court that recombinant DNA research was beneficial, that the experiment under question was important, and that it posed no substantial risk. The court went on to state that “the Recombinant DNA Research Guidelines represent an effort by many scientists to evaluate the hazards and provide safe methods for their control. The record reflects that NIH has carefully considered the potential risks of this experiment under the guidelines and has taken the necessary precautions.”

The EIS does represent a “hard look” by NIH at recombinant DNA research performed in accordance with its guidelines. It appears that compliance with the NIH guidelines will insure that no recombinant DNA molecules will escape from the carefully controlled laboratory to the environment.

Patent Policy. Shortly before release of the NIH Guidelines in June 1978, NIH received a letter from Stanford University noting that both Stanford and the University of California were
applying for patent protection for recombinant DNA inventions developed by their NIH-supported investigators, and asking NIH to review relevant DHEW patent agreements with universities. The universities, in turn, expressed a public interest in this research generally, the two universities felt the need for a formal advisory opinion on the patenting of such inventions developed under NIH grants or contracts. A number of other universities indicated a similar interest in obtaining the official NIH view.

Prior to making an official pronouncement of DHEW-NIH policy with respect to recombinant DNA research inventions, NIH decided to solicit comments from a broad range of individuals and institutions. An analysis of the comments received was completed in December 1976 and was referred to the Federal Interagency Committee on Recombinant DNA Research.

When the guidelines were released in June 1976, a key public issue was their extension to the rest of the public and private sectors. Commentators whose views were solicited agreed that there must be standards to govern recombinant DNA research and that the NIH Guidelines could provide the standards for such research nationally. They were divided, however, on whether to approach that goal through the use of patent agreements. They noted that the implementation of the NIH Guidelines through licenses granted under patents would be awkward at best and only a partial solution.

The Interagency Committee members reviewed the matter in April and May of 1977. Most members voiced strong support for DHEW policies governing Institutional Patent Agreements (IPA's), and all except representatives of the Department of Justice believed that recombinant DNA inventions should be handled within the existing terms of the IPA. The Justice Department opinions rested heavily on a draft bill originally proposed by Senator Kennedy for the regulation of recombinant DNA research activities. Specifically, Justice referred to the patent sections of this bill that were based on the concept of Government ownership of recombinant DNA research inventions. In subsequent versions of this bill, however, all references to patents were eliminated.

On the basis of the review by the Interagency Committee and by the Assistant Secretary for Health and the General Counsel for DHEW, it was decided that, at least for the present, recombinant DNA research inventions developed under DHEW-NIH support should continue to be administered within current DHEW patent agreements with universities. Each university agreement, however, will be amended to permit the institution to grant a license under patents secured on any such invention only if the licensee provides assurance of compliance with the physical and biological containment standards set forth in the guidelines. Thus, the requirements set for NIH grantees and contractors will thus be honored by licensees as well.

Legislative Developments. The Federal Interagency Committee on Recombinant DNA Research recommended in March 1977 that legislation be passed to extend the standards of the NIH Guidelines to all recombinant DNA activities in the public and private sectors. On the basis of the recommendations, legislation was developed under HEW Secretary Joseph A. Califano, Jr., and an Administration bill was introduced in the Congress. The bill was considered in Congressional hearings; other bills on the subject were introduced. After several drafts by the relevant subcommittees during 1977, a Senate bill was reported to the Floor and a House bill was reported to the House.

The two bills reported out contained many elements of the original Administration bill. A number of differences emerged, however, that would necessarily involve a greater administrative burden and some further delays and duplication in handling the highly technical matters involved in standard-setting and monitoring.

Pending legislation introduced in 1978 provides the most promising solution yet available for establishing national standards for the use of recombinant DNA techniques. The bill H.R. 11192 was reported by the Committee on Interstate and Foreign Commerce on March 24, 1978. It sets an interim 2-year measure that provides for sensible regulation and public oversight. It was referred to the Committee on Science and Technology, was considered by its Subcommittee on Science, Research and Technology for a period of 21 days, and was reported from the Committee for House action on April 21. H.R. 11192 reflects new scientific information and administrative developments since the release of the NIH Guidelines in June 1976. The general administrative structure of the guidelines and the standards for biological and physical containment are endorsed for purposes of regulation. Thus, flexible regulation with national standards is the intent of the bill.

International activities

During the legislative hearings on recombinant DNA research, a number of questions were raised concerning international activities in this field. In light of this interest, the Federal Interagency Committee, at the request of Congress, from the State Department, undertook a review of activities in other countries. This review was the basis for a Committee report issued in November 1977 on recombinant DNA activities throughout the world. The recommendations for fostering common safety standards. Scientists abroad, as in the United States, have played a major role in bringing potential hazards of recombinant DNA research to the attention of scientists, governments, and international organizations.

The issue of recombinant DNA research has been studied by national and international bodies. In many cases some form of control has been adopted, but nowhere has the research been totally banned. The United Kingdom, Canada, France, the Federal Republic of Germany, and the Soviet Union have issued guidelines that differ in detail but are similar conceptually to the NIH Guidelines. Other countries are generally following the NIH or U.K. Guidelines, including Denmark, the Netherlands, Israel, Sweden, and Switzerland. The European Science Foundation (ESF) has endorsed the U.K. Guidelines; the European Molecular Biology Organization (EMBO) has endorsed use of either the U.K. or the NIH Guidelines; and the International Council of Scientific Unions (ICSU) and the World Health Organization (WHO) have urged nations to adopt the principles that these two sets of guidelines embody.

As of the summer of 1977, there were an estimated 150 research projects using recombinant DNA techniques underway in Europe, 300 in the United States, and perhaps 20-25 altogether in Australia, Japan, and the Soviet Union. All appear to be conducted under some form of safety practices and procedures.

A number of national and international activities foster the monitoring of recombinant DNA research for purposes of safety and health. In the United Kingdom, the government's health and safety executive will be responsible after October 1978 for insuring that the standards of the United Kingdom Genetic Manipulation Advisory Group (GMAG) are followed in matters relating to safety of employees and the general public. The GMAG, consisting of representatives from the scientific, public, and private sectors, reviews recombinant DNA research projects for conformance to appropriate safety standards and practices. Similar activities have also been established in other European countries, and efforts are underway to identify appropriate governmental bodies to insure compliance with GMAG standards.

Proposed Revised Guidelines

The RAC-proposed revisions
In December 1975 the Recombinant Advisory Committee recommended proposed guidelines for review and decision by the Director, NIH. To assist in the review, a special meeting of the Advisory Committee to the Director, NIH, was convened in February 1976. Members of the committee represented not only science but such other disciplines and public affairs. Comments received from committee members and a number of public witnesses represented a wide range of views. A number of issues were referred back to the Recombinant Advisory Committee for their comments in April 1976. On the basis of all the comments received and the responses of the RAC, the NIH guidelines were finalized by the Director, NIH, and released in June 1976 with an extensive “Decision document.”

In 1977 the Recombinant Advisory Committee, in accordance with its mandate in the original guidelines, began the process of proposing revisions to them. A subcommittee of the RAC held open meetings in March and April. Following this, the proposed revisions were considered and revised by the full committee at open meetings in May and June. On September 1, 1977, the RAC’s proposed revised guidelines were referred to the Director, NIH, for consideration and decision.

These proposed guidelines were published in the NIH Recombinant DNA Technical Bulletin. The bulletin is a new NIH publication that links recombinant DNA investigators in the United States and abroad with the advisory groups and organizations active in this field. To provide further opportunity for public comment, the proposed revised guidelines were published in the Federal Register on September 27, 1977 (42 FR 49596), and notice of a public hearing was published in the Federal Register on November 22, 1977 (42 FR 59918). In December the RAC-proposed revisions were considered by the Federal Register. The revisions proposed by the RAC are described in detail in the following assessment, but the key changes can be summarized as follows.

**Definition.** A new definition was proposed to cover only “novel recombinant DNA”—namely, DNA segments from species not known to exchange chromosomal DNA by natural physiological processes. Accordingly, a class of recombinant DNA, to be exempt from the guidelines, would have to appear on a list of “non-novel exchangers.”

**Physical Containment.** Revisions here incorporated the philosophy and guidelines used by NIH and the European Molecular Biology Organization (EMBO) on the requirement of physical containment. A number of revisions were also made in the organization of this section.

**Biological Containment.** This section was expanded from the 1976 guidelines to include (1) a new nomenclature—HV1, HV2, and HV3—incorporating a variety of host-vector systems into the framework initially established for E. coli K-12; (2) a more restrictive set of requirements for HV3 host-vector systems; and (3) a new section describing mechanisms for certification of host-vector systems.

**Prohibited Experiments.** A major recommendation would allow the Director, NIH, to exercise discretion in permitting exceptions to the prohibited experiments, as in studies of risk assessment.

**Permissible Experiments.** On the basis of the scientific evidence on the safety of E. coli K-12, some categories of experiments were classified at lower containment levels. Several other categories, however, remained the same as in the current guidelines. For certain categories, discretion was permitted by the investigator, and some categories of experiments were exempted.

**Implementation.** Several changes were recommended in the responsibilities for the local committees, the recommendations included requirements for training of research personnel, criteria for determining the need for medical procedures, clarification of membership on institutional bio-hazard committees, and the requirements for a biological safety officer where work is being done at the F3 and F4 levels.

**The NIH-proposed revisions**

The proposed revisions by the Recombinant Advisory Committee were published in the Federal Register for comment on September 27, 1977 (42 FR 49596), and notice of a public hearing was published in the Federal Register on November 22, 1977 (42 FR 59918). In December the RAC-proposed revisions were considered by the Federal Register. The revisions proposed by the RAC are described in detail in the following assessment, but the key changes can be summarized as follows.

The recommendations by the Recombinant Advisory Committee were generally supported. There was universal sentiment for giving the Director, NIH, discretion to exempt certain experiments from the provisions of the guidelines, especially when this would permit knowledge to be gained bearing on the provisions themselves. There was overwhelming sentiment for exempting from the guidelines experiments involving most “self-cloning” systems, as well as pairs of harmless organisms that transfer genes in nature. That is, many of the experiments currently classified at the P1 + EK1 level should be exempted from the guidelines. And witnesses from the scientific community strongly advocated further consideration of revisions involving work with viruses and plant pathogens.

On the basis of these suggestions, a “Joint United States-EMBO Workshop to Assess Risks for Recombinant DNA Experiments Involving the Genomes of Animal, Plant, and Insect Viruses” was convened in Ascut, 1978, in Ascut, England. The report of the workshop (see appendix E) was reviewed by a working group sponsored by NIH on April 6-7, and the recommendations from that group (see appendix F) were referred to the Recombinant Advisory Committee. The committee, in turn, lent their endorsement in recommendations at a meeting held at NIH on April 27-29. The analysis of the risks of cloning viral DNA in a bacterium like E. coli is not greater, and is usually much less, than the risk of handling the parent virus itself.

Further, a meeting of agricultural scientists was convened on March 20-21, 1978, under the joint sponsorship of the Department of Agriculture, the National Science Foundation, and the National Institutes of Health. Their recommendations were also reviewed by the Recombinant Advisory Committee at their April meeting. It was the conclusion of the agricultural scientists that containment conditions for incorporation of DNA from plant pathogens into E. coli K-12 were unconstitutionally.
- International scientific representatives present at the hearing reported on guidelines prevailing in the United Kingdom and Western Europe and on their interpretation by Genetic Manipulation Advisory Groups. It was pointed out that some experiments are permitted in Europe which are not permitted in America. More importantly, it was noted that there is no factual basis upon which to defend the greater stringency of the U.S. (NIH) guidelines.

- There was special emphasis by public commentators on the need for procedures at the local and national level to insure public participation and oversight. The public and scientific commentators were especially concerned that there should be a commitment at the local and national levels to the training of all laboratory personnel, and to health surveillance, when feasible, to insure occupational health and safety. Concern was also expressed for local community participation to insure that practices in the laboratory meet public and environmental safety requirements.

- Several representatives from the private sector urged that NIH consider introducing mechanisms into the proposed revisions to allow private-sector participation through the guidelines. They urged that NIH provide for their voluntary registration, certification of their host-vector systems, and provision for the protection of proprietary information and patent rights.

- Strong support came from both the scientific community and the public for clear enunciation of the benefits and potential risks of this research. In addition, several of the public commentators urged that the rationale for the classification of permissible experiments be stated more clearly.

- Finally, a number of commentators in the scientific community and representatives from institutional biohazards committees advocated more flexible implementation of the NIH guidelines. Specifically, the locus of responsibility for the use of the guidelines must shift further toward the institutions conducting the research. Present requirements for NIH approval before an experiment may proceed have caused delays unjustified by proof that safety has been enhanced.

All of the issues raised by the commentators were carefully analyzed. A number of possible revisions were developed and referred to the Recombinant Advisory Committee for review. The following items were among those on the agenda of the Recombinant Advisory Committee at its April 1978 meeting:

- To redefine the scope of the guidelines, including construction of a first list of "exempted exchangers";
- To review selected issues on the guidelines raised by the public commentators;
- To review the containment levels for experiments with viral DNA or viral vectors and with plant pathogens or viruses.

On the basis of the issues raised and the response of the Recombinant Advisory Committee, a decision and environmental impact assessment on proposed revisions is offered for public comment. The assessment that follows explains the present guidelines, the RAC's alternatives, the alternatives posed by the public and scientific commentators at the public hearing and in correspondence, the RAC's views on the issues raised at the April 1978 meeting, and the assessment of the revisions as proposed by the Director, NIH.

**The Recombinant DNA Experimental Process**

All living things, from subcellular particles to higher organisms, contain the specific information needed for their reproduction and functions. The basic source of this information is deoxyribonucleic acid (DNA), which is the principal substance of the genes—the units of heredity. Genes determine the characteristics of the species as well as individual traits such as size and eye color.

Each cell of an organism is composed of various organized structures, several of which contain DNA. Figure 1 illustrates a typical eukaryotic, or nucleated, cell. Bacterial cells (prokaryotic) are much less complex, showing fewer organelles and no organized nucleus.

![Figure 1](image-url)

DNA plays two roles: (1) provides information for the reproduction, growth, and functions of the cell, and (2) preserves and directs replication of this information and transfers it to the offspring. These two roles of DNA are common to animals, plants, single-cell organisms, and many viruses. The DNA of cells is mainly found in organized structures called "chromosomes."

Intracellular DNA also occurs outside of the chromosomes as separately replicating molecules. Such DNA molecules include the plasmids, found in bacteria; the DNA of chloroplasts, common to green plants; and the DNA of mitochondria, the energy-producing units of the cells of complex organisms. These DNA's, while not strictly part of the inherent genetic make-up of a cell, help define the cell's functional capability. Another type of DNA commonly found in cells is the DNA of infecting viruses.
During the past 30 years the structure of DNA molecules has been studied intensively, and it can now be described in much detail. The molecule may be compared to a long-twisted stepladder with thousands to millions of rungs. A short piece of DNA is represented in Figure 2.

**Figure 2**

![Diagram of DNA molecule](image)

The formation of "recombinant DNA" in the laboratory was made possible by a series of discoveries. W. Arber and D. Dussoix, in 1962, showed that bacteria contain substances called restriction enzymes. Serving to defend the bacteria against viruses, these enzymes can split foreign DNA molecules into specific fragments. R. Yoshimori, in H. Boyer's laboratory, isolated a restriction enzyme that was later found to split DNA into fragments whose ends stick together when they touch.

In 1973 S. Cohen and others succeeded in combining genes of different species and introducing them into bacteria. Then they grew the bacteria in cultures, multiplying the combined characteristics.

The capabilities sketched here—to split DNA selectively, to recombine it by virtue of "sticky" ends, to reintroduce it into cells, and to cultivate the cells—constitute the recombinant DNA technique.

In the recombinant DNA experiments that are the subject of the NIH guidelines, the DNA can be derived from widely divergent sources. DNA from one of the sources may serve as a carrier, or "vector," for the insertion of the recombinant DNA into a cell, or "host." The vector may be a plasmid, usually derived from the same species as the host, or it may be a virus. The DNA to be inserted is called the "foreign" DNA. When a large mixture of DNA fragments from the foreign source is used in the joining, the experiment is referred to as a "shotgun" experiment. In other instances, a particular DNA fragment of interest will be purified and then incorporated in the vector.

From a growth culture of the host cells, one containing the interesting DNA fragment is selected and allowed to multiply. The resulting population of identical cells is called a "clone." In some experiments the DNA will be extracted from the cells for study; in others, the properties of the cells themselves will be investigated.

In the experiments discussed in the guidelines, the host cells are generally single-cell microorganisms such as bacteria, or animal or plant cells that were originally obtained from living tissue but are grown as single cells under special laboratory conditions.

The process of producing recombinant DNA molecules and introducing them into cells is illustrated in figure 3.

**Figure 3**

![Diagram of recombinant DNA](image)

A gene is a portion of the DNA molecule which codes for the manufacture of a protein. In higher organisms, much of the DNA may not serve as genes in this sense, but may regulate the activity of nearby genes. It is possible to break open cells and isolate DNA, free of other cellular constituents.
derived from any living species, and the foreign DNA might contain chromosomal or nonchromosomal DNA, or both.

In the next steps, the foreign DNA fragment is mixed and combined with the vector DNA, and the recombinant DNA is reinserted into a host cell. In most experiments this host cell will be of the same species as the source of the vector. The recipient cells are then placed under conditions where they grow and multiply by division. Each new cell will contain recombinant DNA.

Recombinant DNA technology represents a method that is applicable to many areas of biological research. Essentially, it represents a new tool. Investigations supported by many NIH Institutes and programs utilize this technique, much as a new instrument is applied in studying many different things. Areas of biological research to which recombinant DNA experiments are underway include the study of bacterial enzymes and metabolism, the synthesis of hormones, the reproduction of viruses, the organization of chromosomes, and the structure and regulation of genes. Except for studies to improve the technology, NIH sponsors no program on recombinant DNA as such; but recombinant DNA technology is used, where applicable, as an additional tool for increasing understanding of normal and abnormal biological processes.

RISKS AND BENEFITS OF RECOMBINANT DNA RESEARCH

Research, by definition, is investigation of the unknown. The results of research, whether beneficial, neutral, detrimental, or some combination of these, cannot be fully predicted ahead of time. The following discussions are assessments based on present knowledge and collective technical judgments. Unexpected benefits and unexpected hazards are possible.

Possible Hazardous Situations

The insertion of DNA derived from a different species into a cell or virus (and thus the progeny thereof) may change certain properties of the host. The changes may affect adversely or beneficially (a) the survival of the recipient species, (b) other forms of life that come in contact with the recipient, and (c) aspects of the nonliving environment. Current knowledge does not permit accurate assessment of such effects in contemplation of every recombinant DNA experiment. At present it is only possible to speculate on ways in which the presence of recombinant DNA in a cell or virus could bring about these effects.

It should be noted that there is no known instance in which a hazardous agent has been created by recombining
The ability of a plasmid to be transferred from the original laboratory host to another cell and thereby perpetuate itself is also important. In short, certain plasmids are incapable of being transferred except under particular and rare conditions. Others transfer more readily. Since the ability to be transferred depends on multiple factors, (2) it is not likely to be increased by insertions of a single foreign DNA fragment. Other than this, no generalization concerning the effect of a foreign DNA fragment on transferability can be made.

The effects of bacteria and viruses containing recombinant DNA on other forms of life

The analysis leading to the guidelines centered on the possibility of deleterious effects, since the concern was the health and safety of living organisms, including humans, and the environment. Agents constructed by recombinant DNA technology could prove hazardous to other forms of life by becoming pathogenic (disease-producing) or toxigenic (toxin-producing), or by becoming more pathogenic or toxigenic than the original agent.

There are two basic mechanisms by which a recipient micro-organism might be altered with regard to its pathogenicity or toxicity as a result of a resident recombinant DNA. (1) The recombinant DNA may result in formation of a protein that has undesirable effects. The case in which bacterial cells are used as carriers of foreign DNA is discussed first. A foreign protein, specified by the foreign DNA, might act after being liberated from the micro-organism, or it could function within the micro-organism and alter, secondarily, normal microbially cell function in such a way that the cell is rendered harmful to other living things. Either means depends on linkage or recombination of the foreign genes; that is, the information in the foreign genes must be used by the recipient bacterium to produce a foreign protein. Examples of proteins that might prove harmful to other organisms are hormones, enzymes, and toxins.

Present evidence suggests that foreign DNA from bacteria of one species, when inserted into bacteria of another species, may be expressed in the recipient, depending on the similarities of the protein synthesis mechanisms in the two organisms. (4) For example, if the donor of the foreign DNA produces a toxic substance, then the recipient cell may produce such a substance, provided the gene for the toxic substance is present in the recombinant. The recipient may or may not be more hazardous than the original donor organism, depending on the relative ability of the two organisms to grow and infect an animal or plant species at risk.

Expression of foreign genes from complex organisms (yeast, fruit flies) in cloned bacteria has recently been demonstrated experimentally. (5) In other experiments, insertion of a synthetic gene into E. coli led to the production of somatostatin, a hormone found in the mammalian brain. (6) Analogous issues must be considered for the case in which animal viruses are the carriers of foreign DNA. Indirect dispersal of such viruses outside the laboratory might result in entry of the recombinant DNA into cells of living organisms. The foreign genes might be expressed, resulting in the uncontrolled synthesis of a normal protein or the formation of a protein foreign to the infected cell. Currently, few relevant experimental data are available. (3)

(2) The recombinant DNA may itself cause pathogenic or toxic effects. As discussed above, foreign DNA inserted in a bacterial gene might so alter the microbial cell's properties that it becomes harmful to other organisms. It is also necessary to consider situations in which DNA molecules themselves may escape from the laboratory or from the experimental host cell and enter cells of living organisms with which they come in contact. Free DNA molecules are themselves relatively fragile, and the probability that they would survive, in a significant form or for a significant time, in air, water, or any medium, is considered remote. DNA that is protected in any of a variety of ways within cells and viruses might be released either into, or close to, a living cell.

When a cell or virus dies, or comes close to or invades the tissue of another living organism, the recombinant DNA may effectively enter a new cell. A hazardous situation similar to that described above might ensue if foreign proteins were manufactured in this "secondary" recipient. The recombinant DNA might survive as an independent cellular component, or it could recombine by natural processes with the DNA of the secondary recipient. Various possible deleterious consequences of such a recombination may be considered.

If the secondary recipient is another micro-organism, the considerations described earlier apply. If the secondary recipient is one of the cells of an animal or plant, the possible effects are different. They include alterations of normal cellular control mechanisms, synthesis of a foreign protein (such as a hormone), and insertion of genes involved in cancer production (if, for example, the foreign DNA were derived from a cancer-producing virus).
It should be pointed out that the likelihood of such a mechanism causing inheritable changes in the offspring of complex organisms is extremely low because of the protection afforded germ-line cells (eggs and sperm) by their location. Thus, it is highly improbable or perhaps impossible for recombined foreign DNA to reach germ-line cells after fertilization. However, secondary recombination can occur.

What is the probability of secondary recombination between prokaryotes and eukaryotes in nature? It is generally held that the recombination in nature is more likely if similar or identical sequences of bases (rungs in the DNA ladder) occur in the two recombining DNA's. The greater the degree of similar sequences, the more likely is recombination. In general, the more closely two species are related, the more likely it is that similar sequences will be found in their DNA's. Thus, DNA from primates has more DNA sequences in common with human DNA than does DNA from mice, or fish, or plants. Recombination may also occur between DNA's not sharing sequences, but at lower frequencies. It is possible that the capacity for interspecies recombination between distantly related species exists in nature. For example, bacteria in animal intestines are constantly exposed to fragments of animal DNA released from dead intestinal cells. Significant recombination, however, would require the uptake of intact segments of animal DNA and their subsequent incorporation into the bacterial DNA. Such uptake and incorporation has been demonstrated. The frequency of such events in nature is unknown.

Similarly, there are very few data permitting assessment of the reverse process; namely, the incorporation of bacterial DNA into the cells, or DNA, of more complex organisms. Although there are reports of experiments in which bacterial DNA was inserted into animal and plant species and production of the bacterial protein followed, the process is very inefficient and many investigators have been unable to repeat these experiments.

There are certain well-documented instances in which the DNA's of different living things become more or less permanently recombined in nature. These instances involve recombination between the DNA's of non-chromosomal genes, such as those of viruses or plasmids, or between the DNA's of viruses or plasmids and chromosomal genes. The former instance, for example, is the mechanism behind the rapid spread of resistance to antibiotics among different bacterial species. The latter instance is accompanied by the prevalent use of antibiotics in medicine and agriculture. Another example is the insertion of DNA from the bacterium Agrobacterium tumefaciens into plant cells.

Expected Benefits of Recombinant DNA Research

Benefits may be divided into two broad categories: an increased understanding of basic biological processes, and practical applications for medicine, agriculture, and industry. At this time, most of the practical applications are speculative. It is important to stress that the most significant results of this work, as with any truly innovative endeavor, are likely to arise in unexpected ways and will almost certainly not follow a predictable path.

Increased understanding of basic biological processes

There are many important fundamental biomedical questions that can be answered or approached by DNA recombinant research. In order to advance against inheritable diseases, we need to understand the structure of genes and how they work. The DNA recombinant methodology provides a simple and inexpensive way to prepare large quantities of specific genetic information in pure form. This should permit elucidation of the organization and function of the genetic information in higher organisms. For example, current estimates of the fraction of this information that codes for proteins are simply educated guesses. There are almost no clues about the function of the portions of DNA that do not code for proteins, although these DNA segments are suspected of being involved in the regulation of gene expression.

The existing state of ignorance is largely attributable to our previous inability to identify large segments of the DNA in a form that permits detailed molecular analysis. Recombinant DNA methodology removes this barrier. Furthermore, ancillary techniques have been developed whereby DNA segments that contain particular sequences of interest can be identified and selected. Of particular interest is the isolation of pure DNA segments that contain the genes for the variable and constant portions of the immunoglobin proteins. The analyses of such segments obtained from both germ-line and somatic cells should be of inestimable value in determining the mechanism of immunologic diversity.

A major problem in understanding the mechanism by which certain viruses cause cancer is how and where the infecting or endogenous viral genomes are integrated into the cell's chromosomes. This bears on the question of how the integrated viral genes affect cellular regulation, thus leading to the abnormal growth characteristics of cancer cells. With the recombinant DNA techniques for isolating and purifying their intact DNA, this research problem is reduced to manageable proportions. It is possible to isolate the desired DNA segment in pure form. Large quantities can be obtained for detailed study by simply extracting a culture of the bacteria carrying the viral DNA segment in a plasmid.

Important recent achievements in recombinant DNA research

It was anticipated (see EIS of October 1977) that the ability to excise, isolate, and amplify specific segments of DNA from higher organisms would provide an unprecedented opportunity to study the structure of eukaryotic genomes and to correlate the results with concepts of how they evolved and are regulated. Recent work has yielded much more. Indeed, some of the genomic structures discovered through use of recombinant DNA techniques have occasioned a substantial reassessment of several major paradigms of molecular biology. Many of the initial studies using recombinant DNA techniques focused on DNA sequences that are repeated in the genomes of eukaryotes. In some instances, these repeated sequences specify an RNA product, such as ribosomal RNA, or fulfill a function as yet unknown—for example, the sequences called "satellite" DNA. The organization of such sequences is being examined extensively with recombinant DNA techniques.

Many of the genes that specify ribosomal RNA are repeated in the eukaryotic genome several hundredfold. It has been known for some years that in a variety of species, such as the frog and the mouse, the sequences are arranged as a series of tandem repeats. Each set of ribosomal genes is separated from its neighbors by regions of DNA, of varying length, that are not transcribed. Cloning of several of these nontranscribed, or "spacer," regions has allowed analysis of the manner in which they are related to one another and proposals of evolutionary mechanisms by which they may have arisen.

Moreover, the availability of these cloned DNA sequences has made it possible to localize the DNA site at which the transcription of the ribosomal genes is initiated. The exact DNA sequence at this site is being determined. Such information will further the understanding of the mechanisms
that regulate gene expression and the construction of new host/vector cloning systems.

Many of the basic concepts of molecular biology have had to be based upon work on prokaryotes. These concepts have influenced two different regions of data on the structure and possible mode of functioning of the eu-karyotic genome. Recombinant DNA technology, however, has allowed the structure of the genomes of higher organisms to be examined in a manner previously restricted to studies on bacteria. Some of the results have upset earlier assumptions. For example, the cloning of eukaryotic DNA sequences that specify the proteins β globin,(24, 25, 30) ovalbumin,(25, 27) y globin,(23) and immunoglobulin(28, 31) has demonstrated that certain basic facts of DNA organization in prokaryotes are not applicable to eukaryotes. The major new finding of “intervening” sequences in these higher forms (discussed in footnote 13 to the “Introduction and Overview” of the accompanying decision document) may provide an explanation for the cause of the hereditary disorder, β* thalassemia. It also demands a reconsideration of the basic, mechanisms of differentiation and evolution.

The work on immunoglobulin(28, 37) has shown that the DNA sequences that encode the different regions of an immunoglobulin polypeptide are widely separated in germ-line cells. During differentiation, these DNA sequences move closer together but do not become contiguous. Detailed examination of cloned fragments has solved one of the fundamental and longstanding puzzles of immunology. Very recent data indicate that the intervening sequences found in the gene for ovalbumin differ from individual to individual(32, 33), indicating that genetic variability may occur within a species to an extent not previously imagined.

Practical implications

The possibility that recombinant DNA techniques could be used to alter the properties of recipient organisms, or to produce desired substances, such as peptide hormones, rests largely upon two factors: (1) the fidelity of the cloning procedures and (2) the ability to obtain expression of the cloned DNA sequence. It has been demonstrated that cloning does provide faithful copies of the original sequence.(34) More recently, experiments in which cloned fragments of yeast DNA were introduced into E. coli have provided further evidence that fidelity is maintained and that expression of cloned sequences can be achieved. All the bacterial strains used contained genetic lesions that rendered them incapable of synthesizing a particular amino acid. However, the yeast DNA sequences were capable of correcting these deficiencies(35) and were shown to specify the synthesis of a yeast protein that substituted successfully for its defective bacterial counterpart.

There have been several accomplishments during the last year and a half that may be expected to yield both economic and medical benefits in the near future. Work has begun on the cloning of the nitrogen fixation genes of the bacterium Klebsiella pneumoniae.(36) The introduction of these genes into appropriate plant or bacterial hosts may drastically reduce the required effort for malnutrition and fertilizers. Such fertilizers, currently consumed at the rate of 40 million tons per year, are synthesized by processes involving large energy costs.

An area that has proved to be extremely productive has been the cloning of DNA sequences specifying peptide hormones. During 1977 there were successes in the cloning of genes for the following hormones: Insulin,(37) Somatostatin,(6) a hormone that inhibits the secretion of glucagon, insulin, and growth hormone; potentially useful in the treatment of acromegaly, acute pancreatitis, and insulin-dependent diabetes.

Growth hormone,(38) used in the treatment of dwarfish; in short supply throughout the world. Somatomammotropin,(39) a hormone secreted by the placenta; appears to influence lactation and act to ensure that the fetus obtains nutrients required for normal growth.

The cloning of the somatostatin gene is particularly noteworthy, since the gene was synthesized chemically, thus avoiding any risk of inadvertent cloning of contaminating sequences, and was then inserted into a specially constructed plasmid vector. The inserted DNA sequence was expressed and an inactive somatostatin was synthesized and isolated. From this, active somatostatin was subsequently liberated. Because the polypeptide precursor synthesized within the E. coli K-12 host is inactive, the procedure also decreases markedly and likelihood that the host cell itself could be hazardous. This same strategy may be used in the cloning of any of the small peptide hormones.

Long-range implications

The experimental situations treated in the guidelines are those that appear feasible either currently or in the near future. The experiments primarily involve insertion of recombinant DNA into the host genome. In the near future, genetic environments in the host cells might serve to correct an inherited defect in an individual, or to alter heritable characteristics in the offspring of individuals or a given species. The latter type of alteration has been successfully achieved in agriculture through the use of classical breeding techniques. It may be that recombinant DNA methods, should they develop in appropriate ways, will offer new opportunities for specificity and accuracy in animal breeding. It should be noted, however, that the techniques covered by the NIH guidelines involve the recombinating of DNA fragments in the test tube, and the guidelines prohibit the deliberate release into the environment of any organism containing recombinant DNA molecules.

Should the deliberate application of such methods for the correction of individuals genetic defects or the alteration of heritable characteristics in individuals be attempted, such methods should be required to inform both private and public decisionmaking.

Possible Deliberate Misuse

In the event that recombinant DNA technology can yield hazardous agents, such agents might be considered for deliberate perpetration of harm to animals (including humans), plants or the environment. The possibilities include biological warfare or sabotage. Because it is not known whether recombinant DNA technology can yield such agents, discussion of these problems, such as theft by saboteurs, is hypothetical and difficult. With regard to biological warfare, the use of recombinant DNA for such purposes is prohibited by the Biological Weapons Convention. In a statement to the Conference of the Committee of Disarmament, on August 17, 1976, Ambassador Joseph Martin, Jr., made the following remarks on the subject:

When advances in science and technology are made, it is natural to ask about their possible use for hostile purposes and whether or not such uses are prohibited or restricted by existing international agreements. In the case of potential use of recombinant DNA molecules for weapons pur-
posses. It is our view that such use clearly falls within the scope of the Convention’s prohibition.

This interpretation is based upon the negotiating history as well as the explicit language of the Convention, and we believe that it is shared by the other signatories. I do not believe it is possible to read the Biological Weapons Convention and come to any other conclusion. According to the Pre-amble, the States Parties are “determined for the sake of all mankind, to exclude completely the possibility of bacteriological (biological) agents and toxins being used as weapons.” The intent of Article I, which begins, “Each State Party to this Convention undertakes never in any circumstances . . .” is equally forceful and clear. To take a more restricted view would rob the Convention of much of its value and could even lead to States to call into question its scope and continued viability. These were the views of the United States when the Convention was negotiated and ratified. They are still its views today. This is a matter of great importance to my Government and one on which doubt cannot be permitted to exist.

It is noteworthy that, prior to his statement, Dr. David Baltimore had requested an opinion from James D. Watson, General Counsel of the United States Arms Control and Disarmament Agency, on whether the Biological Weapons Convention prohibits production or recombinant DNA molecules for purposes of constructing biological weapons. On July 3, 1975, Mr. Malone replied: “In our opinion the answer is in the affirmative. The use of recombinant DNA molecules for such purposes clearly falls within the scope of the Convention’s provisions.”

References


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**Spacers Interrupt the Ovalbumin Gene.**


1. **I. SCOPE OF THE GUIDELINES**

   **Analysis of Current Guidelines**

   For the purposes of the current Guidelines, recombinant DNA experiments are defined as those involving molecules that consist of segments of DNA from different sources which have been joined together in cell-free systems, and which have the capacity to replicate in some host cell, either autonomously or as an integrated part of the host's genome. The host cells in these experiments are generally single living cells. They may be microorganisms such as bacteria, or animal or plant cells grown in tissue culture.

   **General principles**

   The Guidelines start with a statement of general principles, which are consistent with the conclusions in the report of the International Conference on Recombinant DNA Molecules held at Asilomar, Calif. in February 1975. The first principle is that certain experiments be judged, in the light of currently available information, to present such serious potential hazards that they should not be attempted at this time. Second, a large group of feasible experiments appear to pose less or no potential hazard, and can therefore be performed under appropriate safeguards if the information or benefits sought cannot be obtained by conventional methods. Third, the more serious the nature of any presumed consequence, the more stringent should be the safeguards against escape of the potentially hazardous agents.

   **Experiments to be deferred**

   The first class of experiments described in the Guidelines are those that are not to be carried out at the present time. While it may be argued that a combination of maximal physical and biological safeguards could essentially contain these recombinants, the magnitude of the possible dangers if containment were to fail dictates that these experiments be deferred. This class of experiments includes the following:

   - Those in which any of the recombinant DNA derives from pathogenic organisms listed under classes 3, 4, and 5 of the document Classification of Ectotoxic Agents on the Basis of Hazard, published by the Center for Disease Control (CDC) of the U.S. Public Health Service, or from oncogenic (cancer-causing) viruses classified by the National Cancer Institute as "moderate risk." The CDC document categorizes naturally occurring organisms and viruses known to be pathogenic to man and agriculturally important species, on a scale of increasing hazard from 1 to 5.
   - Those characterized by deliberate formation of recombinants containing the genes for potent toxins. Examples are botulinus or diphtheria toxins, and venoms from insects and snakes.
   - Those involving deliberate creation from plant pathogens of recombinant DNA's that are likely to increase the virulence of the pathogenic material or the range of susceptible species.
   - Those involving transfer of a drug-resistance trait to microorganisms that are not known to acquire it naturally, if this could compromise the use of a drug to control disease in humans, animals, or plants.

   **Other restrictions**

   Concern the volume of recombinant DNA to be produced and the deliberate release of organisms into the environment:

   - Experiments with recombinant DNA's known to make harmful products must be limited in scale to quantities of fluid less than 10 liters. The RAC, in setting this limit, recognized that experiments deemed to be of direct societal benefit, if appropriate equipment is used.
   - The creation of organisms with ability to carry out useful environmental functions has been contemplated. Release of such organisms into the environment may be required to test their efficacy, and certainly to make use of them. The Guidelines, however, prohibit at present the release of any organism containing a recombinant DNA molecule.

   **Alternatives: RAC-Proposed Revisions**

   It was the determination of the Recombinant DNA Advisory Committee that advances in knowledge pertaining to recombinant activities in past years warranted significant revisions in the purpose, definition, and prohibition sections of the NIH Guidelines. A comparison of the "purpose" language of the current Guidelines with that of the proposed revised guidelines of the RAC (hereafter called "PRG-RAC") reveals that the standards for determining whether DNA experiments should be deferred or prohibited are set forth in the class of experiments that are likely to increase the virulence of the pathogenic material or the range of susceptible species.

   **Alternatives: Public Commentators**

   There was considerable discussion at the public hearings over the scope of experiments that were "naked" DNA and whether or not they are contained within a bacterium or virus. The rationale for this change is that DNA by itself (commonly referred to as "naked" DNA) is extremely unlikely to be hazardous under experimental conditions, as it is rapidly inactivated in nature.

   The definition in the PRG-RAC consists of two parts: (1) an operational definition of recombinant DNA and (2) a qualification that the Guidelines prohibits certain recombinant DNA's. The operational definition does not differ significantly from that in the original Guidelines.

   The second part, however, calls for the creation of a list of organisms that exchange genetic information in nature, commonly referred to as "non-novel exchangers." Recombinant DNA formed with DNA from such organisms would be exempted from the provisions of the Guidelines, with the rationale being that the RAC need not concern itself with requiring stringent containment procedures for the handling of recombinants that occur regularly in nature and are not known to be associated with any special hazards.

   The provision of an open-ended listing was recommended rather than issuance of a blanket exemption, because this would allow the RAC and NIH to consider evidence that (1) the putative gene transfer "do take place naturally and are not known to be associated with any special hazards.

   Although the PRG-RAC deal with prohibited experiments under part III, this assessment, for purposes that become apparent below, will consider the definition, exemptions, and prohibitions together under part I.

   A major proposed revision would give the Director, NIH, authority to grant exceptions to any of the six prohibitions. Such a determination must be based upon the recommendation of the RAC, and weight must be given in the decision-making "both to scientific and societal benefits and to potential risks." The rationale for this proposed change was the desire of the RAC not to bar automatically the conduct of experiments desirable for some compelling social or scientific reasons—for example, risk assessment.

   **Alternatives: Public Commentators**

   There was considerable discussion at the public hearings over the scope of
the Guidelines. Some mentioned that the Guidelines were too narrow in their preoccupation with recombinant DNA, as there are other forms of genetic research capable of producing organisms and viruses containing such molecules.

General applicability

Many commentators urged that a statement of general applicability of the Guidelines be included in an early part. The issues relate to (1) the applicability of the Guidelines to non-NIH-funded recombinant DNA molecules. However, there are inherent in these techniques a range of natural barriers to the formation of hazardous organisms which apparently afford adequate containment, making unnecessary the issuance of Federal standards. Such techniques have been used in the laboratory for decades with no known harmful effects on either the public health or the environment. The entire area of laboratory safety is of primary concern to NIH and is the subject of constant review and attention.

There were several suggestions that the purpose of the Guidelines be more clearly stated and that terms be more precisely identified. Therefore, the sections "Purpose," "General Definitions," and "Purpose of the guidelines" have been added to Part I of the guidelines now being proposed by NIH—hereafter called "PRG-NIH."

Purpose of the guidelines

The Introduction to the 1976 Guidelines states that "the purpose of these Guidelines is to recommend safeguards for recombinant DNA molecules." As noted above, to eliminate the handling of naked DNA from the Guidelines, the PRG-RAC proposed this passage to read that the purpose is to "establish procedures for handling organisms and viruses containing recombinant DNA molecules."

This proposed revision would have had the effect of removing from coverage by the guidelines certain experiments that are now prohibited by the 1976 Guidelines—for example, deliberate formation of "naked" recombinant DNA-containing genes for the biosynthesis of potent toxins. The Director, NIH, proposes to resolve this issue conservatively. The language in the PRG-NIH, therefore, clearly states that the Guidelines are intended to pertain to the construction and handling of naked recombinant DNA molecules as well as organisms and viruses containing such molecules.

Definition of recombinant DNA molecules

It became apparent from the comments received that the PRG-RAC definition was inadequate in not addressing the handling of recombinant DNA molecules containing segments of chemically synthesized DNA. It was decided that the most effective way to achieve this objective is simply to include "natural or synthetic DNA" in the definition of a recombinant DNA molecule, and this has been inserted in the PRG-NIH definition. A new section, therefore, has been added to Part III of the PRG-NIH giving containment levels for work with recombinant DNA molecules containing synthetic DNA.

A perceived ambiguity in the PRG-RAC definition has been corrected by the inclusion of language within the PRG-NIH definition which explicitly states that DNA molecules resulting from the replication of recombinant DNA molecules are subject to the safety provisions of the Guidelines.

Finally, no other provisions of the PRG-RAC definition as much comment as did the wording to exclude "non-novel" recombinant DNA from the standards. The ambiguity of such phrases as "known to exchange chromosomal DNA" and "by natural physiological processes" was strongly noted. A greater degree of clarity and objectivity is needed. Thus, it has been decided to eliminate in the PRG-NIH the two conditions cited above as criteria for exemption from the Guidelines. Staff discussions of the public comments made it clear that inclusion of exemption provisions within the definition itself was not desirable; several attempts at appropriate language did not bear careful scrutiny.

Given this situation, and also the realization that certain categories of recombinant DNA experiments are indeed so apparently free of causing harm that they should not continue under the Guidelines, the criterion of "novelty" was removed from the definition and used as a basis for the development of a new section entitled "Exemptions."

Exemptions

The nature of the public comments on the PRG-RAC exclusion of non-novel exchangers can be divided into two categories—those that pertain to the proposed standards and those to the proposed process. The standards proposed by the PRG-RAC were that novel recombinant DNA's consist of "segments of any DNA from different species not known to exchange chromosomal DNA by natural physiological processes.* * *

In general, recombinant DNA molecules will not be considered novel when all the components are derived...
from genomes known to replicate within the organism used to propagate the recombinant DNA." This is qualified, however, by a footnote stating that “recombinant DNA formed between eukaryotic viral DNA and any eukaryotic DNA *** shall not be excluded *** until such time as there is more information about the extent of naturally occurring recombinational events between these DNA's.”

The public comments on these standards raised a number of issues. For example, some said that safety rather than novelty should be the criterion for exclusion. That is, any recombinant molecule that poses a threat to the public health or the environment should be covered by the Guidelines regardless of whether the molecule is a novel one. Others held that the proper criterion should not be safety, but rather whether the potential hazard of the recombinant DNA molecule differs significantly in degree or in kind from those found in nature or from biohazards that are successfully handled by conventional methods. It proved impossible to reconcile these different opinions on the definition itself and so an “Exemptions” section was drafted by NIH staff in conjunction with an RAC working group. It should be noted that no provision in that section may be cited to exempt from the Guidelines an activity listed in the “Prohibitions” section.

The first exemption concerns recombinant DNA molecules that are not in organisms or viruses. This is in recognition that “naked” DNA, which is rapidly inactivated in nature, is extremely unlikely to be hazardous under experimental conditions. To guard, however, against the remote possibility that potentially harmful naked recombinant DNA will become incorporated into an organism, the handling of certain naked recombinant DNA molecules described in the “Prohibitions” section remains prohibited. It should also be noted that the concept of a very low hazard of naked recombinant DNA was included in the PRG-RAC in the section on “Handling Recombinant DNA Molecules” at the end of Part III. This language is more appropriately presented under the “Exemptions” section.

The section exemption pertains to recombinant DNA molecules consisting entirely of DNA segments from a single non-chromosomal or viral source. The statement clarifies the category of “self-cloning” experiments that are considered safe enough to be excluded from the Guidelines. This is a concept which the RAC tried to convey in the PRG-RAC definition by use of the phrase “different genomes” but which some commentators found ambiguous.

The third exemption concerns “self-cloning.” It exempts from the Guidelines recombinant DNA molecules that are naturally derived DNA of a single organism, including the indigenous plasmids, viruses, mitochondria, or chloroplasts, when propagated only in that organism (or a closely related strain of the same species). This partially responds to the opposition made by many commentators that experiments previously classified as P1- EK1 be excluded from the Guidelines. It also covers some of the cases the RAC was including in the concept of “novelty” and “different genomes.” This exemption, however, does not include recombinant DNA molecules formed between viral DNA and eukaryotic host DNA. In this regard it is analogous to footnote 1 of the PRG-RAC.

The fourth exemption covers certain specified recombinant DNA molecules that consist entirely of DNA segments from different species that exchange DNA by known physiological processes. In this case a list is prepared and periodically revised by the Director, NIH, on the recommendation of the RAC, after appropriate notice and opportunity for public comment. This list is analogous to the list of “non-novel exchanges” proposed in Appendix A to the PRG-NIH gives a proposed list for this exemption. This list is discussed in Appendix D to the present document.

The fifth exemption allows the Director, NIH, on the recommendation of the RAC and after appropriate notice and opportunity for public comment, to exempt other classes of recombinant DNA molecules if he finds that “they do not present a significant risk to health or the environment.” This language for exempting classes of experiments is used in proposed legislation (H.R. 11192) recently reported out of the Committee on Interstate and Foreign Commerce and the Committee on Science, Technology of the U.S. House of Representatives. In addition to these comments pertaining to the standards for exemption in the PRG-RAC, the following were directed toward the processes whereby exemption would be made:

1. Rather than compile a list of non-novel exchanges exempt from the Guidelines, the burden of proof should be on the Director to compile a list of novel exchanges that are subject to the Guidelines.
2. The procedures and criteria used in the development of the list should be thoroughly explained, and adequate opportunity should be given for public review and comment.

Before an organism is placed on the list, all the data pertaining to the application should be available for public review.

In response to these comments, the PRG-NIH specifies that for exemptions I-E-1 and I-E-2 the RAC will develop lists after appropriate notice and opportunity for public comment. The initial list proposed in Appendix A to the PRG-NIH is submitted for public comment along with the entire revision of the Guidelines. In the future, appropriate notice and opportunity for public comment will precede any additions to Appendix A or exemptions I-E-5.

Prohibitions

Two changes in this section have been initiated to make it more compatible with the new “Definition” and “Exemptions” sections. The first was to transfer this section from Part III of the Guidelines to Part I, reemphasizing that the exemptions are not applicable to the six activities specifically prohibited. The second was to drop all references to novel recombinant DNA’s and natural genetic exchange. Other alternatives suggested by commenters:

1. There was a general endorsement for the provision in this section which grants to the Director, NIH, upon the recommendation of the RAC, the authority to waive any of the prohibitions. The widespread support for this authority reflects the realization that many important risk-assessment experiments would not be able to proceed otherwise. NIH is now supporting and will continue to support experiments that will yield knowledge contributing to a better understanding of the nature of potential risks of recombinant DNA.
2. It was urged that the advice of other Government agencies, such as the Environmental Protection Agency and the Occupational Safety and Health Administration, be sought when the Director, NIH, considers invoking this waiver authority. The Federal Interagency Committee on Recombinant DNA Research provides for coordination of policies in this area. EPA and OSHA are represented on the Committee. The advice of relevant research and regulatory agencies will continue to be sought when appropriate.

It was suggested that the RAC as presently constituted should not be the sole advisory body because societal as well as scientific considerations must enter into the waiver decision. As explained in greater detail in Part IV of this document, the membership of the RAC will be broadened modestly
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as needed for expertise, but provision for public notice and opportunity to comment, and other appropriate administrative practices should be used to insure adequate public input when the issues warrant.

It was suggested that an Environmental Impact Assessment or Statement should accompany each waiver. Waiver decisions rest in the consideration of the potential environmental impact, and certain decisions may be accompanied by a formal assessment or statement. This must be determined on a case-by-case basis.

It was suggested that waiver of the prohibition on the large-scale use of cultures containing recombinant DNA's be issued on the basis of industry's experience in dealing with such cultures. While experience will surely be weighed in the decisionmaking, it would not be the sole criterion for granting such a waiver.

Agricultural scientists noted the importance to their research community of being allowed eventually to release organisms containing recombinant DNA into the environment. When the original Guidelines were proposed to the NIH Director in draft form in 1976, the release of organisms containing recombinant DNA molecules into the environment was to be allowed if a series of controlled tests had been done to leave no reasonable doubt of safety. This waiver provision was rejected at that time because of the limited scientific evidence available that any of the potential benefits from such a release were near realization. As now proposed, the prohibition of deliberate release into the environment of recombinant-DNA-containing organisms can be waived if all the requirements for a waiver (and those of the National Environmental Policy Act) are met. Given the limited experience of NIH in agricultural research, the U.S. Department of Agriculture would have to be deeply involved in this process, and written notice of this suggestion has been given to the appropriate officials at USDA.

The Standing Advisory Committee on Recombinant DNA Research of the European Molecular Biology Organization (EMBO) has noted that the list of pathogenic organisms under prohibition I-D-1, especially those in Class 5, may not be appropriate for all European countries. The decision as to which pathogenic organisms should be classified as too dangerous to work with must be the responsibility of national or regional authorities. EMBO has recommended that a footnote be added to the Guidelines stating that the prohibitions contained therein are intended to pertain to the construction and handling of naked recombinant DNA molecules as well as organisms and viruses containing such molecules. This is to insure that the prohibitions against use of naked DNA remain in effect. And the definition now explicitly includes synthetic molecules under the standards of the Guidelines, thereby increasing the margin of safety.

In response to the recommendations of public commentators, the PRG-NIH now require that all recombinant DNA research at NIH-funded institutions comply with the safety standards of the Guidelines and be under the purview of local institutional biohazard committees. Appropriate officials at NIH have been taken to minimize the environmental impact, if any, of this research.

The list of exemptions, as previously explained, provides that certain recombinant DNA research need not be subject to the control of the NIH Guidelines on the basis of safety to the laboratory personnel, to the greater community, and to the environment. The proposed exemptions in large part are responsive to the great number of comments received. The "Prohibitions" section, in the 1976 Guidelines under Part III, has been transposed to Part I in the PRG-NIH to insure that none of the "Exemptions" apply to the "Prohibitions." Thus, once again, care has been taken to minimize the possibility of environmental impact.

Under the first exemption, experiments with recombinant DNA molecules that are not in an organism need not be prohibited. Pragmatically, in some cases recombinant DNA experiments are performed in vitro, that is, outside the organism or cell. Thus, it was thought appropriate to permit experiments that mimic exchanges already occurring in nature. It allows certain of the experiments previously classified as P1+EK1 to be excluded from the Guidelines. This is based on the safety of these experiments. The second exemption permits certain "self-cloning" experiments to be done outside the jurisdiction of the Guidelines. Again the basis is occupational and environmental safety. The third exemption also concerns "self-cloning" and permits certain experiments previously classified as P1+EK1 to be excluded from the Guidelines. This was strongly endorsed by several public commentators on the basis of no hazard.

The fourth exemption deals with experiments that mimic exchanges already occurring in nature. It allows certain of the experiments previously classified as P1+EK1 to be excluded from the Guidelines. Once again, care has been taken to minimize the possibility of environmental impact. This standard was expressly recommended as the basis for exemption by several public commentators, especially from environmental groups, and is directly responsive to the concerns that there be an explicit reference to health or the environment for the basis of exemption. Further, in the exercise of this and the previous exemption, several criteria have been introduced that will afford significant opportunity for public comment to insure appropriate attention
to occupational and environmental concerns.

A waiver provision in the section on "Prohibitions" will permit NIH support and conduct of risk-assessment experiments of crucial importance to the design of safer and more extensive microbiological practices in the future. Recommendations from the scientific community, the public, and relevant Federal agencies will be sought for their advice on specific projects. Waiver decisions will include a careful consideration of potential environmental impact.

In summary, a number of safety standards and procedural requirements have been included in the PHS-NIH to assure minimal environmental impact. All risk containment approaches as outlined from the Guidelines are of minimal speculative risk and present no significant hazard to health or the environment.

II. Containment

Analysis of Current Guidelines

Two approaches to the problem of containing potentially hazardous organisms have been developed and used previously for containment procedures. Such innovative approaches involve the limitation of the actual physical escape of organisms and is referred to as "physical containment." The second approach is the use of biological barriers, to be described later as "biological containment." (The October 1977 EIS on the current guidelines, in response to comments received on the draft EIS, documents in considerable detail the adequacy of the containment requirements and shows the basis on which judgments in this regard have been made.)

Physical containment

A major aspect of physical containment is the set of standard microbiological practices that have been developed over many years and are widely used for handling pathogenic organisms. In the hands of well-trained personnel, these procedures have proved to be effective both in laboratory and clinical settings. A second major aspect of physical containment involves the use of special kinds of equipment and facilities (1) for limiting the spread of aerosols, (2) for decontamination and containing laboratory air and wastes, and (3) for restricting access to laboratories. As with standard microbiological techniques, the type of equipment and facilities are not new but have been developed and used previously for containment of known pathogens.

The guidelines go into some detail concerning the practices and facilities required for physical containment. Four levels are specified: P1, P2, P3, and P4, in the order of increasing safeguards. P1 consists in the use of the standard microbiological practices mentioned above. P2 and the next higher level, P3, require special procedures and facilities designed to limit to increasing extents any possible accidental escape of potentially hazardous organisms. Finally, P4, the maximum level of containment, requires sophisticated and isolated facilities designed for maximum containment.

Each of the levels from P2 through P4 assumes that the standard microbiological practices demanded by P1 will also be followed. Furthermore, for each level, relevant training of personnel is mandatory. The training is to include the nature of the potential hazards, the technical manipulations; each serving to provide instruction in the biology of the relevant organisms and systems. Specific emergency plans, to be used in case of accident, are required; and serological monitoring is to be provided where appropriate.

Biological containment

Biological containment is defined as the use of host cells and vectors with limited ability to survive outside the laboratory and the natural environment. This is an integral part of the experimental design, since the host and vector will need to be chosen, in any given experiment, with a view to the purpose of the experiment as well as to containment.

The guidelines stress that physical and biological containment procedures are complementary, each serving to control any possible failure in the order. The use of both in a given experiment affords much higher levels of containment than either alone. Therefore, the guidelines always recommend both a particular level of physical containment and a level of biological containment for any given experiment. The guidelines explicitly recognize that better physical containment capabilities are likely to evolve as research proceeds and may reduce the need for the standard physical containment procedures. Such innovations are to be considered as part of the on-going review of the guidelines for appropriate revision.

The Use of Bacterial Hosts and Vectors

In recognition of the relation between the host-vector system required by the experiment and the design of suitable biological containment, experiments using the same host-vector system are grouped together. At present, the system of choice for many experiments is the common laboratory bacterium E. coli, strain K-12, and independent genetic elements (plasmids and bacteriophage) known to reside or replicate in this strain. There are several factors contributing to this (discussed more fully in part III). Strain K-12 has been studied extensively and can be readily manipulated for recombinant DNA experiments. This extensive experience and ease of manipulation permit modification of E. coli K-12 and vectors used with it by classical genetic techniques for the purpose of establishing biological containment.

The guidelines discuss arguments against as well as for the use of E. coli K-12. Main arguments against it is the intimate association of various other strains of E. coli with humans. By reason of the prevalence of E. coli strains (but not K-12) in mammals, the guidelines recommend the cautious use of E. coli and analogous systems and urge that efforts be made to develop alternate hosts and vectors.

E. coli K-12 appears to be harmless: it does not usually establish itself in the normal bowel or multiply significantly in the alimentary tract. These facts suggest that accidental ingestion of a small number of bacteria by a laboratory worker would not result in their extensive spread outside the laboratory system. The organism may be altered, however, when the infected person is taking antibiotics or has certain abnormal digestive conditions, and it is recommended that such persons not work for the duration of the experiment.

While E. coli K-12 does not establish itself as a growing strain in the normal bowel, it does remain alive during its passage through the intestinal tract. Therefore, transfer of plasmid or bacteriophage DNA from the original E. coli K-12 host to bacteria resident in the intestines or encountered after excretion must be considered. The guidelines take into account the transferability of certain vectors in recombinant research. In brief, host-vector systems derived from E. coli K-12 and certain plasmids or bacteriophage appear to have extremely limited ability to spread recombinant DNA molecules.

Considering, then, the properties of E. coli K-12 and the known plasmid and bacteriophage vectors, the guidelines conclude that recombinant DNA's manipulated through such host-vector systems are unlikely to be spread by the ingestion or dissemination of the few hundred or thousand bacteria that might be involved in a laboratory accident, given standard microbiological practices and these existing systems, and analogous combinations of E. coli K-12 with other vectors and bacteriophage, are judged to offer a moderate level of bio-
logical containment and are defined as EK1.

As with physical containment levels, increased numbers specify increasing levels of biological containment for E. coli systems. For the next level, called EK2, host-vector combinations must be demonstrated to provide a high level of biological containment by suitable laboratory procedures. Specific combinations that are obtained by genetic modifications of either E. coli K-12 host cells or the relevant plasmids and bacteriophage or both. Various examples of the types of necessary modifications are suggested in the guidelines.

One additional level of contained E. coli host-vector systems, defined in the guidelines, is called EK3. EK3 systems are EK2 systems for which the specified containment properties have been demonstrated, not only by microbiological and genetic analysis but by appropriate tests in animals, including humans or primates and other relevant environments.

EK2 and EK3 host-vector systems must be certified as such by the Director, NIH, after evaluation and recommendation by the Recombinant Advisory Committee.

Alternatives: RAC-Proposed Revisions

Physical containment

Two major changes were proposed in the physical containment section of the PRG-RAC. One deals with the organization of the section; the other incorporates into the PRG-RAC the philosophy and guidance of the report of the NIH-European Molecular Biology Organization (EMBO) workshop on parameters of physical containment.

Physical containment requirements for each P-level have been organized under the topic headings “Laboratory Practices,” “Containment Equipment,” and “Special Laboratory Design.” This was done to emphasize the importance of laboratory practices and containment equipment in achieving the desired safety objective.

Other proposed revisions contained in the physical containment section reflect a conscious effort to encourage international uniformity with respect to recombinant DNA guidelines. This has been achieved by revising the containment descriptions so that they are consistent with the guidance provided in the NIH/EMBO report. In addition, some statements have been rewritten and others added in order to clarify the basic requirements for each level of containment. The most significant clarifications have been made in the areas on containment equipment and special facility design. The revisions, however, have not resulted in changing the purpose or intent of the physical containment descriptions in the 1976 guidelines.

One specific addition to the PRG-RAC that has originated from the NIH/EMBO report is the inclusion of design or layout around each of the laboratory in which personnel wear positive-pressure suits ventilated by life-support systems. This added approach provides a level of physical containment equivalent to that afforded by glove-boxes at the P4 level.

Other important recommended changes include:

- Certain good microbiological practices are mandatory at the P1 level in the PRG-RAC (the 1976 guidelines encourage but do not require such practices);
- At the P2 level, prohibitions against eating, drinking, smoking, and storage of foods have been extended from the work area to the entire laboratory.
- The universal biohazard sign is now required at the P2 level, and its use has been extended to equipment such as freezers and refrigerators in which organisms containing recombinant DNA molecules are stored.
- Access procedures have been specified for controlled areas adjacent to P3 laboratories;
- Installation of foot-, elbow-, or automatically-operated, safety-glass washing hands is now required for all laboratories in which P3-level work is done;
- Specific guidance on containment equipment appropriate for laboratory animals has been added to the P3 and P4 sections; and
- The labeling requirements for shipment of etiologic agents now apply to all organisms containing recombinant DNA molecules. Thus, the Center for Disease Control, U.S. Public Health Service, must be notified in the event of any accidental breakage during shipment. Also, agents requiring P4 containment must be packaged according to strict Federal standards and shipped by registered mail or an equivalent system that provides for sending notifications to the shipper upon delivery.

The PRG-NIH adopt these suggestions in large part. Thus, they strengthen the safety standards and procedures for physical containment and move toward international agreement.

Biological containment

The PRG-RAC describe the categories of hosts and vectors to be used in minimizing the spread of organisms containing recombinant DNA. The PRG-RAC differ from the 1976 guidelines in that they were expanded to include (1) further definitions of host-vector systems, (2) a more restrictive set of requirements for HV3 systems (see below), and (3) a new section describing mechanisms for certification.

Definitions of Host-Vector Systems

A new nomenclature—HV1, HV2, and HV3—was developed to incorporate a variety of hosts and vectors into the framework initially established for E. coli K-12. In particular, the PRG-RAC provide criteria for HV1 systems other than E. coli K-12. In the 1976 guidelines, cloning systems other than those based on E. coli K-12 were to be considered only if superior to K-12 in containment properties; but it is now recognized that many useful experiments can only be conducted using host-vector systems other than those based on E. coli K-12, and that such experiments should be permitted so long as the proposed system provides equivalent biological containment.

Three new systems are suggested in the guidelines. This was done to emphasize international uniformity with respect to the categories of hosts and vectors. The three new systems are EK2 systems for which the guidelines, is called EK3. EK3 systems are EK2 systems for which the specified containment properties have been demonstrated, not only by microbiological and genetic analysis but by appropriate tests in animals, including humans or primates and other relevant environments.

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that allows various combinations of containment safeguards, (2) the adequacy of risk-assessment studies in relation to physical containment, (3) the adequacy of training in laboratory safety practices, (4) plans for dealing with emergencies, and (5) various aspects of the biological safety concepts. NIH has considered a number of recommendations made by ESCO. Public commentators have made additional suggestions relating to actions at specific levels of physical containment and to shipment of recombinant DNA materials.

**Concept of “flexibility”**

Some commentators have expressed concern over the flexibility provided in tables I and II which allows various combinations of containment safeguards. Some feel, for example, that work in a P3 facility conveys a desirable sense of hazard, whereas a reduction to the P2 level will promote an undesirable relaxation of vigilance. It has also been suggested that an increase in the options augments the difficulty of control and implementation. Some commentators object to specific options provided at the P3 and P4 levels.

**Risk assessment**

Many commentators have urged more studies in risk assessment. It has been pointed out that assumptions about biological containment may not be valid and that all components should be tested. Concern has been expressed that the biological containment safety systems may fail altogether.

Some risk-assessment studies are prohibited by the 1976 Guidelines. Under the FRG-RAC, however, the Director, NIH, on recommendation of the RAC, would have discretion to permit such risk-assessment experiments by granting a waiver from a specific prohibition. There was virtually unanimous support for this discretion at the public hearing in December 1977. Of course, its exercise must be consistent with standards of due process for the scientific community and the public.

**Training**

A number of commentators urge that specific curricula be developed for training of researchers and that the Guidelines stipulate requirements for certification in safety practices. NIH has a contract with the American Society for Microbiology to develop minimum standards for training participants in recombinant DNA research. The work panel's report is to be used by the IBCs and investigators to set appropriate standards.

**Emergency plans**

In response to the concerns of commentators, the elements of emergency plans to handle possible safety problems are described more clearly in the Guidelines. A Supplement to the NIH Guidelines for Recombinant DNA Research. Further, NIH staff have recently met with representatives of CDC to establish a mechanism for providing advice, consultation, or assistance if necessary in case of an emergency, such as a laboratory accident involving recombinant DNA.

**Biological containment considerations**

Considerations of biological containment related mainly to the development of alternative host-vector systems. Many commentators from the scientific community believe that the FRG-RAC discriminate against host-vector systems alternate to E. coli K-12. They urge development of other systems that maintain that they will be needed increasingly both in pure research and in industry and should be certified as soon as possible. It is unlikely, according to one commentator, that agriculture will best be served through the use of E. coli K-12 or E. coli (for example, a Class III biological safety cabinet). The larger the number of alternate host-vector systems, the greater the problem of monitoring the work.

Clearly, however, research address to the development of other host-vector systems must proceed. This is particularly evident in the agricultural sector, where the potential for immediate benefit to man is great. At present, a number of alternate systems are being developed by NIH grantees. In the use of such systems, the same con-
considerations of safety and risk associated with the use of E. coli K-12 will, of course, apply.

**Mouth pipetting at the P1 level**

Both the 1976 guidelines and the PRG-RAC prohibit mouth pipetting at the P2, P3, and P4 levels. For the P1 level, however, they state, "Although pipetting by mouth is permitted, it is preferable that mechanical pipetting devices be used." A number of commentators have urged that mouth pipetting be prohibited at the P1 level of physical containment. The decision accompanying the PRG-NIH discusses in detail the arguments of various groups on both sides of the issue. In resolving this, the Director, NIH, has decided to adopt the conservative position and ban mouth pipetting. Accordingly, language has been inserted in the PRG-NIH saying that at the P1 level "mechanical pipetting devices shall be used; pipetting by mouth is prohibited." Since mouth pipetting had already been banned at the P2-P4 levels, this means that mouth pipetting would now be banned for all experiments covered by these guidelines.

**Proposed Action: Environmental Impact Assessment**

**Physical containment**

The PRG-NIH include the following specific changes at each P level, aimed at clarifying and strengthening physical containment requirements and thereby reducing the probability of recombinant DNA molecules being accidentally released into the environment.

**P1 Level**

The 1976 guidelines establish as a principle of containment the adherence to good microbiological practices. At the P1 level, however, certain practices are not required but merely encouraged. The PRG-NIH now make adherence to certain of these practices mandatory at all four physical containment levels.

A major change in the PRG-NIH is the banning of mouth pipetting at the P1 level, meaning that mouth pipetting is now banned for all experiments covered by the guidelines. Since the only plausible way E. coli K-12 could gain entry into laboratory workers by oral ingestion, this ban greatly reduces the possibility that any organisms containing recombinant DNA will escape and thus minimizes the risk of environmental impact.

**P2 Level**

The PRG-NIH have extended the prohibitions against eating, drinking, smoking, and storage of foods from just the work area to the entire P2 laboratory. This change was made to achieve consistency with recommended practices in laboratories where research with low-risk human pathogens is conducted.

The PRG-NIH call for posting of the universal biohazard sign on storage freezers and refrigerators. This additional requirement was specified to facilitate safe storage of organisms containing recombinant DNA molecules when research with them is not in progress. The change was made to eliminate the possibility of containing the P3 laboratory from areas open to unrestricted traffic flow. Access procedures for this area are specified, clarifying the juxtaposition of the P3 laboratory and uncontrolled areas.

The PRG-NIH require the installation of foot, elbow, or automatically operated facilities for washing hands in laboratories in which P0-level work is conducted. This additional requirement was made to eliminate the possibility of contaminating faucets through contact. The requirement is consistent with practices common to infectious disease laboratories.

The PRG-NIH would permit recirculation of untreated air within individual rooms of the P3 laboratory. Such recirculation can conserve energy without compromising safety. Reference to recirculation of treated air to other areas of the building has been eliminated, because this approach to energy conservation is generally not practical.

Some commentators pointed out that the PRG-RAC did not require an autoclave in the P3 laboratory itself but only within the building. It has been suggested that the autoclave should be as close as possible to the controlled area of the P3 laboratory. The language of the 1976 guidelines, stating a preference for the autoclave to be within the controlled laboratory area, is therefore retained in the PRG-NIH. A requirement, however, that the autoclave be within the controlled area would increase costs, and in the view of NIH would not add measurably to safety.

**P4 Level**

In the PRG-NIH the minimal age for entry into a P4 laboratory has been raised to 18 years, the commonly accepted legal age.

The PRG-NIH specify containment equipment appropriate for the isolation of experimental animals. This was added because the lack of guidance in the current guidelines has led to confusion in their application to animal experimentation.

The PRG-NIH provide flexibility in selecting combinations of physical and biological containment to be used for a given experiment. All possible combinations available for selecting achieve P4-level safety objectives. This approach was patterned after the guidance provided in the NIH/EMBO report.

The PRG-NIH specify design criteria for a suit area where personnel wear positive-pressure suits that are ventilated by life-support systems. This provides an option to the class III cabinet-system requirement at the P4 level of physical containment. This option has been used successfully in research with extremely hazardous human pathogens. Without compromising safety, it provides an opportunity to conduct research procedures that cannot be confined to conventional class III cabinet systems.

**Shipment**

In the PRG-NIH, the labeling requirements for the shipment of etiologic agents apply to all organisms containing recombinant DNA molecules, rather than to just those containing molecules derived from an etiologic agent listed in 42 CFR 77.25. This change was made in order to ensure that the Center for Disease Control, U.S. Public Health Service, be notified in the event of accidental breakage during shipment. The PRG-NIH also specify that agents requiring P4 physical containment must be shipped by registered mail or an equivalent system that provides for sending notifications to the shipper immediately upon delivery. This change would impose on the shipment of organisms requiring P4 containment the same standards used for shipment of high-risk human pathogens.

**Biological containment**

A number of alternate systems for biological containment are being developed by NIH grantees, including ones using Bacillus subtilis and Saccharomyces cerevisiae. To assure adequate safety control, a new section of certification of host-vector systems has been added to the guidelines. HV1 systems other than E. coli K-12 are reviewed by an expert working group, then by the RAC, which makes appropriate recommendations to the Director, NIH. Descriptions of the organism, its biology, and the characteristics of the particular strains to be used are considered. The same standards of safety and risk associated with the use of E. coli K-12 will apply to any new host-vector systems to be certified in the future.

**HV2 Level**

For the HV2 level of containment, the RAC, on June 23, 1977, unanimously approved a document entitled "Instructions to Investigators Concerning Data To Be Submitted on Host-Plasmid Systems Proposed for EK2 Certification." Although not officially, part of the PRG-RAC, this document sets forth criteria that any putative EK2 host-vector systems must meet before recommendation by the RAC for certification (see H of the October 1977 EIS). The committee applied these criteria in reviewing new systems (pBR322 and pBR313 in...
x176) at the June 23 meeting, and will do so for all future submissions. These criteria are clearly more stringent than previous ones, and this means that EK2 host-vector systems approved now and in the future will be even safer than those approved previously.

**HV3 Level.** Requirements for HV3 systems have been made more stringent than those in the 1976 guidelines. The additional requirements mean that only some HV3 systems are eligible for consideration as HV3 systems and therefore increase the safety of experiments involving these systems. In addition, to develop HV3 systems that meet, these criteria should simultaneously upgrade the HV2 systems in use, since it is to the experimenter's advantage to use the HV2 systems that have the greatest likelihood of meeting HV3 criteria.

**Certification of HV Systems.** A new section has been added to clarify responsibility for certification of all host-vector systems, the types of data to be submitted, and the mechanisms for distributing strains once certified. The section delineates procedures used by the RAC for the past year and thus represents no change from practices under the 1976 guidelines.

Under the PRG-NIH, HV1 systems other than E. coli K-12 and HV2 and HV3 systems are considered by an expert working group and then by the RAC, which makes appropriate recommendations to the Director, NIH. Modifications of HV2 and HV3 systems must be independently certified by NIH. Data to be submitted are detailed. All HV2 and HV3 systems are to be obtained from NIH or its designee, and recipients are to report to NIH any discrepancies from the expected properties. If the strains are propagated by NIH, a sample will be tested for relevant properties prior to distribution. The requirements assure adequate controls in the certification and distribution of host-vector systems and provide sufficient protection against potential hazards to the environment.

**Containment Properties of Hosts and Vectors.** In regard to containment properties of individual organisms used in recombinant DNA research, recent experimental evidence supports the view that biological containment works well. This is particularly borne out by results from experiments specifically designed to test the survivability and colonizing ability of E. coli K-12 and EK2 host-vector systems and the transmissibility of plasmids and phage vectors. At the time of the release of the current guidelines in 1976, EK2 systems were defined but none existed. An experimental contract program was initiated to develop safer host-vector systems and to verify their genotypic constitution and phenotypic traits. The program is administered by the National Institute of Allergy and Infectious Diseases. The ability of these systems to survive in laboratory and natural environments was determined. As a result of this contract program and of work by other investigators of EK2 host-vector systems was developed. The RAC subjected these to great scrutiny and finally recommended them for certification. A list of certified EK2 host-vector systems appears in appendix H of the October 1977 EIS.

**III. Containment Guidelines for Covered Experiments**

**Analysis of Current Guidelines**

**E. Coli K-12 Host-Vector Systems**

The several levels of physical and biological containment are defined in part II, and specific recommendations are given for experiments using the E. coli K-12 host-vector systems. Each type of experiment is assigned both a physical containment level (that is, a P level) and a biological containment level (that is, a B level). The particular combination of the two reflects the severity of the estimated potential hazard.

The guidelines are organized for the E. coli systems according to the source and nature of the foreign DNA. A sample of DNA containing essentially all the genetic information of an organism can be isolated and fragmented. If the experiment involves such a mixture of DNA fragments, it is referred to as a "shotgun" and will call for a certain level of containment. Experiments involving such mixtures of DNA fragments are assumed to be of higher potential hazard than those done with a single, purified fragment, because of the greater likelihood of dangerous and unknown genes being introduced into a recipient cell. Purified fragments generally are those whose properties are known and are not harmful yet offer less potential hazard than a shotgun experiment.

In some instances, the foreign DNA will be derived from extra chromosomal genetic elements. Such elements include the DNA of animal viruses, plant viruses, other eukaryote organelles such as mitochondria and chloroplasts, as well as prokaryote plasmids or bacteriophages of the same type used as vectors. Each of these cases is treated separately in the guidelines. The prokaryote sources are treated differently, depending on whether the "foreign" DNA is from an organism that does or does not exchange genetic information with E. Coli in nature.

The physical and biological containment is listed for various possible DNA sources, both those which can or cannot complement each other. For example, DNA from primates requires the most stringent containment, since the estimated potential hazard, either from genes that might function in humans with untoward effects or from pathogenic viral DNA's residing in primate tissue, is judged to be most serious. The experiments now require either P3 + EK3 or P4 + EK2; and it should be noted that only the latter combination, even only at the limited number of P4 facilities.

In two instances—primates and cold-blooded vertebrates—containment requirements are the same as those involving embryonic or germ-line material, since such material is less likely to be contaminated by pathogenic viruses than is adult tissue. Thus, if the foreign DNA is from cold-blooded vertebrates and P2 are required, but P2 and EK1 can be used if the DNA is from embryonic or germ-line tissues. If the cold-blooded vertebrate is known to produce a potent toxin, P3 and EK1 must be used. In some instances, for example, the guidelines require more or less stringent conditions, depending on whether or not the source of foreign DNA is known to be pathogenic or toxigenic, or might be infected with a pathogen, even known to make a harmful product. The guidelines for shotgun experiments, when the source of the DNA is a prokaryotic organism, may be summarized. First those probes that are known to exchange genetic information with E. Coli in nature may be considered. The containment requirements are low for this group, since it is unlikely that the experiments will create new genetic combinations. Requirements vary with the pathogenicity of the source of foreign DNA. When the source is a prokaryote that does not naturally exchange genetic material with E. Coli, the containment recommendations are high, for there is a greater potential for new genetic combinations to be formed and expressed. Further, it is assumed that the more similar the DNA's of donor and host, the greater the probability of expression of foreign DNA or of derepression of host genes.

Characterized clones obtained from shotgun experiments may not be as potentially hazardous as the original mixture of cells. Clones of the recipient host cell containing the DNA fragment of interest will be one of the normal aims of any recombinant DNA experiment. The guidelines state that
Both viruses are oncogenic—that is, polyoma and simian virus 40 (SV40). There are now two unimal viruses laboratory workers become infected. Similarly, when the initial recombination involves a purified segment of the foreign chromosomal DNA, rather than a mixture, the potential for growth of a hazardous organism will be less, since the number of clones that must be examined to obtain the desired clone is markedly reduced. If certain criteria for purity are met, the investigator may lower the containment conditions from those recommended for shotgun experiments with DNA of the same source by one step either in physical containment or biological containment. Thus, for example, shotgun experiments with DNA from birds and adaptable viral fragments from birds that is free from harmful genes, and 99-percent purer before being joined to a vector, would require either P2 + EK2 or P3 + EK1.

The final group of E. Coli experiments considered are those in which the foreign DNA is itself from an extrachromosomal element. It is assumed that such DNA is purified away from chromosomal DNA before recombination. For example, DNA from all or part of the genome of an animal virus requires P4 physical containment and an EK2 vector-host system, or P3 + EK3. If the recombinants have been purified by cloning and shown to be free of harmful regions of the viral genome, then experiments can be at P3 + EK2.

When complementary DNA's, synthesized in vitro from RNA preparations, are used in recombinant DNA experiments, the containment requirements are as described for isolated DNA preparations.

**Animal host-vector systems**

Many recombinant DNA experiments will involve the use of systems in which the host cells are eukaryotes grown as single cells in tissue culture. Useful vectors may include extrachromosomal DNA elements, such as the DNA of organelles or viruses. The cells themselves are fragile and fastidious, and there is little or no chance that a living cell could escape from a laboratory in the way that an E. Coli cell might. Therefore, containment considerations focus on the outer DNA and the viruses. Animal viruses can escape the laboratory in a viable form, especially if laboratory workers become infected. There are now two animal viruses whose DNAs are useful as vectors, polyoma and simian virus 40 (SV40). Both viruses are oncogenic—that is, they cause tumors in small newborn laboratory mammals. Polyoma virus, however, does not infect human cells grown in the laboratory or, judged by the lack of antibody formation, infect whole human beings. SV40 does colonize humans. Indeed, the virus contaminated the early Salk polio vaccine, and millions of people were inadvertently inoculated with it in the 1950's. To date, there is the hint that the recipients suffered some related disease. But under the Guidelines, more stringent physical containment is required for SV40 than for polyoma.

The Guidelines require that the viral DNA used for recombination with a foreign DNA must itself be defective—that is, its propagation as a virus must be dependent on the presence of helper virus that supplies the genes for the missing functions. This helper can be nondefective under certain conditions. In some experiments, no production of viral particles is required and no helper may be needed. These experiments are inherently greater in the absence of virus particles, since cells themselves are relatively easy to contain. In experiments using a virus as vector, the particular levels of physical containment depend on the source of the foreign DNA, on whether polyoma or SV40 is the chosen vector, and whether virus particles are produced.

**Plant host-vector systems**

The Guidelines also cover experiments in which plant cells will serve as hosts for recombinant DNA. The cells might be single plant cells grown under laboratory conditions, or seedling plant tissue in whole plants. This is the only instance where the Guidelines address the question of recombinant DNA experiments with whole organisms. Directions are given for modification of the specifications for P1, P2, and P3 containment in order to provide conditions appropriate for work with plants.

Vectors for use in experiments with plants include plant organellar DNA such as that of chloroplasts, and DNA of viruses of low pathogenicity and restricted host range. These vectors offer moderate levels of biological containment. The requirements are organized according to the source of the foreign DNA and to whether it is a species in which the vector DNA is known to replicate. P2 conditions are required if the source is not dangerous and is one in which replication of the vector occurs. If the foreign DNA is derived from a species in which the vector is not known to replicate, then requirements range up to P4 depending on whether the DNA is purified and whether it contains harmful genes.

**Other host-vector systems**

Theoretically, there are a variety of organisms, both prokaryotes and lower eukaryotes such as fungi and yeasts, which will be useful hosts for experiments with recombinant DNA's. Some may offer the special advantage of not infecting humans, animals, or other important ecological niches. The growth characteristics of such hosts indicate that containment problems will be like those for E. Coli K-12. The Guidelines urge development of these systems and point out that the detailed recommendations made for E. Coli K-12 systems can serve as a guide in determining physical and biological containment requirements when necessary.

**Alternatives: RAC-Proposed Revisions**

A major concern for all individuals who have participated in establishing guidelines for recombinant DNA research is that any guidelines that are drafted and adopted be reassessed periodically and changed when modified by new information. In keeping with this responsibility, the RAC has compiled additional information pertaining to risk assessment in recombinant research. The information is from the following sources:

- Consultations with scientists expert in the areas of evolution, plant biology, bacteriology, virology, and human and animal infectious diseases;
- Results from experiments specifically designed to test (1) the survivability and colonizing ability of E. Coli K-12 and EK2 host-vector systems, (2) the transmissibility of plasmids and phage vectors, (3) the potential of E. Coli K-12 for pathogenicity, and (4) the potential for genetic exchange between diverse bacteria and between prokaryotic and eukaryotic organisms.

Each category of experiments in Part III of the 1976 Guidelines was then extensively examined, and the following criteria were applied to the new information:

- The degree to which the DNA segment has been purified away from other genes and shown to be free of harmful characteristics.
The potential biohazard associated with the DNA of the cell or microorganism that serves as the DNA source (e.g., genes for toxin production).

The potential biohazard associated with the vector that serves to transport the source DNA to a recipient host cell.

The ability of the vector to survive in natural environments or habitats.

The kinds and number of organisms that are susceptible to infection by the vector or recipient.

The potential biohazard of the recipient host cell that serves to replicate the recombinant DNA molecules.

The ability of the host cell to survive in natural environments or habitats.

The ability of the host cell to transmit the recombinant DNA molecule to other cells capable of surviving in natural environments or habitats.

The potential of the host cell to obtain the source DNA by natural means.

The evolutionary relatedness of the DNA source to humans. The potential dangers are considered to increase as the organism providing the source DNA approaches humans phylogenetically. For example, source DNA from primate cells is considered to be more potentially dangerous than that from prokaryotes.

In an effort to present more clearly the changes in containment levels proposed by the PRG-RAC, a table was prepared for use at the December 1977 DAC meeting which compared the containment levels in the original (current) Guidelines and the PRG-RAC. This table has now been expanded with a third column to show the containment levels of the PRG-NIH-IBC (Appendix A). The remainder of this section summarizes a number of the proposed changes, comparing the current Guidelines with the PRG-RAC. (Not all the changes are discussed here; certain items in which the PRG-NIH differs significantly from the PRG-RAC are discussed below under "Alternatives: Public Commentators." The numbers in parentheses indicate the line numbers on the table to which the proposed revision applies.

Several categories of experiments (primarily those involving prokaryotes that are exchangers of genetic information with E. coli in nature) would no longer be subject to the Guidelines because of the changes in the definition. (See lines 20, 21, 27, 46, and 47.)

Shotgun experiments involving birds and mammals other than primates were the subject of lowering of containment from P3+EK2 to P2+EK2. This action reflects the increased confidence of the RAC in the EK2 host-vector systems. (See lines 4 and 5.)

Another category which the RAC decided was in need of revision was that pertaining to the cloning of DNA from organisms that have a toxic product. This was clarified in the PRG-RAC by setting containment levels according to whether polyepitope toxins are produced. Polyepitope toxins from certain organisms might be encoded by a single gene or cluster of genes, whereas toxins of other chemical structure would not. (See lines 8, 9, 10, 11, 12, 16, 17, and 18.)

For several categories of experiments, it is proposed that the investigator have the option of working at P2+EK1 or P1+EK2 rather than the P2+EK2 levels previously specified. This again reflects confidence in the EK2 systems. (See lines 7, 14, and 15.)

The lowering of containment for experiments with rigorously characterized clones free of harmful genes has been revised to provide more flexibility. Under the PRG-RAC, Institutional Biosafety Committees (IBC's) would be able to lower containment by a single level. The IBC should consider the purity, extent of characterization, and harmlessness of the clone before allowing such lowering. Reduction of containment by more than one level would require approval by NIH. Under the 1976 Guidelines, NIH had the option of lowering containment down to certain specified levels or not lowering it at all. The PRG-RAC would allow NIH to consider all available data for the clone and to lower containment accordingly.

Alternatives: Public Commentators

During the development of the original Guidelines in early 1976, Part III was the section most commented upon. There was also much comment on this section in the PRG-RAC. Many of the issues raised, however, did not address the specific proposals to alter the containment levels but more general topics, such as the need for a rationale for each of the changes.

Rationale

A number of commentators asked that the rationale for the classification of permissible experiments be elucidated. Concern was expressed that:

- It was difficult for a layman to understand the entire section on permissible experiments because the rationale is not detailed in either the current Guidelines or the PRG-RAC.

The whole categorization is dependent upon investigational confidence rather than documented fact; and

- The quantification of containment levels, the means whereby they were decided, and the rationale for raising and lowering them is not clear.

In general, the classification is somewhat arbitrary. It depends in large part on the scientific judgment of the RAC rather than on demonstrable risk, because there is in fact no actual scientific evidence that this is a hazard in any recombinant DNA experiment. The rationale for classifying recombinant DNA experiments at several containment levels was explained in the "Decision of the Director, National Institutes of Health, To Release Guidelines for Research on Recombinant DNA Molecules," which was published along with the current Guidelines in the Federal Register on July 7, 1978 (page 27980), as follows:

The guidelines assign different levels of containment for experiments in which DNA from different sources is to be introduced into an E. coli K-12 host-vector system. The variation is based on both facts and assumptions. There are some prokaryotes (bacteria) that constantly exchange DNA with E. coli. Here it is assumed that experimental conditions beyond those obtained in careful, controlled microbiology laboratories are often arrived at through chance, because any exchange experiments have undoubtedly been performed already in nature.

In every instance of artificial recombination, consideration must be given to the possibility that foreign DNA may be translated into a protein (expressed), and also the possibility that normally repressed genes of the host may be expressed and thus change, undesirably, the characteristics of the strain. It is assumed that the more similar the DNAs of donor and host, the greater the probability of expression of foreign DNA, or of possible depressor effect on host genes. In these cases where the donor exchanges DNA with E. coli in nature, it is unlikely that recombination experiments will create new genetic combinations. When prokaryotes not known to exchange DNA with E. coli in nature are used, however, there is a greater potential for new genetic combinations to be formed and be expressed. Therefore it is required that experiments involving prokaryotic DNA from a donor that is not known to exchange DNA with E. coli in nature be carried out at a higher level of containment. Recombination using prokaryotic DNA from an organism known to be highly pathogenic is prohibited.

There are only limited data available concerning the expression of DNA from higher forms of life (eukaryotes) in E. coli (or any other prokaryote). Therefore, the containment prescriptions for experiments inserting eukaryotic DNA into prokaryotes are based on the risk having quite uncertain probabilities.

On the assumption that a prokaryotic host cell that could not translate eukaryotic DNA, it is further presumed that the product of that foreign gene would be most harmful to man if it were an enzyme, hormone, or other protein that was similar (homologous) to proteins already produced by or active in man. An example is a bacterium that could produce insulin. Such a "wrong" bacterium could only be of benefit if there is a possibly dangerous if capable of surviving in nature. This is one reason that the higher the phylogenetic order of the eukary
yote, the higher the recommended containment, at least until the efficiency of expression of DNA from higher eukaryotes in prokaryotes can be determined.

The structure of the classification for permission to conduct recombinant DNA experiments has been changed, therefore, on the scientific assumptions governing potential risk. It should be emphasized that although a wide variety of recombinant DNA experiments have now been performed for over 5 years, in hundreds of laboratories throughout the world, no case of hazard has been demonstrated.

Part III of the Guidelines assigns to each specified class of experiments a level of physical containment and a level of biological containment at which the experiments shall be performed. As noted before, there is a 4-5 log protection in going from P1 to P3 or from P3 to P4. For biological containment, there is the criterion for the HV2 system that the chances of the recombinant DNA escaping, either via survival of the organisms or via transmission of recombinant DNA to other organisms, should be less than 10^-8 (1 in 100,000,000) under specified conditions.

Commentators said that the revisions did not bring the Guidelines any closer to establishing absolute levels of hazard. It was brought out, however, that in the use of E. coli K-12, a level of no risk is nearer. Data presented at the Falmouth Conference indicate that it is essentially impossible for E. coli K-12 to be transformed into a wild-type pathogen. An E. coli K-12 containing tox genes through recombination could present a risk, for example, to the laboratory worker who ingested it. But it would only be a risk to that person.

Harmful genes will have a very low probability of being transferred from E. coli to another organism. For example, the plasmids at the HV2 level are engineered so that they neither self-transfer, nor transfer when another plasmid induces conjugation. Current work is designed to determine the probability of E. coli K-12 as a host taking up plasmids from the environment that can then receive the recombinant DNA molecules from the engineered plasmid. Recent work indicate that the probability is extremely low. Thus, it is clear that this host-vector system offers a high degree of safety and at present is preferable to any other.

**Comments on use of E. coli K-12**

A number of comments were made concerning the use of E. coli host-vector systems. One commentator stressed that because E. coli K-12 is currently a "poor" pathogen does not mean that one or two genes might not convert it to a "good" pathogen. The enfeebled nature of E. coli K-12 is presumably the consequence of mutation(s) introduced during its laboratory passage, but different strains of K-12 with different histories may not all be similarly enfeebled.

Further, it was claimed that the failure to confirm the pathway by the use of certain plasmids or *Salmonella* genes is not definitive. To be definitive, we must have the detailed nature of the mutations in K-12 that "prevent the expression of pathogenicity." Also, it was suggested that there is no way to assess the absolute risk associated with these experiments, and that it is important to assess the potential harm not only to man but to plants, animals, and the environment.

Another commentator urged that this section of the Guidelines be supplemented with evidence from the Falmouth conference to show that the potential risk is minimal. A commentator, with risk on the basis that "virtually any highly conserved physiologically active eukaryotic protein or fragment thereof could be highly toxic when introduced out of context by a bacterium which contains the appropriate genes in a recombination experiment." This criticism of E. coli K-12 does not detract from the scientific knowledge over the past two years of the great safety of the system. A summary of the Falmouth conference is presented in detail in the following section, "Environmental Impact of the Proposed Action."

Different strains of K-12 with different histories may not all be similarly enfeebled, and failure so far to convert K-12 to a pathogen does not prove it can never happen. However, the safety of E. coli K-12 has been clearly shown, and there is no need to limit or specify particular strains for EK1. After 30 years of work with many different strains, there is still no known pathogenic E. coli K-12 strain. Thus, there is presumptive evidence that all K-12 strains are safe. They are well suited for laboratory experiments because they take up DNA easily, but their cell wall makes them unsuited to compete in nature with wild-type E. coli.

Still, it is impossible to refute the criticism that absolute conclusions as to risk have not been reached. There is always one more experiment to be performed that would help in analyzing the safety aspects of any potentially hazardous research activity. Two years ago the Director, NIH, in releasing the Guidelines, stated that NIH would proceed with recombinant DNA work in a deliberately cautious manner while simultaneously evaluating all the evidence pertaining to the potential risks. That statement is reaffirmed.

**General classification**

There was disagreement expressed over whether the PRG/RAC were too stringent or too lax. Those arguing the former position maintain that the RAC did not relax the Guidelines enough, because all the experimental evidence gathered and analyzed in the Falmouth Conference indicated that the initial fears concerning the potential hazards were severely exaggerated. It was also pointed out that recombinant DNA experiments not allowed under the current NIH Guidelines are proceeding without the approval of responsible national committees in a number of European countries.

Those concerned that the PRG/RAC were too lax point to the inadequacy of experimental data for a sound evaluation of the potential risks. And they argue that a recombinant DNA experiment permitted under less stringent safety conditions in Europe is irrelevant to the establishment of standards in the United States.

One of the comments at the December 1977 DAC meeting was that "the NIH Guidelines do not adequately deal with the use of DNA from wild-type pathogens in plants." Other commentators expressed similar sentiments, including the suggestion that "a subcommittee be formed to deal with plants and plant pathogens and make specific recommendations for revision of the Guidelines." In response to this, a Workshop on Risk Assessment of Agricultural Pathogens, composed of distinguished American plant pathologists, was held on March 20-21, 1978 (as announced on March 6 in the Federal Register). Sponsored by the U.S. Department of Agriculture, the National Science Foundation, and the National Institutes of Health, the report of the Workshop is Appendix O to this document. The report was presented to the RAC at its meeting of April 27-28, 1978, and was unanimously endorsed with certain minor amendments. The recommendations, with certain additional minor amendments, have been incorporated into the PRG-NIH.

Two new paragraphs have been inserted at the beginning of Part III of the PRG-NIH. The first reminds the reader to consult Part I, "where a listing is given of prohibited experiments and experiments exempt from these Guidelines." The second is a "general flexibility clause."

Insertion of the latter passage was recommended by the RAC at its April 27-28 meeting. It recognizes that the classification of experiments given in Part III will necessarily be imperfect in the future. It also recognizes that investigators in the future devise new ways to conduct recombinant DNA research which are not currently foreseen and therefore not explicitly considered in the Guidelines. Also, new data may become available showing that certain experiments are clearly necessary.
more (or less) safe than seen at this time and that the currently assigned containment level should be changed. Therefore the inserted passage states that “changes in these levels for specific experiments (or the assignment of levels to experiments not explicitly considered in this section) may be considered and expressly approved by the Director, NIH, on the recommendation of the Recombinant DNA Advisory Committee.”

Permissible experiments using E. Coli

K-12 host-vector systems

Eukaryotic DNA Sources. There was disagreement over those provisions in the Guidelines that allow the principal investigator to choose between two containment levels for shotgun cloning. One commentator of CDC felt that in all cases where the containment level of P2+EK2 is given, the option of P3+EK1 be allowed. However, the RAC felt that in view of the increased confidence in the organisms and containment offered by the EK2 system, P2+EK2 offers more containment than P3+EK1, and that P2+EK2 without the option of P3+EK1 should be the containment level for certain specific classes of experiments. Therefore, there is specified in the PRG-NIH the containment levels of P2+EK2 without the option of P3+EK1 in every case where it appeared in the PRG-RAC.

Discussed below and in the accompanying “Decision” document is the reassessment which was made of the cloning of viral DNA into E. coli K-12 at the Ascot Workshop and the April 6-7, 1978, Working Group meeting that endorsed the Ascot report. The RAC at its April 27-28 meeting unanimously endorsed the Working Group report recommending lower containment levels for deliberate cloning of viral DNA into E. coli K-12. One of the reasons given originally for the higher containment level for shotgun experiments involving primate DNA into E. coli K-12 was the possible inadvertent cloning of viral DNA. In view of their recommendation of lower containment for deliberate cloning of viral DNA into E. coli K-12, the RAC on April 27-28, 1978, reconsidered primate shotgun cloning levels and voted essentially for a new language as follows: “Primates. P2 physical containment + an EK2 host-vector. Any lowering of containment below these levels (i.e., for purified DNA or characterized clones) cannot be made by the experimental institutional biosafety committee but requires NIH approval.” This new language is inserted in the PRG-NIH, as well as a similar lowering of containment for shotgun cloning of cold-adapted vertebrate DNA into E. coli K-12.

Prokaryotic DNA Sources. In the 1976 guidelines the section dealing with shotgun experiments in which the DNA source was K-12 was subdivided into two parts—“Prokaryotes That Exchange Genetic Information with E. coli” and “Prokaryotes That Do Not Exchange Genetic Information with E. coli.” In commenting on the PRG-RAC proposed that the containment level be P2+EK1, with the PRG-NIH the containment level for all experiments involving nonpathogenic prokaryotes that do not exchange genetic information with E. coli.

The PRG-RAC received substantial criticisms for identifying all agents classified as class 2 in the CDC’s publication “Classification of Etiologic Agents on the Basis of Hazard” (fourth edition, July 1974) as being stringent with regard to lower containment levels. Several commentators stated that many of the organisms so classified were harmless and that others were of such low pathogenicity that severe safety precautions were unwarranted. It was also pointed out that the pathogenicity of an intact microorganism and the conjectural hazard of a piece of DNA from such an organism with E. coli K-12 were quite different. The suggestion of these commentators has been accepted, and thus footnote 1 has been added to the PRG-NIH. This gives NIH the authority, upon the recommendation of the RAC, to consider certain class 2 agents as class 1 for the purpose of these guidelines.

Plasmid, Phage, and Virus DNA Sources. Many of the commentators agreed that both the original guidelines and the PRG-RAC were overly stringent with regard to use of experiments. In commenting on the PRG-RAC, the EMBO Standing Advisory Committee on Recombinant DNA Research wrote, “The EMBO Committee believes that the containment categorization of experiments with animal virus DNA’s which is proposed by the NIH Advisory Committee is too indiscriminate and excessively stringent considering the proposed classification of experiments with other classes of DNA and the longstanding, accepted safety precautions for handling intact virus particles and viral nucleic acids.” The EMBO Committee proposed (1) that experiments with viral DNA be considered on a case-by-case basis or (2) that a detailed set of recommended categories for such experiments be produced.

A joint United States-EMBO Workshop to Assess Risks for Recombinant DNA Experiments Involving the Genomes of Animal, Plant, and Insert Viruses was held in Ascot, England, on January 26-28, 1978. The workshop
was attended by 27 distinguished virologists and other scientists from the United States, the United Kingdom, West Germany, Sweden, and Switzerland. A report was published in the Federal Register on March 31, 1978 (43 FR 13748) and constitutes appendix E to the present document. The "Ascot Workshop" concluded:

"The probability that K12 organisms carrying viral DNA inserts could represent a significant hazard to the community is so small as to be of no practical consequence...". Viral genomes or fragments thereof, cloned in E. coli K12 using approved plasmid or phage vectors pose no more risk than work with the infectious virus or its nucleic acid and in most, if not all cases, clearly present less risk. In fact, the workshop participants agreed that cloning of viral DNA in E. coli K12 may provide a unique opportunity to study DNA generally reduced risk, the biology of extremely pathogenic and virulent viruses.

On April 6-7, 1978 (as announced in the Mar. 17 Federal Register), an RAC-sponsored working group composed of distinguished American microbiologists met to review the report of the Ascot Workshop. The report of this working group is appendix F. The group unanimously endorsed the Ascot report, with certain minor amendments. Their report was presented to the RAC, was unanimously accepted, and has been substantially adopted in part III of the PRG-NIH.

Characterised and Purified Clones. Concern was expressed by several commentaries about the revisions in the PRG-RAC which would allow the local IBC (with notification to be sent to NIH) to reduce either the biological or physical containment level by one step if (1) the DNA is 99%-percent purified and shown to be free of harmful genes before its insertion into a recombinant molecule or (2) the clone replicating the DNA is rigorously characterised and free of harmful genes. In the original guidelines, the reduction in case (2) could only be done with prior NIH approval.

There was support from several commentators for the changes in this subsection. The rationale is explained in the PRG-RAC and the PRG-NIH:

Many of the risks which might conceivably arise from some types of recombinant DNA experiments, particularly shotgun experiments, would result from the inadvertent cloning of a harmful sequence. Therefore, in cases where the risk of inadvertent cloning the "wrong" DNA is reduced by prior enrichment for the desired piece, or in which a clone, made from a random assortment of DNA's, has been purified and the absence of harmful sequences established, the containment conditions for further work may be reduced.

Some commentators noted the ambiguity and difficulty attendant in the phrase "free of harmful genes." The aforementioned EMBO Committee reports that "several national guidelines for recombinant DNA research state that the containment level may be relaxed once a cloned DNA fragment has been biochemically characterized and shown to be free of harmful genes (NIH guidelines) or devoid of any known pathogenic characteristic (EMBO guidelines) reducing containment for experiments with many DNA's, has been purified and the committee believes the latter to be a more feasible requirement, but neither can readily be met, and the committee finds it difficult to suggest what sorts of experimental tests might be devised to meet these requirements."

The terms "characterized" and "free of harmful genes" are unavoidably vague. However, footnote 3 of the PRG-NIH goes on to list five types of data which are not considered in making this determination.

Some commentators were also concerned that this granting of additional authority to the local IBC's for single-step lowering in containment levels might be the introduction of recombinant DNA's into human cells, using viruses as vectors, were unwarranted. The EMBO Standing Advisory Committee on Recombinant DNA Research wrote:

In experiments involving the introduction of foreign DNA into cultured cells of animals using DNA viruses as vectors, biological containment is assured by the very restricted permissive conditions for the host cells; the only routes by which the recombinant molecule might escape are by chance infection of a contaminating microorganism or within a viral capsid and the size of the recombinant molecule may well preclude its encapsidation... For example, cloning of mouse DNA using polyoma virus as a vector in mouse cells as well mouse cells as well mouse cells and mouse cells and mouse cells and mouse cells and mouse cells and mouse cells and mouse cells and mouse cells and mouse cells and mouse cells and mouse cells and mouse cells and mouse cells and mouse cells and mouse cells and mouse cells and mouse cells and mouse cells and mouse cells and mouse cells... The EMBO Committee finds the proposals for this class of experiments in the revised NIH Guidelines not sufficiently discriminating because they would impose unnecessarily high levels of physical containment for experiments with many eukaryotic DNA's.

Discuss earlier within the present document was the Ascot Workshop report (appendix E) and the report of the Working Group that met on April 6-7, 1978 (Appendix F). The recommendations of the Working Group have been accepted and incorporated into the PRG-NIH.

Plant Host-Vector Systems. Discussed earlier was the Workshop on Risk Assessment of Agricultural Pathogens, held on March 20-21, 1978, under the sponsorship of USDA, NSF,
and NIH. This section of the PRG-NIH has been rewritten on the basis of the Workshop report (see Appendix G of the present document) and the PRG-RAC (see App. A). To assist further in the consideration of experiments under the guidelines, NIH reviewed all experiments supported by NIH as of December 15, 1977, and characterized them in the PRG-NIH (see App. B). This shows the containment levels required for these experiments under the current guidelines, the PRG-RAC, and the PRG-NIH.

The major areas where changes have occurred in the PRG-NIH include the five categories of exempt experiments and those other classes of experiments for which containment levels are lowered. Many of the experiments under the current guidelines would be exempt under the "Exemptions" section of the PRG-NIH, including those in which recombinant DNA molecules are not in organisms or viruses, are from a single nonrecombinant or viral source, or are from species that exchange DNA by known physiological processes. These exemptions are proposed because evidence has led to the conclusion that the experiments pose no significant risk to health or the environment.

Permissible experiments involving \textit{E. coli} K-12 as a host-vector system in the PRG-NIH may generally be done at lower levels of physical and biological containment. A basis for this is the abundant scientific evidence that \textit{E. coli} K-12 cannot be transformed into a pathogen. (See Pt. III of this document for a summary of the scientific information on the safety of this host-vector system.)

Another reason for reducing containment levels when eukaryotic DNA is inserted "shotgun" into \textit{E. coli} K-12 is new knowledge obtained only recently concerning the significant difference between prokaryotes and eukaryotes in the way proteins are synthesized. This newly discovered phenomenon of "intervening," or "spacer," sequences in eukaryotic DNA (1) is discussed in footnote 13 to the "Introduction and Overview" of the accompanying decision document. It makes the expression of eukaryotic DNA inserted "shotgun" into \textit{E. coli} K-12 using "nonengineered" plasmids less likely than had been postulated 2 years ago before the phenomenon of "intervening" sequences in eukaryotes was discovered.

In the PRG-NIH, containment levels have been significantly reduced for the use of viruses as vectors and as a source of DNA for insertion into \textit{E. coli} K-12. The basis for this was the strong support at the public hearing in December 1977 for a scientific analysis of the use of viruses in these experiments. As a result, a meeting sponsored by NIH and the European Molecular Biology Organization, held in Ascot, England, January 1978, provided a rationale for revising containment levels for recombinant DNA experiments involving viral DNA. On the basis of the NIH/EMBO report and a workshop supported by the NIH, the RAC at its April 1978 meeting recommended a complete revision of the sections of the guidelines dealing with viral DNA that is largely reflected in the PRG-NIH. The bases for these revisions are explained in detail in the reports of the Ascot Conference and the NIH working group which appear in Appendices E and F. The Ascot conclusions relating to the insignificance of the hazard associated with viral DNA inserts in \textit{E. coli} K-12 are quoted on page 108.

Few recombinant DNA experiments have been conducted with viral DNA, since the overly stringent containment levels of the current guidelines greatly inhibited their use. Under the PRG-NIH, such work would be carefully monitored to insure that any new information on safety or risk were quickly reviewed and any appropriate amendments to the guidelines were made.

Another major area where containment levels have been reduced involves experiments with plant DNA. At the December public hearing of the Advisory Committee to the Director, NIH, scientists from that scientific community strongly recommended that the guidelines pertaining to experiments with plants be reviewed. In February, NIH, USDA, and NSF convened a meeting of plant scientists who made a number of recommendations to the RAC. The RAC's recommendations from its April 1978 meeting are reflected in the PRG-NIH.

Few NIH experiments are in this area, and these that are under the PRG-NIH using vectors are closely monitored by the NSF and USDA to determine what work is being done. Again the recommendations comport with safety requirements to assure no significant risk to health or the environment.

In effect, all of the recommendations for permissible experiments and for those exempt from the guidelines are based on new scientific findings or on reassessment of previous information. Evidence indicates that work should proceed because many recombinant DNA molecules produced in laboratories mimic those already present in nature. The PRG-NIH focuses on areas of experimental work that need special attention for the possibility of potential hazard. Work in progress that is expected to yield valuable new information will need to be monitored—for example, experiments in which "engineered" systems should permit intentional expression of ge-
The changes in the eukaryotic host-vector systems reflect in large part the recommendations concerning the interaction with viruses and plants. As noted in the original EIS, recombinant DNA experiments here involve the use of systems in which the host cells have little or no chance of escaping from the laboratory as an E. coli cell might.

New scientific information indicates that a variety of organisms, such as the lower eukaryotes fungus and yeast, may be useful hosts for experiments with recombinant DNA’s; and useful vectors are now becoming available for these systems. Hence, this section of the guidelines has been expanded to detail safe use of these systems. In addition, because of the ability to use synthetic DNA in recombinant DNA experiments, a new section has been added to the PRG-NIH to specify safe containment levels for this research.

NIH has been mindful of the concerns of those who requested that the EIS on the original guidelines contain further information on individual experiments. We have tried to meet that need by the analysis provided in this section and in Appendix B.

At the public hearing on the PRG-RAC in December 1977, some critical comments were directed at NIH’s EIS on the original guidelines. Most of the comments centered on NIH policies vis-a-vis permissible experiments. An analysis of those comments appears as Appendix C.

Because of the critical importance of E. coli K-12 in recombinant DNA research, an assessment of the use of this organism in recombinant DNA experiments follows.

**Background on the use of E. coli K-12 in recombinant DNA experiments**

*Escherichia coli* designates a range of bacterial strains. Each is adapted to live in a certain habitat. Its habitats are found primarily in the vertebrate gut, and it cannot long survive elsewhere—for example, in sewage. Some strains are pathogenic, causing disease in the gastrointestinal tract of man or other animals. (3) One strain of *E. coli*, called "K-12," has been used in laboratory experiments for over 50 years. (2) It is not known to have ever caused disease. (3) K-12 became the favorite organism for genetic research because it reproduces rapidly and thrives under controlled laboratory conditions. No living creature is known more thoroughly. Its single chromosome can be easily manipulated by genetic means, permitting its gene structure to be mapped. This work has greatly advanced understanding of how genes express and regulate inherited characteristics.

The chromosome of K-12 is a circular molecule of DNA with about 4 million subunits. These compose 3,000 or 4,000 genes, of which about 650 have been identified and assigned locations. (5) An arc of the genetic map of *E. coli* K-12 is shown below. (5) The NIH guidelines limit the vast majority of recombinant DNA experiments to the use of *E. coli* K-12 as host for the foreign genes. This is because the unaltered organism is non-pathogenic and well known in its natural properties—both factors lending confidence that it can be handled safely.
There are those, however, who view the ubiquity of _E. coli_ in vertebrates as an argument against the use of even the _K-12_ strain as a host for foreign DNA. Concern has been expressed, for instance, that the bowels of persons on antibiotics, ill persons, human infants, or members of other species may be susceptible to colonization. However, if _E. coli_ K-12 can survive in a person or animal, it might confer genetic characteristics to harder bacterial inhabitants.

Scientists engaged or interested in recombinant DNA research have addressed these concerns in three ways—first, through guidelines specifying practices and conditions of containment for experiments classified according to the presumed hazard; second, through attempts to develop safer hosts and vectors; and third, through risk-assessment studies. The results of a workshop held in June 1977 at Falmouth, Mass., to evaluate the potential risk of recombinant DNA experimentation with _E. coli_ K-12 will be discussed below.

The Evidence That _E. Coli_ K-12 Is Nonpathogenic. The laboratory variants of _K-12_ permitted in recombinant DNA experiments have never been reported to cause disease, even in laboratory workers. _K-12_ has been grown in large quantities—up to hundreds of liters containing as many as a trillion particles—without incident. These cultures have been produced in countless laboratories throughout the world and under containment conditions lower than the minimal ones in the NIH guidelines. _K-12_ has none of the properties generally associated with pathogenic bacteria. It does not—

- survive and multiply readily in natural environments,
- spread from animal to animal or plant to plant,
- multiply readily on body surfaces or intestines and lungs,
- penetrate animal cells or spread through animal bodies,
- produce a toxin or otherwise alter other living things to cause disease, or
- resist normal body defense mechanisms.

Even after as many as 10 billion _K-12_ organisms have been ingested, their multiplication in normal humans is only transient, and after a time none can be recovered. Thus, _K-12_ does not establish itself as a permanent resident of human beings. On the other hand, _K-12_ can reside under abnormal conditions, as during antibiotic therapy.

A micro-organism, in order to cause disease, must have the capability to do so, as well as the ability to establish itself in the body. It is difficult to conceive how _K-12_, itself nonpathogenic, could become pathogenic as a result of genetic manipulation. Highly attenuated, it is known only to inhabit the biological laboratory.

Even when genetic determinants of pathogenicity in other _E. coli_ strains were introduced into _K-12_, no instance of capacity to induce diarrheal disease or urinary tract infection could be detected. Indeed, the number of characteristics that a microbe must have in order to cause disease is believed to be great, not to mention additional characteristics needed to produce an epidemic.

Transfer of Foreign DNA from _E. coli_ K-12. While it would appear impossible to render _E. coli_ K-12 pathogenic by the introduction of foreign DNA, there is still to be considered whether the inserted fragment could be transmitted to another bacterium with which the _K-12_ comes in contact, including other strains of _E. coli_. Such a transmission might convert the recipient into a pathogen or render a pathogen more viable. The case of plasmid vectors is considered first.

Plasmids are intracellular particles composed of DNA and not dependent on chromosomes for their replication. Hence, they can be used as vectors, or vehicles, for transporting foreign DNA into the bacterial host, where they multiply and propagate the genes they bear. Certain plasmids (called "conjugative") are inherently capable of migrating from one bacterial cell to another. These are prohibited for nearly all recombinant DNA experiments. Only plasmids not capable of or barely capable of spontaneous intercellular migration ("nonconjugative") may be used.

The nonconjugative plasmid's ability to migrate is augmented if the cell harboring it is invaded by a conjuga-tive plasmid, which may confer this property. Then even the non-conjugative plasmid may become a potential DNA-bearing invader. It has been calculated, however, that the chance of this occurring with certain _K-12_ plasmid systems is less than 1 in 10^8 (10 quadrillion) _K-12_ 's surviving per day in the intestine of warm-blooded animals. The probability is even lower in sewers, sewage treatment plants, and wastewater. It should be noted that since most of the estimates of probability are based on data obtained under laboratory conditions, animal and human feeding studies are needed to verify the predictions.

Consideration must also be given to the question of transfer of foreign DNA from the initial _K-12_ host to other bacteria by means of bacteriophage vectors. Bacteriophages are viruses that infect only bacteria. They could escape the laboratory either as mature infectious particles or in bacterial hosts in which the phage DNA is carried as a plasmid or within the DNA of the host.

The survival of phage DNA when released as infectious particles depends on their stability in nature, their infectivity, and the probability of effective encounters with naturally occurring _E. coli_. The bacteriophage used in recombinant DNA experiments is known as _lambda_. It is considered very unlikely to survive and to infect resident _E. coli_ in animals and humans, being highly sensitive to stomach acid, reluctant to infect smooth _E. coli_ cells (the type normally found in the gut), and susceptible to drying, as would occur if it escaped into the air. Moreover, _E. coli_ vulnerable to _lambda_ is uncommon in nature. Infective _lambda_ ingested in large amounts (10^14, or 100 billion, particles) could not be detected in human feces.

Establishment of _lambda_ as a resident of the _E. coli_ host cell's DNA is a well-known example of natural recombination. In certain cases, it is a frequent event, as likely to occur as not. Hence, this mode of escape would be the preponderant laboratory hazard.

However, most variants of _lambda_, used (or under consideration for use) in recombinant DNA experiments have a much reduced ability to become incorporated. Here the probability drops to 10^{-5} or 10^{-4} in 100,000 or 1,000,000. The estimates for containment in the use of bacteriophage host-vectors, while not exact, are sufficient to assure that the probability of transferring a foreign DNA fragment from the original _K-12_ host to other bacteria is remote.

Ability of _E. coli_ K-12 To Survive and Spread in Nature. Thus far, the suitability of _K-12_ for recombinant DNA experiments has been considered in relation to its ability to do harm
either directly or through transfer of a foreign DNA fragment to another bacterial cell. These properties will depend on the ability of K-12 to survive, multiply, and infect other living organisms. An inability of K-12 to do both would mean that K-12 is poorly equipped to survive in natural environments; but if it should survive and multiply, it is still unlikely to infect living things. E. coli are seldom spread by aerosols; they are primarily spread by the fecal-oral route. An inability of E. coli to contaminate food and water. Between 10^9 and 10^10 (1 million to 1 billion) cells of pathogenic E. coli are required to cause disease (12,25). In other words, at least a million bacteria would be required to cause disease in a single person if some K-12 did become pathogenic.

The guidelines emphasize protection of laboratory workers because they are the persons most at risk. They are also the most likely means by which recombinant DNA might be spread. Should a worker carry such agents out of the laboratory, however, the probability that the agent will still be alive after the exposure is still very low, and the risk of a resulting epidemic is virtually nonexistent. There is abundant evidence for this assertion. It has long been known that the separation of sewage from food and water has been practiced for millennia because of enteric bacteria such as E. coli.

The following excerpt from a letter by Roy Curtis III to Donald S. Fredrickson discusses the K-12 strain of E. coli in relation to infectivity.(13)

In terms of communicability of E. coli K-12, we know that enteric diseases caused by enteropathogenic E. coli and various strains of Shigella, Salmonella and Vibrio are transmitted by contaminated food and water and that manifestation of disease symptoms requires consumption of approximately 1 million bacteria. Such enteric diseases are seldom spread by aerosols. Indeed, it is well known, for example, that cages of mice infected with Salmonella can be housed in the same room with uninfected mice which remain uninfected. The finding that E. coli cells can be recovered from the nasopharynx of approximately 5 percent of these humans tested might suggest that aerosol spread could occur. Such E. coli cells, however, are only intermittently present in the nasopharynx and are usually found at concentrations too low to initiate an infection even if they were representative of a pathogenic strain. They most likely get into the nasopharynx due to poor personal hygiene. After learning of these observations quite some years ago, I monitored my nostrils and skin for the presence of those E. coli K-12 strains I was studying. I was surprised in detecting these strains about 10 percent of the time when the monitoring was done at the end of the work day, but never obtained positive results when the monitoring was done the next morning. I should hasten to add that my research with E. coli K-12 at that time had involved a number of other aerosol-generating procedures on an open lab bench: procedures and conditions which are not permitted by the NIH Guidelines. These results, preliminary as they are, nevertheless suggest that E. coli K-12 does not colonize the nasopharynx. Based on these observations, the fact that E. coli’s normal ecological niche is the colon and the fact that transmission of enteric disease is by ingestion of contaminated water and food, I doubt that E. coli K-12 could be converted to an air-borne pathogen by introduction of recombinant DNA. In terms of the more usual means for spread of enteric pathogens, it is evident that enteric diseases are very well controlled in the United States by sanitary engineering, even though there have been reports of poor water quality in some parts of the country and higher-than-desired levels of pollution of rivers, streams, etc. There is however, a concerted effort to improve biological wastewater treatment and thus lessen pollution and improve water quality. Even if there were a natural catastrophe such as caused by an earthquake, tornado, hurricane, etc., it is unlikely that E. coli K-12 containing recombinant DNA could initiate or sustain an epidemic in view of K-12’s inability to colonize or overcome host defense mechanisms.

Seeking a consensus on the matter of risk assessment in recombinant DNA research, the guidelines refer to the use of E. coli, the National Institutes of Health sponsored a workshop in Falmouth, Mass., on June 20-21, 1977. In attendance were approximately 50 invited participants and observers, from the United States and abroad, including experts on all aspects of infectious disease. The following excerpt from a letter by the workshop chairman, Sherwood L. Gorbach, to Donald S. Fredrickson summarizes the principal conclusion:

CONSENSUS AGREEMENT

An important consensus was reached at the assembled group which I felt was of sufficient interest to be brought directly to your attention. The participants arrived at unanimous agreement that E. coli K-12 cannot be converted into an epidemic pathogen by laboratory manipulations with DNA inserts. On the basis of extensive studies already completed, it appears that E. coli K-12 does not implant in the intestinal tract of man. There is no evidence that non-transformable plasmids can be spread from E. coli K-12 to other host bacteria within the gut. Finally, extensive studies in the laboratory indicate virulence is not determined by insertion of known plasmids and chromosomal segments coding for virulence factors, using standard bacterial genetic techniques, have proven unsuccessful in producing a fully pathogenic strain. As a result of these discussions, it was believed that the proposed hazards concerning E. coli K-12 as an epidemic pathogen have been overstated. Such concerns are not compatible with the extensive scientific evidence that has already been accumulated, all of which provides assurance that E. coli K-12 is inherently enfeebled and not capable of pathogenic transformation by DNA insertions.

The entire letter from Gorbach is quoted in the NIH environmental impact statement, part II, appendix M.27. The proceedings of the Falmouth workshop on risk-assessment have been published in the May 1978 Journal of Infectious Diseases.

There remains the question whether the insertion of a foreign DNA fragment into K-12 will significantly alter the bacterial cell. Aside from the matters of control and safety, the most critical question is the issue of virulence with regard to survival and multiplication, or the ability of the plasmid and bacteriophage vectors to be spread. The improbability of converting K-12 to a pathogen has already been discussed. Changes in vital ability such as metabolism or ability to multiply would be expected to involve not only the changes in the K-12 itself, or the plasmid or bacteriophage, but also the nature of the environment in which the K-12 finds itself. The subject is discussed in the section of the document entitled “Risk and Benefits of Recombinant DNA Research.”

Attenuated K-12 Systems. Theoretically, the most desirable bacterial recipient of recombinant DNA would be a species uniquely adapted to carefully controlled laboratory conditions and unable to survive or transmit DNA to other organisms in any natural environment. This means that it should be unable to establish itself as a long-lived and multiplying resident in or on living things, or in soil or water. In addition, these properties should not be significantly altered by recombination of the bacterium’s DNA. The organism should also, of course, lend itself to manipulation for successful execution of experiments.

No bacterium meeting all these requirements is known. It is possible that no such creature exists in nature. Available bacterial systems must be evaluated for relative safety and utility, depending on the extent to which they approach the ideal. The following summary of knowledge concerning K-12 and its known plasmids and bacteriophages indicates that these systems measure up well with the ideal criteria, and can therefore be recommended for use in recombinant DNA research.

The K-12 systems, extant and projected, are known as EK1, EK2, and EK3, referring to increasing degrees of attenuation. The guidelines permit the use of all for laboratory experiments whose potential for hazard is regarded as nil, low, or minimal. For experiments judged to have a somewhat higher (though still conjectural) potential for hazard, the guidelines require the further attenuated system EK2. Here, properties of the K-12 and the vectors must be so modified as to minimize the chance of the vector surviving in its host outside the laboratory and migrating to other hosts. EK3 systems are even stricter, requiring, for example, the use of vectors that cannot propagate outside the host. So far, no EK3 systems have been certified. In the proposed revised Guidelines (PRG-NIH), the EK
systems are retained within the broader host-vector systems (HV) classification, providing more specificity.


A very large safety factor is added by the provision in the present guidelines for biological containment. All work with mammalian DNA must be carried out in E2K strains, which have a drastically impaired ability to multiply, or to transfer their plasmid, except under very special conditions provided in the laboratory. The presently certified E2K strain has several stable mutational defects (e.g., deletions) that prevent it from multiplying under the nutritional conditions of the gut. But the protection goes much further, and reaches a degree that is unprecedented in the annals of man's exploration of potentially hazardous new materials: this material has been coded for self-destruction. For example, these mutant plasmids, which are a constituent of cell wall; and without it they cannot continue to grow and expand but cannot form more wall. and so they quickly burst. Accordingly, under conditions similar to those in the gut such an E2K strain not only fails to multiply, but less than 1 in 10<sup>6</sup> cells survives after 24 hours—and it would be an extraordinarily sloppy laboratory accident that would result in ingestion of as many as 10<sup>9</sup> cells. In addition, while the cells are dying, in the absence of diaminopimelate they are severely impaired in their ability to transfer plasmids to other, well-adapted cells—and this is the important point for the danger of spreading harmful genes. Finally, not only the cells but also the plasmids being used to carry recombinant genes are also weakened mutant derivatives, selected for severe impairment of their ability to be transmitted from the host cell to another cell.

We thus see that, even with a strain known to carry the gene for a potent toxin, the production of disease in a laboratory worker would require the compoundung of two low probabilities: that the strain will initiate an infection and that it will survive long enough to cause harm despite its several disadvantages—that of being a plasmid, a plasmid is virulent, and that of carrying the burden of foreign DNA, and that of carrying the very large burden of being a suicidal E2K strain.

The criteria for NIH certification of an E2K system have been defined and enlarged during the past year. Extensive data are required and very demanding standards have been set. Such organisms are being designed and constructed by NIH contractors and other interested investigators. Their use in recombinant DNA experiments is not allowed until they have been certified by the Director, NIH, upon recommendation by the Recombinant Advisory Committee. The NIH environmental impact statement describes the criteria for certification and lists the certified E2K systems as of July 1977. It should be noted that the same depth of experience with K-12 that recommends its utility as a host for recombinant DNA experiments is central to the ability to manipulate it for the purpose of improving its safety.

An important recent paper was published by two British workers, Petrochelliou and Richmond on the absence of plasmid or E. coli K-12 infection among laboratory personnel. In testimony before the Subcommittee on Science, Technology, and Space of the Senate Committee on Commerce, Science, and Transportation, on November 10, 1977, Dr. Oliver Smithies, professor of medical genetics and genetics at the University of Wisconsin, interpreted the Petrochelliou and Richmond results as follows:

Two weeks for over 2 years these workers tested the foci of five laboratory persons who had been using without special precautions the laboratory strain of E. coli, K-12, together with a transmissible plasmid. Neither the E. coli K-12 nor the transmissible plasmid was ever found in the foci of these tests. Transmissible plasmids are naturally found in small circular pieces of DNA that can replicate inside bacteria and which, in nature, transfer genes between them. So, with E. coli K-12 and a transmissible plasmid, the risk of the plasmid or its host K-12 getting into the foci and surviving to any appreciable extent is less than one per laboratory worker per 10 years of lab work, even when no special precautions are taken.

Now, under the NIH guidelines, none of the even conceivably hazardous experiments are performed in this type of E. coli, K-12. Such experiments require a specially weakened strain, chol 1776, which introduces a safety factor for survival of greater than 100 million. Chol 1776 has been proven by tests to survive 100-million times less well than K-12.

In addition, such experiments require the use of a nontransmissible plasmid which introduces a safety factor for transfer of the plasmid to other bacteria of about 100 million.

Let me emphasize again that this type of work requires a nontransmissible plasmid; that is, a plasmid derived from a transmissible plasmid by eliminating the mechanisms for transfer of the plasmid between bacteria.

So the risk of chol 1776 strain of E. coli K-12 surviving in the foci or of the recombinant DNA being transferred to some other bacteria becomes less than one chance per 100,000 laboratory workers working for 10,000 years without special physical precautions.

This is what is meant by a "negligible risk." When we consider that the guidelines require also very special physical precautions, you can see why I think the risk is no longer worth considering.

REFERENCES

IV. ROLES AND RESPONSIBILITIES

Analysis of Current Guidelines

The Guidelines contain a large section, Part IV, defining the roles and responsibilities of individuals and institutions in assuring compliance with required containment levels. The procedures described are primarily directed at grantees of the National Institutes of Health. Similar procedures are in force for work within NIH laboratories and for work sponsored by NIH under contract.

The principal investigator is required to assess any potential biohazards, to institute appropriate safeguards and procedures, to minimize effects of possible accidents, to plan, to train and inform all personnel, and to report any accident or any serious or extended illness of a worker. All of these must be carried out on a continuing basis. Thus, the primary responsibility for conducting experiments according to the Guidelines is in the investigator's hands.

Further, in applying for grants to carry out experiments with recombinant DNA molecules, the investigator must include an estimate of the potential biohazards and a statement of the containment procedures to be used. The application must include certification of the existence and availability of appropriate facilities, procedures, and training. The Guidelines indicate that institutions in which recombinant DNA experiments are carried out must establish biohazard committees that examine equipment and facilities and certify their compliance with the requirements. Such committees will also serve as a source of advice and reference on physical containment facilities, on properties of biological containment, and on training of personnel.

According to the Guidelines, the certification and the investigator's assessment of the hazard and containment would be considered by NIH study sections during the scientific review of the application. The Guidelines leave flexible the question of resolving any differences between the investigator's evaluation and that of the study section. The Guidelines do state, however, that if differences cannot be resolved, the matter should be referred to the Recombinant Advisory Committee or the NIH Office of Recombinant DNA Activities.

Application of the guidelines to work not supported by NIH

Several agencies of the U.S. Government other than the National Institutes of Health provide support for biological and medical research. Some of these currently sponsor recombinant DNA experiments, and others may do so in the future. Activities of the research agencies represented by the Federal Interagency Committee on Recombinant DNA Research were reviewed by the Committee in the fall of 1976. All member research agencies adopted the NIH Guidelines and standards, including the National Science Foundation, the Department of Agriculture, the Energy Research and Development Administration, the Department of Defense, the National Aeronautics and Space Administration, and the Veteran's Administration.

Several conferences have been held at NIH and at other relevant Government agencies with representatives of private industry in the United States. As best determined by the Federal agencies and the Veterans Administration, these conferences conducted in the private sector comply with the physical and biological standards of the NIH Guidelines. Relevant industries have agreed to follow the Guidelines on a voluntary basis.

The issue of recombinant DNA research has been studied by national and international bodies in many countries. In most cases some form of control has been recommended, but nowhere has a total ban on the research been advocated. Canada, the Federal Republic of Germany, France, the Soviet Union, and the United Kingdom have issued guidelines that differ in detail but in some substantial respects are substantially similar to the NIH Guidelines. Other countries are generally following the NIH or U.K. Guidelines, including Denmark, Israel, the Netherlands, Sweden, and Switzerland. The International Council of Scientific Unions and the World Health Organization have urged nations to adopt the principles embodied in these two sets of guidelines. The U.K. Guidelines have been endorsed by the European Science Foundation and the European Molecular Biology Organization.

Scientific and governmental activities comparable to those in the United States have been under way in the United Kingdom since January 1976. A working party established at that time recommended that recombinant DNA research in the United Kingdom be permitted to continue under appropriate controls. In August 1976 a followup working group chaired by Sir Robert Williams issued a report establishing guidelines. In Canada, in March 1976, a special committee of the Canadian Medical Research Council recommended guidelines to govern the handling of recombinant DNA molecules in Council-sponsored research. The Council adopted these guidelines in February 1977.

Many other nations have reviewed recombinant DNA activities to determine what measures were necessary for safety. With the urging of regional and international bodies, most have adopted the NIH or U.K. Guidelines as a basic framework for safety practices and procedures.

Alternatives: RAC-Proposed Revisions

Part IV (Roles and Responsibilities) of the PRG-RAC is described below. As in the current (1976) Guidelines,
this part of the PRG-RAC was designed to provide an administrative framework for implementation.

**Institution**

In the PRG-RAC as compared with the current Guidelines, several changes were proposed in the responsibilities of the institution. Responsibilities that were added or further detailed included (1) a requirement for insuring the training of research personnel and the use of good microbiological technique, and (2) a requirement to determine the need for medical procedures, with recommendations of possible specific practices.

**Institutional biosafety committees**

Membership of the IBC's was clarified by a recommendation to include other than scientific members. In the PRG-RAC, institutional biosafety committees (called "biohazards committees" in the current Guidelines) are given the discretion to approve single-step inductions in containment levels for experiments with characterized clones and purified DNA. The IBC's would be required to notify the NIH Office of Recombinant DNA Activities (ORDA) of these approvals.

**Biological safety officer**

Institutions at which P3 and P4 level recombinant DNA work is conducted would be required to have a biological safety officer, whose specific roles and responsibilities are outlined.

**Principal Investigator**

The role and responsibilities of the principal investigator would remain basically the same, except for the important addition of a requirement for training in microbiological techniques. Responsibility for the determination of the practices necessary for medical surveillance would be relocated to the institution.

**NIH responsibilities**

**Office of the Director**

The responsibilities of the Director remain unchanged. A sentence has been added that clarifies the Director's authority to implement the Guidelines and to be the final arbiter in their interpretation.

**Recombinant advisory committee**

There were no changes in the current responsibilities of the RAC. There were, however, clarifications of the scope of some duties—for example, the certification process. The language of the 1976 Guidelines caused some confusion about the certification of EK2 (HV2) and EK3 (HV3) host-vector systems. In practice, the certification process, clarified in the PRG-RAC, involves a two-step procedure: (1) The RAC's recommendation to the Director, NIH, that a particular host-vector system be certified; and (2) certification of the system by the Director. The rationale for the procedure is that it allows the Director to solicit the opinions of additional experts before making a financial decision on certification.

The RAC's authority to recommend exceptions from the prohibitions was also clarified. The 1976 version of the Guidelines envisioned the possibility of the RAC's recommending an exception to the 10-liter limit on culture volume for recombinant DNA's known to make harmful products. The proposed revision would extend the possibility of an exception to the five other classes of currently prohibited experiments.

The general rationale for this addition is twofold: the RAC's inability to foresee all possible future circumstances and its desire to specify, within the limits of strict safeguards, the possibility of an exception for compelling social or scientific reasons. A more immediate and specific justification for the paragraph on exceptions from the prohibitions is that the risk-assessment studies recently done for a clearer understanding of the potential biohazards of recombinant DNA research may be technically prohibited by the current Guidelines, unless there is a mechanism for approving exceptions.

**Alternatives: Public Commentators**

**Institutional responsibilities**

This section of the Guidelines drew considerable comment directed to the roles and responsibility of the local institution and its several constituents. Generally, commentators requested more information and greater clarification of the structure and operation of the IBC, the function of the biological safety officer, and the duties of the institution. The suggestions and comments were carefully considered, in view of the importance of this section to successful implementation of the Guidelines and the safe conduct of research.

NIH has a special responsibility for leadership in developing and promoting safety programs relevant to recombinant DNA experiments. Accordingly, as in 1976, another committee chaired by Dr. W. Emmett Barkley, Director of the National Cancer Institute's Office of Research Safety, was convened to address concerns raised. As a result, and in response to a number of commentators' requests, the substance of Appendix D has been revised and republished as a supplement to the Guidelines. The revised Guidelines also retain requirements for emergency plans to cover accidents and improvements for training of all recombinant DNA researchers in safe laboratory procedures.

Since the intent of this section, as before, is to integrate safety practice into the conduct of recombinant DNA research and to assign responsibilities for this to the principal investigator, institution, IBC, and biological safety officer. It is important that these responsibilities be stated in an unambiguous manner in response to any investigator. Part IV has been restructured to present some of these functions in greater detail and clarity. The appendices contain additional complementary information on roles and responsibilities, including material for IBC's and biological safety officers.

**Expanded Responsibilities.** In response to several comments, the review of research has been broadened in the PRG-NIH to cover all recombinant DNA research at an institution receiving NIH funds for this purpose, whether or not the specific recombinant DNA project is funded by NIH. While this increases the responsibility of the institution and the IBC, it is believed that the overall safety of recombinant DNA research will be enhanced. To reflect more closely the spirit of the Guidelines, the name "institutional biohazards committee" is proposed to be changed to "institutional biosafety committee."

Several generic comments deserve to be highlighted, as they represent significantly increased authority to be delegated to the institution. In 1976 the RAC did not accept commentators' suggestions to require local committees to make an independent evaluation of the containment levels required by the Guidelines for individual research projects. It was therefore stated in the 1976 Decision that NIH would not require local institutions to have their committees perform this function, although they would not be prohibited from doing so. Commentators have now noted that an IBC, in order to accomplish its mandated responsibilities under the 1976 Guidelines, including the review of recombinant DNA research projects, must implicitly determine containment conditions. In order to clarify the committee's role, the assessment of appropriate containment levels is now made an explicit responsibility of the IBC.

In addition, institutions through their biosafety committees would be given increased responsibility for primary overview of this research, as they have been delegated the authority to approve or disapprove proposed recombinant DNA projects. NIH, through ORDA, will conduct a review of institutions' actions, upon registration of the projects, to ensure compliance with the NIH Guidelines, thereby maintaining a national standard. This action has been in response to several comments calling for increased local responsibility and a simpler adminis-
In view of the high priority of Federal surveillance to enforce these standards, it is essential to increase the authority and responsibility of the local institution. It was requested that the IBC's have a role if legislation in this area is adopted. This concept is endorsed by the House Committee on Interstate and Foreign Commerce in its Bill Report of March 24, 1978, on the Recombinant DNA Act:

It is the view of the committee that the appropriate portions of the desired substantive requirements of section IV of the NIH Guidelines are a reasonable model upon which the Secretary could base administrative regulations. In particular, the current practice in the NIH Guidelines of delegating to local biohazards committees most of the responsibility for the inspection of facilities and the approval of the specific safety requirements appropriate to each project or activity is an effective and relatively inexpensive administrative mechanism.

A number of recommendations were received regarding the membership of IBCs. In 1976, suggestions were made for broadening IBC representation to cover not only various disciplines related to recombinant DNA technology, safety and health, but also to include members knowledgeable in applicable laws and regulations, standards of practice, community attitudes, and health and environmental considerations. These diverse points of view were either included in the PRG-NIH that "no IBC may consist entirely of persons who are officers, employees, or agents of, or are otherwise associated with the institution, apart from their membership on the IBC."

A number of other recommendations were received from public commentators relating to more specific issues concerning the various responsibilities of the institution and its constituents. These recommendations and the PRG-NIH decision are considered below under the appropriate headings.

**Institution.** A number of points were raised by commentators concerning health monitoring by institutions. NIH was requested to develop a model for institutional medical surveillance for recombinant DNA research workers. An NIH committee is reviewing this area and has made recommendations as to what such a program might include. This proposal, which calls for monitoring illnesses, collecting serum samples, and keeping a register of agents handled, is responsive to several suggestions received on this issue, and has therefore been adopted in the PRG-NIH. Additionally, Appendix D will provide additional information on medical surveillance.

A collaborative effort has been initiated between NIH and the Center for Disease Control (CDC) to establish a mechanism for providing advice, consultation, and assistance regarding major accidents in laboratories conducting recombinant DNA research. It was not considered necessary to have a standing "strike force" suggested by one commentator but in the event of an emergency, a team of experts from NIH and CDC could be formed to respond.

The issue of medical monitoring is one of considerable interest to NIH. This is a general problem not unique to DNA research. As one commentator noted, a routine health monitoring and reporting program might well be instituted for personnel engaged in assessing research besides recombinant DNA, such as tumor viruses and pathogenic organisms. The state-of-the-art, however, is primitive in terms of what can be done to monitor workers' health, and particularly in the area of recombinant DNA research, where there is no known hazard.

Grievance procedures for workers under the Guidelines were requested, but this is not considered necessary, as the rules and regulations of the Occupational Safety and Health Act (OSHA) already provide such a mechanism. OSHA standards and procedures apply to most institutions, so it is not considered necessary to require in the Guidelines that IBCs ensure OSHA compliance. Further, the Federal Interagency Committee on Recombinant DNA Research includes the Occupational Safety and Health Administration (Department of Labor), ensuring cooperation at the Federal level.

Institutional Biosafety Committee. Several commentators requested more detail on IBC duties. This has been accomplished in "Laboratory Safety Monograph—A Supplement to the NIH Guidelines for Recombinant DNA Research." For example, information is included there on facility certification, periodic inspections, and monitoring.

It was suggested that biosafety committee meetings be open to the public. The Guidelines currently require only that the minutes by publicly available. In view of possible discussion of proprietary information and patent rights, meetings cannot always be open. Local committees, however, should consider having open meetings when possible.

The question was raised concerning conflict of interest of local committee members. Addressing this important point, a provision in the PRG-NIH prohibits an individual from being involved in the review of a recombinant DNA project in which he or she was engaged or had a direct financial interest.

**Biological Safety Officer.** Since the passage of OSHA, most institutions have established occupational safety and health departments for biosafety officers. There are no standard certification procedures for such individuals, although their qualifications, in many cases, could be commensurate with those of a biological safety officer. The Laboratory Safety Monograph provides in detail the kinds of qualifications biosafety officers should have.

NIH is developing a training course for biological safety officers and other campus safety personnel. Requests for information should be directed to Dr. Emmett Barkley, Office of Research Safety, National Cancer Institute, NIH.

Principal Investigator. Commentators remain concerned about the quality and uniformity of safety training. NIH is responding to this by placing as a high priority the development of training standards and courses. Currently, NIH is supporting a Working Panel of the American Society for Microbiology (ASM) that is considering standards of training in micro-biological techniques for recombinant DNA research. When a report is submitted to NIH, it will be shared with institutions, IBC's, and principal investigators for their use. National certification, however, should not be attempted until the ASM-NIH criteria for training have been adopted and evaluated.

It should be noted that, aside from the Nuclear Regulatory Commission's standards for training in radiolabel work, there seem to be no other training criteria at present in biomedical research. Thus, the work of the ASM Panel will establish a precedent. For these reasons NIH should proceed carefully and in stages while promoting safety training for researchers. NIH will develop training courses based on these standards and will make them widely available.

**NIH responsibilities.** As in the public hearing on the Guidelines as proposed in 1976, many commentators again urge openness, candor, and public participation in the revision process, emphasizing shared responsibility and accountability from the local to the national level.

**Due-Process Considerations.** A focus of public comment at the December 1977 hearing was on "procedural due process" to ensure public participation in the development of NIH recombinant DNA policies. Much of the public testimony and comment in letters focused on public representation on
committees. Also stressed was the need for public notice of all meetings, and for procedures to ensure public participation in the exercise of responsibilities by the NIH Recombinant DNA Advisory Committee (RAC), the Office of the NIH Director, and the Advisory Committee to the Director (DAC).

Several commentators specifically urged that the Guidelines spell out procedures—

- To develop and promulgate the list of "non-novel experiments" and to amend the list;
- To certify host-vector systems;
- To permit the Director, on the advice of the RAC, to grant exceptions from prohibited experiments (as for risk-assessment studies), and
- To modify the Guidelines in the future.

There were also suggestions that guidance be given on how to deal with infractions of the guidelines. Specifically, one commentator suggested that procedures should outline in detail—

- How charges of noncompliance could be brought;
- How charges of noncompliance would be evaluated;
- What opportunities would be provided for the principal investigator and his institution to defend themselves against charges, and
- What procedures would be available before the termination of funding or other penalties were invoked.

Because of the RAC's key role in the development and monitoring of NIH recombinant DNA policies, a number of comments were directed to the committee's nature and functions. Many commentators focused on its membership, urging that the guidelines define procedures for the nomination and selection of members. Suggestions for potential membership included more representation for certain scientific disciplines, as virology and microbiology; greater representation from the occupational and environmental health and safety community; and more public representation, including perhaps a "dissenter" from current NIH policies.

A number of comments concerned RAC operations. The committee was urged to formalize schedules so that all concerned would know when meetings would be held over the next 2 to 3 years. Further, it was urged that notices and complete agendas be placed in the Federal Register for each meeting, that all documents for committee consideration be made available to the public, and that the NIH pay for public witnesses to attend RAC meetings.

In response to these comments, part IV of the PRG-NIH has been reorganized extensively. The responsibilities from the local to the national level are more clearly stated and defined. For NIH responsibilities, procedures suggest that federal laws have been specified to afford opportunity for public comment. A special appendix to the PRG-NIH includes relevant implementation documents from ORDA that explain the administration of the NIH guidelines at the local and national levels.

Part IV of the PRG-NIH has more clearly defined a structure for responsibilities at those levels, with opportunity for public and scientific participation. It formalizes a process that has been occurring informally. Flexibility, however, remains essential to avoid unnecessary and protracted delays in decisionmaking. Clearly, a full panoply of clearance procedures, including a public hearing, is not essential for most of the functions under the guidelines. For many functions, the need for public review can be met through publication in the Federal Register. For certain functions, comment may be solicited. Because procedures by which policies will be developed at the national and local levels are of key importance, notice is required for major policy initiatives.

Application of the Private Sector. Several commentators spoke on the application of the NIH guidelines to the private sector. Specifically, NIH was urged to provide voluntarily to private industry—

- Advice on interpretation of the guidelines,
- Registration of projects,
- Certification of host-vector systems,
- Advice on the operation of institutional biosafety committees, and
- Protection for patent and proprietary information.

In June 1976 representatives of private industry were invited to NIH to be briefed on the guidelines about to be released. Since their release, NIH has held several other meetings with representatives from the private sector. Commerce Department representatives on the interagency committee played a leading role in working with private industry on adoption of the guidelines. In 1976, NIH has extended other meetings with representatives from the private sector. Commerce Department representatives on the interagency committee played a leading role in working with private industry on adoption of the guidelines. In 1976, NIH has extended other meetings with representatives from the private sector. Commerce Department representatives on the interagency committee played a leading role in working with private industry on adoption of the guidelines. All relevant industries have agreed to abide by those standards. However, many of the services provided to NIH grantees and contractors have not been extended to the private sector. In large part, efforts to do so have been held in abeyance because of possible Federal legislation.

After carefully considering the comments at the public hearing and in letters received, NIH will extend certain added services to the private sector in several of the areas suggested by the commentators. It is still important, despite proposed legislation, that the NIH provide for mechanisms to allow private-sector participation. Further, if legislation is enacted, the NIH guidelines will serve as the basis for regulation that will encompass private industry. Thus, a new section has been added to part IV that provides the opportunity for industry's participation in a voluntary fashion.

Office of the Director. As suggested by the commentators, the responsibilities of the Director have been grouped, for purposes of clarity, under specific headline "Office. It is essential that the committee have the technical expertise necessary to develop, modify, and interpret the guidelines in light of scientific evidence. Representative have been added from scientific disciplines, such as biology, to ensure a broad scientific overview. As a bridge between the implications for science and public policy, public members now serve on the committee, and additional public members may be added. Current public members include Dr. R. S. Redford, Ashbel Smith, professor of government and public affairs at the Lyndon B. Johnson School of Public Affairs, University of Texas, at Austin, and Dr. LeRoy Walters, director for the Center of Bioethics, Kennedy-Institute, Georgetown University.

In order to ensure fairness and sensitivity to the public commentators, procedures for nomination to the RAC will be in accord with the report by the NIH Grants Peer Review Study Committee. Thus, NIH will publish an announcement of upcoming vacancies periodically, with instructions on how to submit nominations. By this means, a wide spectrum of nominations will be considered nominations suit to the RAC's needs.

In brief, the operations of the RAC will be more clearly detailed in the PRG-NIH. The procedures for the selection of members and the operations
NOTICES

of the committee are in the process of being formalized for the benefit of the scientific community and the public.

NIH Components. A new section in the PRG-NIH now covers the functions of NIH, including the responsibilities of the Office of Recombinant DNA Activities (ORDA). It should be noted that the responsibility of the peer review groups (study sections) for review of the recombinant DNA research protocols has been eliminated. This responsibility would be solely ORDA's in conjunction with the local institutional biosafety committee.

Several commentators urged new responsibilities for ORDA and additional personnel to fulfill them. Some recommended that the Office be responsible for inspecting and certifying laboratories at the P3 level. Currently NIH has the responsibility for certifying only P4 facilities. At present NIH operates, at the Frederick Cancer Research Center in Frederick, Md., and at NIH in Bethesda the only P4 facilities in the country. Responsibilities for certification fall to NIH because of the special nature of P4 facilities. P3 facilities, on the other hand, do not require special expertise at the national level, and there is no need for them to be nationally certified. As specified, the local institution has and should have responsibility for monitoring and certifying P1, P2, and P3 facilities.

Several commentators urged an increased flow of information to the public and scientific community alike. ORDA is playing a key role in disseminating information through the Recombinant DNA Technical Bulletin. This is a new publication that attempts to link investigators involved in recombinant DNA research, both in the United States and abroad, with the active advisory groups and organizations. In light of comments received, the bulletin will contain even far more information for institutional biosafety committees and for the several advisory groups at the national and social levels.

In response to another suggestion, ORDA will be as available as possible to State and local governments for technical advice. Currently ORDA serves as a clearinghouse for information related to recombinant DNA activities internationally, nationally, and locally.

Registration and compliance

It has become clear over the 2 years of administration of the guidelines that a new section must be added on general requirements for registration with NIH. This should apply not only to NIH grantees and contractors, but also to the private sector on a voluntary basis. Further, in light of the review of DH/ EW policies on the patenting of recombinant DNA research inventions, a section on disclosure of information is also necessary. Finally, as suggested, a section on compliance with the guidelines is needed. Thus, new sections C and D on registration (including disclosure of information) and compliance have been added to the roles and responsibilities section of the PRG-NIH. These provisions, recommended in many comments on the guidelines and at the December public hearing, are necessary in the absence of legislation.

Registration. A number of commentators asked that the guidelines specify the requirements for registration. Accordingly, a new subsection has been added delineating the elements. If other requirements need be added, notice will be given of any change. All projects subject to agreements and to be registered with ORDA. Voluntary registration for the private sector is provided in the revision, in response to suggestions by private-sector representatives.

Disclosure. Many comments, as previously noted, were directed to the protection of proprietary information. A new subsection outlining the elements for protection of proprietary data is included in response to these suggestions.

One commentator urged that no patents be granted for recombinant DNA research.

Shortly after the release of the Guidelines in 1978, NIH received a letter requesting a review of DH/ EW policies relating to the patenting of recombinant DNA research inventions. The letter prompted NIH to review current patent regulations governing institutional patent agreements and to consider how recombinant DNA research inventions should be handled under those terms. On the basis of extensive Department and Interagency Commission, NIH recommended that, at least for the present, recombinant DNA research inventions developed under DH/ EW/NIH support should continue to be administered within current DH/ EW patent agreements. Each agreement, however, would require assurance of compliance with the physical and biological containment standards set forth in the Guidelines as a condition for the granting of a license.

Policy on Noncompliance. A commentator urged that a system of fines be spelled out. Monetary fines, more appropriate for regulations under legislation, will not be specified or assessed under the Guidelines. NIH has no current authority to impose fines. It will, however, suspend, limit, or terminate a grant or contract for noncompliance. A commentator recommended that penalty procedures be specified. Should it be necessary to suspend, limit, or terminate a grant, appropriate HEW procedures will be followed.

In summary, Part IV of the Guidelines- Roles and Responsibilities has been substantially revised in response to suggestions from many commentators. The PRG-NIH now provides even more opportunity for advice from the local to the national level. The spirit of cooperation and effective overview will be enhanced by the PRG-NIH at the local level between the research community and the public and at the national level among Federal agencies, the scientific community, and the private sectors.

Proposed Action: Environmental Impact Assessment

The recommendations of the Recombinant Advisory Committee have been carefully weighed, along with other public and scientific comments received on the Roles and Responsibilities section. In general, PRA-RAC proposals have been adopted in the PRG-NIH, with certain modifications based on issues raised by the Director's Advisory Committee and other commentators. The issues considered by the Director and a discussion of them follow.

The Draft EIS on the original Guidelines published in 1978 elicited a number of recommendations that greater detail be provided on NIH implementation of the Guidelines for NIH grantees and contractors. They also recommended extending the Guideline standards to all public and private sectors where such research is being conducted. More specifically, commentators expressed the following concerns.

- That the membership of institutional biohazards committees (IBCs) should include specialists in population dynamics, ecology, and other disciplines;
- That the Draft EIS did not emphasize relevant safety training for laboratory personnel;
- That the NIH Guidelines had a far too limited scope, not reaching research in the non-Federal sectors;
- That the termination of NIH funds for violation of the Guidelines may not be the best sanction;
- That the inspection, certification, and surveillance processes might not insure compliance;
- That more attention should be given to medical surveillance and epidemiologic measures in the event of possible infection of the laboratory worker or contamination of the environment; and
- That local and State authorities be involved in the review and containment processes at the local level.

These comments were specifically addressed in the Final EIS. It was
noted that the Guidelines established an administrative framework for assessing recombinant DNA research—a responsibility shared among principal investigators, their institutions, and NIH. The institutions were required to establish biosafety committees to carry out institutional responsibilities.

As discussed in the Final EIS, there were several factors contributing to the expectation that NIH grantees, contractors, and intramural scientists would comply with the Guidelines. They included the fact that noncompliance could result in the termination of funding; that investigators and their institutions share responsibilities for compliance; and poor performance on investigators for compliance would be accomplished through responsible institutional officers, local biosafety committees, and NIH review.

The Final EIS also disclosed, in response to several minor general Federal regulations of all such research to be insured that work beyond the aegis of NIH would be done under the safety standards of the Guidelines. A Federal Interagency Committee, chartered by the Secretary of HEW with the approval of the President, was convened under the chairmanship of Dr. Donald S. Fredrickson, Director, NIH. In March 1977 that committee with representatives of all relevant research and regulatory agencies recommended to the Secretary of HEW that legislation be enacted to regulate all recombinant DNA research. HEW Secretary Califano had legislation developed in light of the committee’s recommendations. An administration bill drafted by the Department was introduced in the Senate by Senator Edward M. Kennedy, Chairman of the Subcommittee on Health and Scientific Research of the Senate Committee on Human Resources, and in the House by Representatives Paul C. Rogers, Chairman of the Subcommittee on Health and the Environment of the Interstate and Foreign Commerce Committee.

Congressional hearings were held, and respective committee bills were drafted, but not acted upon by Congress in its first session. New committee bills are pending congressional action.

The PRG-NIH, Parts I through III, reflect in large measure the safety of many of the experiments that would be exempt from the Guidelines or allowed lower containment conditions. These changes are now proposed following an assessment that there would be no significant impact on the environment from the proposed revisions. The changes in Part IV largely reflect the need to improve environmental safety and on explicit penalties for noncompliance. In addition, the committee decided that changes would allow private-sector engagement with the NIH, including registration of recombinant DNA activities.

To address occupational and environmental health and safety concerns, the PRG-RAC proposed a reassessment of the current categorization of containment levels. This should minimize any significant environmental impact. These modifications primarily focus on restructure the categories of Part IV, “Roles and Responsibilities,” and an important and significantly expanded delegation of authority to local institutions. These major changes from the 1976 Guidelines, which extend beyond the PRG-RAC, have resulted from a careful consideration of recent comments received. The concern that during this process was to insure occupational and environmental safety, while at the same time refining the interdependent roles necessary to achieve this goal. Several changes are designed to clarify administration of the Guidelines. As suggested by several commentators, thereby promoting a more successful application of their safety features. The revisions that have been proposed for Part IV represent a further step toward insuring the safe conduct of this research and minimizing the possibility of any untoward environmental effects.

In response to several requests for expanding the applicability of the guidelines, institutions receiving NIH funds for recombinant DNA projects and their “biosafety committees” (the proposed new designation for biosafety committees) are given responsibility for reviewing all recombinant DNA work conducted at the institution regardless of source of funds. This increase in the scope of review will better insure the safe conduct of recombinant DNA research.

Further, biosafety committees (IBCs) have been given broader responsibilities. The PRG-RAC proposed to allow the IBC's to approve single-step reductions in containment levels in experiments with purified DNA or characterized clones. This is retained in the PRG-NIH. In response to other comments, however, it is deemed necessary to specify IBC responsibilities concerning containment levels required by the guidelines. The PRG-NIH requires the IBC's to make independent evaluations of these containment levels. This should strengthen safety considerations locally.

It was also suggested that NIH delegate to biosafety committees the responsibility for approving or disapproving, on behalf of the institution, recombinant DNA research based on their independent assessment of the safety standards applied, and that IBC approval be sufficient for the research to proceed. NIH, through ORDA, would review all local committee actions in the context of the guidelines, thereby maintaining national standards. This proposal has a number of advantages. It would simplify previous approval procedures and minimize delays due to NIH administration. Accountability for safe conduct of the research would reside at the local level, with appropriate federal overview.

It is believed that incorporation of these recommendations for increased local authority would enhance implementation of the guidelines, since important responsibilities are clarified and more suitably located.

As mentioned earlier, another major change includes the restructuring and amplification of Part IV of the guidelines. Publication of the Director’s decision on the 1976 guidelines, the draft EIS, and the PRG-RAC elicited numerous comments calling for more discussion and information on implementation, particularly for further clarification of responsibilities and roles at the local level. Accordingly, the contents of Part IV are presented in a format different from the current guidelines and the PRG-RAC, with the intent of more clearly aligning the various duties.

At the request of several commentators, Appendix D, dropped from the PRG-RAC, has been revised and updated as “Laboratory Safety Monograph—A Supplement to the NIH Guidelines for Recombinant DNA Research.” It provides a compendium of useful safety information, including instructions on emergency procedures, laboratory techniques for biohazard control, and decontamination and disposal methods. It provides complementary information on roles and responsibilities, it provides direction for the operation of a biosafety committee, suggestions to increase the biological safety officer’s efficiency, and more detail on the elements of a medical surveillance program. Criteria for certifying biological safety cabinets illustrate the level of detail. It is believed that the PRG-NIH, strengthened by these additions, provide a higher measure of protection for researchers, the public, and the environment.

Considerable attention has been focused on the institutional biosafety committee. These changes are proposed to enhance the performance of the environmental commentators for greater emphasis on training in occupational and environmental safety and on explicit penalties for noncompliance. In addition, the committee decided that changes would allow private-sector engagement with the NIH, including registration of recombinant DNA activities.
Noninstitutional representation is now proposed on biosafety committees, going beyond the PRG-RAC.

The role and responsibilities of the local biosafety committees have been restated and refined in response to numerous comments. They are also strengthened by the required membership of the biosafety officer by the PRG-RAC proposed the designation of a biological safety officer for each institute where P3- and P4-level recombinant DNA research was conducted, reflecting the practice of a growing number of American institutions and the recommendations of the British "Williams Committee Report." The requirement is intended to insure that a clearly designated individual will have the primary administrative responsibility for the implementation of institutional policies and biosafety committee decisions.

A related issue which drew several comments and recommendations concerned medical surveillance, or health monitoring. Responsibility for determining medical surveillance procedures for research personnel was transferred from the principal investigator to the institution, because the RAC felt that the institution would have access to a broader range of expertise.

Specific information on medical conditions was moved to the laboratory safety monograph, which includes additional recommendations on health monitoring and program content. General language describing the elements of a medical surveillance program was retained in Part IV as part of the institution's responsibility.

The addition of information and the further emphasis on health monitoring should enhance occupational health and safety at the local level. It should be noted that a collaborative effort is underway between NIH and the Center for Disease Control to establish a mechanism for providing emergency teams of experts to respond to major laboratory accidents.

Probably no other issue generated as much comment as that of training. According to one commentator, training "probably represents the key to safety." He goes on to say that any break in technique could destroy physical containment procedures. Indeed, training in good microbiological practices could be considered the first line of defense, as it serves to protect the worker as well as prevent contamination of the environment inside and outside the laboratory. The PRG-RAC proposed the addition of a requirement for the training of research personnel in the use of good microbiological techniques. In the PRG-NIH, the principal investigator must be trained, and must insure the training of laboratory personnel, before undertaking recombinant DNA experiments. The laboratory safety monograph includes a section on "Laboratory Techniques for Biohazard Control" which describes good practices regarding pipetting, centrifuging, and the use of syringes and needles. Altogether, training requirements have been further emphasized and strengthened in the PRG-NIH.

Several commenters wanted training standards to be set in the Guidelines or by NIH, the institution, or the biosafety committees. Others opposed setting standards. Still others recommended mandatory, formal evaluation and certification of investigators to test for competency in microbiological techniques. NIH is currently funding a Working Panel of the American Society of Microbiology (ASM) which is considering standards of training in microbiological techniques for recombinant DNA research. For all of these reasons and the dissemination of a report for the use of institutions, IBC's, and principal investigators, once NIH receives the recommendation of the ASM Panel.

NIH considers it premature to require national certification, as suggested by some. There are so few models for formal training standards in biomedical research that NIH has decided to proceed cautiously, while continuing to promote safety training. As yet, there is no consensus, no one best way to accomplish this training, and therefore the desired results may best be achieved by allowing institutions, biosafety committees, and investigators some flexibility. Meanwhile, NIH plans to develop courses to be based on the NIH/ASM standards and to offer them widely. The Laboratory Safety Monograph also contains a summary of safety training aids, materials, and courses offered by the NIH and others.

From the discussion of these issues, it should be evident that measures have been undertaken in the revision of Part IV of the Guidelines to emphasize occupational health and safety. The principal measures would be the strengthening of training requirements and activities, the designation of someone in the institution as a member of the biosafety committee to handle biological safety questions generally, the delegation of more authority to the institution, and better definition of responsibilities at the local level. The impact of these actions will be the promotion of safer conduct of this research, thus affording a greater measure of protection to the environment.

In summary, a key focus of public comment was on "procedural due process" to ensure public participation in the development of NIH recombinant DNA policies. In response to those suggestions in several instances, opportunity for public comment is afforded through activities of the Director, NIH, and the RAC. In addition, public representation on the RAC will be considered further, with a nomination process to insure a wide range of individuals for selection. New general compliance and registration sections have been included in the PRG-NIH that do not appear in the current Guidelines. These sections are directly responsive to stated concerns that the importance of these safety standards and procedures be emphasized.

NIH will continue to work closely with other relevant research and regulatory agencies, particularly the Environmental Protection Agency and the Occupational Safety and Health Administration. Both of these agencies are represented on the Federal Interagency Committee on Recombinant DNA Research.

NIH has created over the past 2 years several internal committees that are critically examining areas where work with potential biohazards is involved in the laboratory.

Finally, a key concern of all commentators was the need for programs in occupational and environmental safety which would include health surveillance for laboratory personnel and the community. Recombinant DNA research policies have stimulated a broad NIH commitment and interest in laboratory safety. NIH has a mandate for national leadership in laboratory safety programs, and the proposed revisions reflect full acceptance of that responsibility.

APPENDIX A-1

Table: Comparison of Containment Levels

<table>
<thead>
<tr>
<th>Levels</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A-I</td>
<td>Low risk, minor containment</td>
</tr>
<tr>
<td>A-II</td>
<td>Moderate risk, intermediate containment</td>
</tr>
<tr>
<td>A-III</td>
<td>High risk, stringent containment</td>
</tr>
</tbody>
</table>

The following table compares the containment levels for all permissible types of recombinant DNA experiments. It designates the levels under the Guidelines now in effect (since June 1976), under those proposed by the RAC (September 1977), and under the present NIH-proposed revisions.

A dash (--) indicates that the category is not classified in the edition of the Guidelines under which the dash appears.

It should be stressed that the table is not definitive, since the containment levels of the Guidelines have been redefined and other requirements modified.
## Appendix A

### COMPARISON OF THE CONTAINMENT LEVELS OF THE 1976 GUIDELINES AND THE PROPOSED REVISED GUIDELINES

<table>
<thead>
<tr>
<th>Shotgun Experiments</th>
<th>June 1976 Guidelines</th>
<th>FAC Proposed Revised Guidelines</th>
<th>NIH Director's Revised Guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Physical</td>
<td>Biological</td>
<td>Physical</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Primate</td>
<td>P4</td>
<td>EX2</td>
<td>P4</td>
</tr>
<tr>
<td></td>
<td>or P3</td>
<td></td>
<td>or P3</td>
</tr>
<tr>
<td>2. Primate DNA from uninfected cells</td>
<td></td>
<td></td>
<td>P3</td>
</tr>
<tr>
<td>3. Embryonic primate</td>
<td>P3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Mammals (other than primates)</td>
<td>P3</td>
<td>EX2</td>
<td>P3</td>
</tr>
<tr>
<td>5. Birds</td>
<td>P3</td>
<td>EX2</td>
<td>P3</td>
</tr>
<tr>
<td>6. Cold blooded vertebrates</td>
<td>P3</td>
<td>EX2</td>
<td>P3</td>
</tr>
<tr>
<td>7. Embryonic and germ line</td>
<td>P2</td>
<td>EX1</td>
<td>P2</td>
</tr>
<tr>
<td>8. Producing potent toxins</td>
<td>P3</td>
<td>EX2</td>
<td></td>
</tr>
<tr>
<td>9. Producing potent polypeptide toxins</td>
<td></td>
<td></td>
<td>P3</td>
</tr>
<tr>
<td>Lower eukaryotes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. Producing toxins, or are pathogens</td>
<td>P3</td>
<td>EX2</td>
<td>P3</td>
</tr>
<tr>
<td>Shotgun Experiments (Cont.)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. Producing potent polypeptide toxins, or are pathogens</td>
<td></td>
<td></td>
<td>P3</td>
</tr>
<tr>
<td>12. Producing non-polypeptide toxins</td>
<td></td>
<td></td>
<td>P3</td>
</tr>
<tr>
<td>13. Producing toxins affecting invertebrates or plants.</td>
<td></td>
<td></td>
<td>P3</td>
</tr>
<tr>
<td>14. Remainder of species</td>
<td>P2</td>
<td>EX1</td>
<td>P2</td>
</tr>
<tr>
<td>15. Plants</td>
<td>P2</td>
<td>EX1</td>
<td>P2</td>
</tr>
<tr>
<td>16. Carrying pathogens or making dangerous products</td>
<td>P3</td>
<td>EX2</td>
<td>P3</td>
</tr>
<tr>
<td>17. Carrying pathogens or making polypeptide toxins</td>
<td></td>
<td></td>
<td>P3</td>
</tr>
<tr>
<td>18. Making potent polypeptide toxins</td>
<td></td>
<td></td>
<td>P3</td>
</tr>
<tr>
<td>19. Making non-polypeptide toxins</td>
<td></td>
<td></td>
<td>or P2</td>
</tr>
</tbody>
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FEDERAL REGISTER, VOL 43, NO. 146—FRIDAY, JULY 28, 1978
### Comparison of the Containment Levels of the 1976 Guidelines and the Proposed Revised Guidelines

#### Prokaryotes Exchanging Genetic Information with *E. coli*

<table>
<thead>
<tr>
<th>Class</th>
<th>CDC agents</th>
<th>Physical</th>
<th>Biological</th>
<th>Proposed Revised Guidelines</th>
<th>Revised Guidelines</th>
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<tr>
<td>20.</td>
<td>Class 1 CDC agents</td>
<td>P1</td>
<td>EK1</td>
<td>-</td>
<td>P1</td>
</tr>
<tr>
<td>21.</td>
<td>Class 2 CDC agents</td>
<td>P2 or P2</td>
<td>EK1</td>
<td>-</td>
<td>P2</td>
</tr>
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</table>

#### Prokaryotes Not Exchanging Genetic Information with *E. coli*

<table>
<thead>
<tr>
<th>Class</th>
<th>CDC agents</th>
<th>Physical</th>
<th>Biological</th>
<th>Proposed Revised Guidelines</th>
<th>Revised Guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td>22.</td>
<td>Class 1 CDC agents</td>
<td>P3</td>
<td>EK1</td>
<td>See Prokaryotic DNA recombinants</td>
<td>P2</td>
</tr>
</tbody>
</table>

#### Physical Biological

| Source of DNA | Extensively characterized | F2 | EK1 or P1 | EK2 | P2 | EK1 |

#### Characterized Clones

<table>
<thead>
<tr>
<th>Species</th>
<th>Physical</th>
<th>Biological</th>
<th>Proposed Revised Guidelines</th>
<th>Revised Guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td>21.</td>
<td>See Characterized clones (Category 50)</td>
<td>P1</td>
<td>EK1</td>
<td>-</td>
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</table>

#### Purified DNA Other Than

<table>
<thead>
<tr>
<th>Category</th>
<th>Physical</th>
<th>Biological</th>
<th>Proposed Revised Guidelines</th>
<th>Revised Guidelines</th>
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</thead>
<tbody>
<tr>
<td>29.</td>
<td>Same</td>
<td>See Categories 32-41</td>
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<td></td>
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</table>

#### Plasmids, Bacteriophages, and Other Viruses

<table>
<thead>
<tr>
<th>Category</th>
<th>Physical</th>
<th>Biological</th>
<th>Proposed Revised Guidelines</th>
<th>Revised Guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td>30.</td>
<td>See Categories 32-41</td>
<td>-</td>
<td>-</td>
<td>-</td>
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</table>

#### Animal Viruses

<table>
<thead>
<tr>
<th>Category</th>
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<th>Biological</th>
<th>Proposed Revised Guidelines</th>
<th>Revised Guidelines</th>
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</thead>
<tbody>
<tr>
<td>31.</td>
<td>See Categories 32-41</td>
<td>-</td>
<td>-</td>
<td>-</td>
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#### Viruses of Warm-Blooded Vertebrates

<table>
<thead>
<tr>
<th>Category</th>
<th>Physical</th>
<th>Biological</th>
<th>Proposed Revised Guidelines</th>
<th>Revised Guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td>32.</td>
<td>See Categories 32-41</td>
<td>-</td>
<td>-</td>
<td>-</td>
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</table>
### INSURED DNA

<table>
<thead>
<tr>
<th>INSERTED DNA</th>
<th>CONTAINMENT LEVELS</th>
<th>JUNE 1976 GUIDELINES</th>
<th>JAC PROPOSED REVISED GUIDELINES</th>
<th>NIH DIRECTOR'S REVISED GUIDELINES</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>PHYSICAL</td>
<td>BIOLOGICAL</td>
<td>PHYSICAL</td>
<td>BIOLOGICAL</td>
</tr>
<tr>
<td>33. for purified subgenomic segments or less than complete genome</td>
<td>—</td>
<td>—</td>
<td>F3</td>
<td>EX2</td>
</tr>
<tr>
<td>DNA transcripts of other DNA viruses</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>34. non-segmented genome</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>35. segmented genome</td>
<td>—</td>
<td>—</td>
<td>F3</td>
<td>EX2</td>
</tr>
<tr>
<td>Viruses of Cold-Blooded Vertebrates</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>36. DNA viruses &amp; transcripts of retrovirus genome</td>
<td>—</td>
<td>—</td>
<td>F4</td>
<td>EX1</td>
</tr>
<tr>
<td>for purified subgenomic segments or less than complete genome</td>
<td>—</td>
<td>—</td>
<td>F3</td>
<td>EX2</td>
</tr>
<tr>
<td>DNA transcripts of other DNA viruses</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>38. non-segmented genome</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>39. segmented genome</td>
<td>—</td>
<td>—</td>
<td>F2</td>
<td>EX2</td>
</tr>
<tr>
<td>Viruses of Invertebrates and Protozoa</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>40. Baculoviruses, EPA registered</td>
<td>—</td>
<td>—</td>
<td>F1</td>
<td>EX2</td>
</tr>
<tr>
<td>or F2</td>
<td>EX1</td>
<td>or F2</td>
<td>EX1</td>
<td>—</td>
</tr>
<tr>
<td>41. Other viruses</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
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<td>42. Plant viruses</td>
<td>E3</td>
<td>EX1</td>
<td>F3</td>
<td>EX1</td>
</tr>
<tr>
<td>or F2</td>
<td>EX2</td>
<td>or F2</td>
<td>EX2</td>
<td>—</td>
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<td>43. Primate mitochondria</td>
<td>P3</td>
<td>EX1</td>
<td>P3</td>
<td>EX1</td>
</tr>
<tr>
<td>or F2</td>
<td>EX2</td>
<td>or F2</td>
<td>EX2</td>
<td>—</td>
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<tr>
<td>44. Other eukaryotic mitochondrial or chloroplast DNA</td>
<td>P2</td>
<td>EX1</td>
<td>F2</td>
<td>EX1</td>
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<tr>
<td>45. Eukaryotic mitochondrial or chloroplast DNA</td>
<td>—</td>
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<td>—</td>
<td>—</td>
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<tr>
<td>46. Plasmid or phage which exchange with E. coli</td>
<td>Same as shotgun conditions for host</td>
<td>—</td>
<td>—</td>
<td>Same as shotgun conditions for host</td>
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<tr>
<td>47. when known not to contain harmful genes, or purified segments</td>
<td>P1</td>
<td>EX1</td>
<td>—</td>
<td>—</td>
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* Federal Register, Vol. 43, No. 146—Friday, July 28, 1978
### COMPARISON OF THE CONTAINMENT LEVELS OF THE 1976 GUIDELINES AND THE PROPOSED REVISED GUIDELINES

<table>
<thead>
<tr>
<th>INSERTED DNA</th>
<th>JUNE 1976 GUIDELINES</th>
<th>RAC PROPOSED REVISED GUIDELINES</th>
<th>NIH DIRECTOR'S REVISED GUIDELINES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prokaryotic plasmid and phage which do not exchange information with E. coli</td>
<td>Same as shotgun conditions for host</td>
<td>Same as shotgun conditions for host</td>
<td>Same as shotgun conditions for host</td>
</tr>
<tr>
<td>JUNE 1976 GUIDELINES</td>
<td>RAC PROPOSED REVISED GUIDELINES</td>
<td>NIH DIRECTOR'S REVISED GUIDELINES</td>
<td></td>
</tr>
<tr>
<td>PHYSICAL</td>
<td>BIOLOGICAL</td>
<td>PHYSICAL</td>
<td>BIOLOGICAL</td>
</tr>
<tr>
<td>48. Prokaryotic plasmid and phage which do not exchange information with E. coli</td>
<td>Same as shotgun conditions for host</td>
<td>Same as shotgun conditions for host</td>
<td>Same as shotgun conditions for host</td>
</tr>
<tr>
<td>49. Minimum containment</td>
<td>P3 or P2 EK1 or EK2</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>50. Characterized Clones</td>
<td>See Characterized clones (Category 27-28)</td>
<td>IBC may approve single-step reduction in physical or biological containment</td>
<td>Reduction of more than one step requires NIH approval</td>
</tr>
</tbody>
</table>

**Animal Host-Vector Systems**

**Defective polynoma virus**

51. Containing DNA of non-pathogenic organism                                    P3 cultured cells  See Categories 58-60  **
52. Containing class 2 animal virus sequences                                     P4 cultured cells  See Categories 58-60  **
53. When clone shown to contain only harmless regions                            P3 cultured cells  See Categories 58-60  **

**Defective SV40 virus**

54. DNA from any non-pathogenic organism or Class 1 virus                        P4 established cell lines  See Categories 61-65  **
55. If inserted segment is purified prokaryotic DNA or previously cloned eukaryotic DNA whose function is known P3 established cell lines  See Categories 61-65  **
56. If defective SV40 lacks late region, there is no helper virus, and no infectious virus is being produced P3 established cell lines  See Categories 61-65  **
57. If non-permissive cells transformed                                          P3 established non-permissive cell lines  See Categories 61-65  **

**Defective or intact polynoma virus**

58. Containing DNA of Class 1 or Class 2 bacteria, except for species producing potent polypeptide toxins — — P3 cultured cells  **
## Comparison of the Containment Levels of the 1976 Guidelines and the Proposed Revised Guidelines

<table>
<thead>
<tr>
<th>INSERTED DNA</th>
<th>JUNE 1976 GUIDELINES</th>
<th>RAC PROPOSED REVISED GUIDELINES</th>
<th>NIH DIRECTOR'S REVISED GUIDELINES</th>
</tr>
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<tr>
<td></td>
<td>PHYSICAL</td>
<td>BIOLOGICAL</td>
<td>PHYSICAL</td>
</tr>
<tr>
<td>59. Containing DNA of eukaryote not producing potent polypeptide toxin</td>
<td>**</td>
<td>**</td>
<td>**</td>
</tr>
<tr>
<td>Unconditionally defective polynuclear virus</td>
<td>**</td>
<td>**</td>
<td>**</td>
</tr>
<tr>
<td>60. Subgenomic segments of Class 1 or Class 2 viruses which do not replicate in mouse cells</td>
<td>**</td>
<td>**</td>
<td>**</td>
</tr>
<tr>
<td>SV40 and Adenovirus Types 2</td>
<td>**</td>
<td>**</td>
<td>**</td>
</tr>
<tr>
<td>Unconditionally defective by deletion in essential gene region</td>
<td>**</td>
<td>**</td>
<td>**</td>
</tr>
<tr>
<td>61. If inserted DNA is from Class 1 or 2 bacteria (except for species producing potent polypeptide toxin) or from eukaryote not producing potent polypeptide toxin</td>
<td>**</td>
<td>**</td>
<td>**</td>
</tr>
<tr>
<td>62. If inserted DNA is purified prokaryotic segment, or identified segment of eukaryotic DNA previously cloned in prokaryotic host-vector system</td>
<td>**</td>
<td>**</td>
<td>**</td>
</tr>
<tr>
<td>63. Unconditionally defective by deletion in capsid genes</td>
<td>**</td>
<td>**</td>
<td>**</td>
</tr>
<tr>
<td>containing DNA from Class 1 agents</td>
<td>**</td>
<td>**</td>
<td>**</td>
</tr>
<tr>
<td>64. If vector is known to be free of complete viral genome</td>
<td>**</td>
<td>**</td>
<td>**</td>
</tr>
<tr>
<td>65. SV40 or Ad 2 and 5 DNA plus subgenomic sequences from eukaryotic organisms or Class 1 or 2 agents; recombinant molecule defective and no virus being produced</td>
<td>**</td>
<td>**</td>
<td>**</td>
</tr>
</tbody>
</table>
FOOTNOTES

1. Lowering of containment below these levels (i.e., for purified DNA or characterized clones) cannot be made solely by an institutional biosafety committee, but requires NIH approval.

2. Plant pathogenic or symbiotic fungi that do not produce potent toxins are specifically included among the remainder of species in this class of lower eukaryotes.

3. It is expected that many of the prokaryotes that exchange genetic information with E. coli by known physiological processes will be exempted from these Guidelines by appearing on the “list of exchangers” (See Guidelines, Section I-E-4.)

*See table III of Guidelines, Section III-A-2-a-(2)-(e).

**See table IV of Guidelines, Section III-C-3.

APPENDIX B-1

Table: Classification of NIH-Funded Experiments as of December 1976

The following table lists all P2 and P3 recombinant DNA research projects supported by NIH as of December 1977. The P1 projects are roughly a 50-percent sample. The table designates the containment labels under the Guidelines now in effect (since June 1976), under those proposed by the RAC (September 1977), and under the present NIH-proposed revisions.
## Appendix B--2

<table>
<thead>
<tr>
<th>Current Containment Levels (P and EK)</th>
<th>Source of DNA</th>
<th>Vector</th>
<th>NAC Revised Containment Level</th>
<th>NIH Revised Containment Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>P2 + EK1</td>
<td>N. subtilis</td>
<td>K-12, C600*</td>
<td>70013</td>
<td>Exempt</td>
</tr>
<tr>
<td>P2 + EK1 or EK2</td>
<td>S. typhimurium</td>
<td>K-12</td>
<td>Exempt</td>
<td>Exempt</td>
</tr>
<tr>
<td>P2 + EK1</td>
<td>Sea Urchin</td>
<td>K-12 pGC101, pE02</td>
<td>P2 + EK1 or</td>
<td>P2 + EK1 or</td>
</tr>
<tr>
<td>P2 + EK1</td>
<td>Silico Moid</td>
<td>K-12 pGC101, pR09</td>
<td>P2 + EK1 or</td>
<td>P2 + EK1 or</td>
</tr>
<tr>
<td>P2 + EK1</td>
<td>Haizo Chloroplast</td>
<td>K-12, N101* various chloroplasts</td>
<td>P2 + EK1 or</td>
<td>P2 + EK1 or</td>
</tr>
<tr>
<td>P2 + EK1</td>
<td>Naupora</td>
<td>K-12 pR09, pR21</td>
<td>P2 + EK1 or</td>
<td>P2 + EK1 or</td>
</tr>
<tr>
<td>P2 + EK1</td>
<td>Embryonic Xenopus</td>
<td>K-12 pGC101</td>
<td>P2 + EK1</td>
<td>P2 + EK1</td>
</tr>
<tr>
<td>P2 + EK1</td>
<td>Characterized Xenopus</td>
<td>=</td>
<td>=</td>
<td>=</td>
</tr>
<tr>
<td>P2 + EK1</td>
<td>N. subtilis</td>
<td>K-12 pR09, pGC101</td>
<td>Exempt</td>
<td>P1 + EK1</td>
</tr>
<tr>
<td>P2 + EK2</td>
<td>Embryonic Xenopus</td>
<td>1776 pR09</td>
<td>P2 + EK1</td>
<td>P2 + EK1</td>
</tr>
<tr>
<td>P2 + EK2</td>
<td>Characterized Xenopus</td>
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## Appendix B--3

<table>
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<tr>
<th>Current Containment Levels (P and EK)</th>
<th>Source of DNA</th>
<th>Vector</th>
<th>NAC Revised Containment Level</th>
<th>NIH Revised Containment Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>P2 + EK1</td>
<td>S. typhimurium</td>
<td>K-12 L, Col EK</td>
<td>Exempt</td>
<td>Exempt</td>
</tr>
<tr>
<td>P2 + EK1</td>
<td>Characterized Xenopus</td>
<td>K-12 A</td>
<td>P2 + EK1</td>
<td>P1 + EK1</td>
</tr>
<tr>
<td>P2 + EK1</td>
<td>Mouse Mitochondria</td>
<td>C600* pGC101, pR09</td>
<td>P2 + EK1</td>
<td>P2 + EK1</td>
</tr>
<tr>
<td>P2 + EK1</td>
<td>Drosofilla</td>
<td>K-12 various plasmids</td>
<td>P2 + EK1</td>
<td>P2 + EK1</td>
</tr>
<tr>
<td>P2 + EK1</td>
<td>Parasandol</td>
<td>K-12, N101*</td>
<td>P2 + EK1</td>
<td>P2 + EK1</td>
</tr>
<tr>
<td>P2 + EK1</td>
<td>Sea Urchin</td>
<td>K-12</td>
<td>P2 + EK1</td>
<td>P2 + EK1</td>
</tr>
<tr>
<td>P2 + EK2</td>
<td>Actinomycetes</td>
<td>K-12, L, Col EK</td>
<td>P2 + EK2</td>
<td>P3 + EK2</td>
</tr>
<tr>
<td>P2 + EK2 or EK1</td>
<td>Streptococci</td>
<td>K-12, N101* pGC101</td>
<td>P2 + EK2 or</td>
<td>P3 + EK1 or</td>
</tr>
<tr>
<td>P2 + EK2 or EK1</td>
<td>=</td>
<td>=</td>
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<table>
<thead>
<tr>
<th>Current Containment Levels of E1 and E2</th>
<th>Source</th>
<th>RAC Revised Containment Level</th>
<th>NIH Revised Containment Level</th>
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<tbody>
<tr>
<td>P2 + EK1</td>
<td>Dro sophila</td>
<td>K-12 pGC101, Col E1</td>
<td>P2 + EK1 or P1 + EK2</td>
</tr>
<tr>
<td></td>
<td>Sea Urchin</td>
<td>K-12 pMS09, pMS132, pMS214, pGIP120</td>
<td>P2 + EK1 or P1 + EK2</td>
</tr>
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<td>P2 + EK2</td>
<td>Triturus cristatus</td>
<td>C600* pMS09, pGC101, pCM1</td>
<td>P2 + EK2 or P2 + EK1</td>
</tr>
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<td>P2 + EK1</td>
<td>Notophthalmus viridescens</td>
<td>&quot;</td>
<td>P2 + EK1 or P2 + EK1 (NIH decision)</td>
</tr>
<tr>
<td></td>
<td>Silkworm</td>
<td>IM101* pM21</td>
<td>P2 + EK1 or P2 + EK1 (RAC decision)</td>
</tr>
<tr>
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<td>C600* pMS113</td>
<td>P1 + EK1</td>
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<tr>
<td>P2 + EK1</td>
<td>Dro sophila</td>
<td>K-12 Col E1</td>
<td>P2 + EK1 or P1 + EK2</td>
</tr>
<tr>
<td></td>
<td>Embryonic Xenopus</td>
<td>K-12 pGC101, Col E1</td>
<td>P2 + EK1 or P1 + EK2</td>
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**Appendix B—5**

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<tr>
<th>Current Containment Levels of E1 and E2</th>
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<th>NIH Revised Containment Level</th>
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<td>Neurospora</td>
<td>K-12 pMS09, pMS132, p2 + EK1</td>
<td>P2 + EK1 or P1 + EK2</td>
</tr>
<tr>
<td></td>
<td>Dro sophila</td>
<td>C600* pMS09</td>
<td>P2 + EK1 or P1 + EK2</td>
</tr>
<tr>
<td>P2 + EK1</td>
<td>Dro sophila</td>
<td>K-12 pMS09, pGC101, Col E1</td>
<td>P2 + EK1 or P1 + EK2</td>
</tr>
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<td>P2 + EK1</td>
<td>B. subtilis</td>
<td>C600* pMS09, pGC101, tExempt</td>
<td>P1 + EK1</td>
</tr>
<tr>
<td>P2 + EK1</td>
<td>Dro sophila</td>
<td>K-12</td>
<td>P2 + EK1 or P1 + EK2</td>
</tr>
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<td>P2 + EK1</td>
<td>Dro sophila</td>
<td>K-12</td>
<td>P2 + EK1 or P1 + EK2</td>
</tr>
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<td>P2 + EK1</td>
<td>Yeast</td>
<td>K-12, Col E1</td>
<td>P2 + EK1 or P1 + EK2</td>
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FEDERAL REGISTER, VOL. 43, NO. 146—FRIDAY, JULY 28, 1978
<table>
<thead>
<tr>
<th>Current Containment Levels (P and B)</th>
<th>Source of Trans</th>
<th>DAC Revisited Containment Level</th>
<th>NII Revisited Containment Level</th>
</tr>
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<tbody>
<tr>
<td>P2 + BK1</td>
<td>Drosophila</td>
<td>P2 + BK1</td>
<td>P2 + BK1</td>
</tr>
<tr>
<td>P2 + BK1</td>
<td>Yeast</td>
<td>P2 + BK1</td>
<td>P2 + BK1</td>
</tr>
<tr>
<td>P2 + BK1</td>
<td>Drosophila</td>
<td>P2 + BK1</td>
<td>P2 + BK1</td>
</tr>
<tr>
<td>P2 + BK1</td>
<td>Neurospora</td>
<td>P2 + BK1</td>
<td>P2 + BK1</td>
</tr>
<tr>
<td>P2 + BK1</td>
<td>Neurospora</td>
<td>P2 + BK1</td>
<td>P2 + BK1</td>
</tr>
<tr>
<td>P2 + BK1</td>
<td>Drosophila</td>
<td>P2 + BK1</td>
<td>P2 + BK1</td>
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<td>P2 + BK1</td>
<td>Paedobacter crescentus</td>
<td>P2 + BK1</td>
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<table>
<thead>
<tr>
<th>Current Containment Levels (P and B)</th>
<th>Source of Trans</th>
<th>DAC Revisited Containment Level</th>
<th>NII Revisited Containment Level</th>
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<td>P2 + BK1</td>
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<td>P2 + BK1</td>
<td>P2 + BK1</td>
</tr>
<tr>
<td>P2 + BK1</td>
<td>Tetrahymena</td>
<td>P2 + BK1</td>
<td>P2 + BK1</td>
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<td>P2 + BK1</td>
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<td>P2 + BK1</td>
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<td>P2 + BK1</td>
<td>P2 + BK1</td>
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<td>P2 + BK1</td>
<td>S. typhimurium</td>
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NOTICES
### Appendix B—8

<table>
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<th>Current Containment Levels of DNA</th>
<th>Source of DNA</th>
<th>Host</th>
<th>Vector</th>
<th>RAC Revised Containment Level</th>
<th>NIH Revised Containment Level</th>
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</thead>
<tbody>
<tr>
<td>P2 + BK1</td>
<td>Mouse Mitochondria</td>
<td>C600*, pBC101, Col K1</td>
<td>P2 + BK1</td>
<td>P2 + BK1</td>
<td>P2 + BK1</td>
</tr>
<tr>
<td>P2 + BK1</td>
<td>Sino Hold</td>
<td>C600*, pB1009, pB1011, pB1013, pB1012</td>
<td>P2 + BK1</td>
<td>P2 + BK1</td>
<td>P2 + BK1</td>
</tr>
<tr>
<td>P2 + BK1</td>
<td>Drosophila</td>
<td>K-12, pB1012</td>
<td>P2 + BK1</td>
<td>P2 + BK1</td>
<td>P2 + BK1</td>
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<td>P2 + BK1</td>
<td>P2 + BK1</td>
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<tr>
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<td>Drosophila</td>
<td>K-12, pB1013</td>
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<td>P2 + BK1</td>
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### Appendix B—9

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<td>P2 + BK1</td>
<td>P2 + BK1</td>
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<td>P2 + BK1</td>
<td>P2 + BK1</td>
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### Appendix B-10

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<td>pUC101, p2 + X1</td>
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<td>P2 + E1 or P2 + X1</td>
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<td>P2 + X1</td>
<td>p1p2, pSP17</td>
<td>or P1 + E1</td>
<td>or P1 + X1</td>
<td>P1 + E1 or P1 + X1</td>
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<td>E. coli (enteropathogenic)</td>
<td>K-12, pUC101, p2 + X1</td>
<td>pUC101, p214, pMR11, pMR321, pMR033</td>
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<td>Except</td>
</tr>
<tr>
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<td>N. subtilis</td>
<td>K-12</td>
<td>Col E1</td>
<td>P2 + E1 or P2 + X1</td>
<td>P2 + E1 or P2 + X1</td>
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<td>or P1 + X1</td>
<td>or P1 + E1 or P1 + X1</td>
<td>or P1 + E1 or P1 + X1</td>
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<td>P2 + X1</td>
<td>E. coli (enteropathogenic)</td>
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<td>Col E1</td>
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<td>or P1 + E1 or P1 + X1</td>
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<td>p2 + E1 or p2 + X1</td>
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### Appendix B-11

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<td>P2 + E1 or P2 + X1</td>
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<td>p2 + X1</td>
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<td>Except</td>
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### Appendix B—12

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### Appendix B—13

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<td>P2 + EK1 Kleintilla</td>
<td>phiC101, Col E1</td>
<td>?Exempt Exempt</td>
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</tr>
<tr>
<td></td>
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<td>P2 + EK1</td>
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<td></td>
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<td>P1 + EK2</td>
<td>or</td>
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<td>P2 + EK2 Toal K-12</td>
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<td></td>
<td></td>
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<td>or</td>
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<td></td>
<td></td>
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<td></td>
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<td>P3 + EK2</td>
<td>or</td>
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<tr>
<td>P2 + EK1 Sea Urchin K-12</td>
<td>phiD9</td>
<td>P2 + EK1</td>
<td>or</td>
</tr>
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<td></td>
<td>or</td>
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<tr>
<td>P2 + EK1 Yeast K-12</td>
<td>phiD9</td>
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<td></td>
<td>or</td>
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## Appendix B—20

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<td>C600*</td>
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<td>E. coli</td>
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## Appendix B—21

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<td>P2 + EK1</td>
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<td>P2 + EK1</td>
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**NOTES**
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<td>P2 + IX2</td>
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<td>Rat</td>
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<td>P2 + IX2</td>
</tr>
<tr>
<td>Human Embryo</td>
<td>P2 + IX2</td>
<td>P2 + IX2</td>
</tr>
<tr>
<td>Chicken</td>
<td>P2 + IX2</td>
<td>P2 + IX2</td>
</tr>
<tr>
<td>Hamster</td>
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<td>P2 + IX2</td>
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<td>Cultured Rhesus Cells</td>
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<td>P3</td>
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<tr>
<td>Defective</td>
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<tr>
<td>Cultured Rhesus Cells</td>
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**FEDERAL REGISTER, VOL. 43, NO. 146—FRIDAY, JULY 20, 1978**
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<th>NCI Revised Containment Level</th>
<th>NIH Revised Containment Level</th>
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<tbody>
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<td>Chicken</td>
<td>x 1776</td>
<td>pMV9, pB11, Col E1</td>
<td>P2 + BK2</td>
<td>P2 + BK2</td>
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<tr>
<td>P3 + BK2</td>
<td>Bird</td>
<td>x 1776</td>
<td>pCM101, pBR322</td>
<td>P2 + BK2</td>
<td>P2 + BK2</td>
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<tr>
<td>P3 + BK2</td>
<td>House Sarcina et al</td>
<td>x 1776</td>
<td>pCM101, pBR322, pBR133, pBR322</td>
<td>P2 + BK2</td>
<td>P2 + BK2</td>
</tr>
<tr>
<td>P3 + BK2</td>
<td>Hamster</td>
<td>x 1776</td>
<td>pCM101, pBR322</td>
<td>P2 + BK2</td>
<td>P2 + BK2</td>
</tr>
<tr>
<td>P3 + BK2</td>
<td>Chicken</td>
<td>DP50/prep</td>
<td>Charon 4A, Charon 16A</td>
<td>P2 + BK2</td>
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<td>P3 + BK2</td>
<td>Bird</td>
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<td>pCM1, pBR322</td>
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<td>P2 + BK2</td>
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<td>P3 + BK2</td>
<td>Rabbit Globin pBR12</td>
<td>pMV9, pBR322</td>
<td>P2 + BK1, pBR133, pBR322</td>
<td>(NCI decision)</td>
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### Appendix B—26

<table>
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<th>Current Containment Level (P and K)</th>
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<td>P + K2</td>
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<td>pVI101, pHIU32</td>
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<tr>
<td>P + K2</td>
<td>Rat</td>
<td>x 1776 or 650</td>
<td>pVI101, pHIU32, Charon 16A</td>
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### Appendix B—27

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<td>pGC101, pFIN1</td>
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<td>P2 + Ix2</td>
</tr>
<tr>
<td>P + K2</td>
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<td>x 1776</td>
<td>pGC102, pFIN2, pHG19</td>
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### Appendix B—30

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<th>Current Containment Level</th>
<th>Source of Pathogen</th>
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<td>K-12</td>
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<td>Except</td>
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<tr>
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<td>Col El</td>
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<td>yd59, JHC122</td>
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### Appendix B—31

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FEDERAL REGISTER, VOL. 43, NO. 146—FRIDAY, JULY 20, 1978
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<td>Col E1, K12, Col E1</td>
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<tr>
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<td>Except</td>
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<th>Vector</th>
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### Table: Current Containment Levels and Source of DNA

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*derivatives of E. coli K-12.*
APPENDIX C

RESPONSES TO SOME COMMENTS ON THE NIH ENVIRONMENTAL IMPACT STATEMENT, BY PUBLIC WITNESSES AT THE RAC MEETING, DECEMBER 15-16, 1977

At the public meeting of the Advisory Committee to the Director, NIH, held at the National Institutes of Health in December 1977, witnesses representing environmental groups commented on the "Environmental Impact Statement on NIH Guidelines for Research Involving Recombinant DNA Molecules," published by NIH in October 1977. Some of the comments and responses by the Office of the Director, NIH, are summarized below.

Comment 1. The environmental impact statement does not respond to the arguments that any gene, if expressed out of its normal context, has the potential for being "harmful." Appendix K59-62" (of the EIS).

Response. Page 23 of the EIS (section IV-C) discusses ways in which hazardous agents as those coding for synthesis of toxin. The section proceeds to discuss ways in which hazardous agents might be produced. Factors such as survival of the host cell, survival of vectors, and effects of hosts or vectors on other forms of life are considered. Moreover, the guidelines classify all DNA that might be manipulated, so that some measure of containment is required for any recombination. Thus "any gene" is covered.

Comment 2. "The EIS does not respond to the argument that while E. coli K-12 does not normally colonize the human colon, it is incorrect to infer that this property renders it harmless to humans. Appendix K62-84.

Response. The letter cited (Zimmerman, Environmental Defense Fund) is not the issue—that genetic exchange is. The point is covered in section IV-C-1-b-(2) on page 29 of the EIS: "When a cell or virus dies, or comes close to invading another living organism, the recombinant DNA may effectively enter a new cell. A hazard might ensue if foreign proteins were manufactured in this "secondary" cell. Further treatment of the issue is presented in section VI-C, page 76, under the heading "Transfer of Foreign DNA from E. coli K-12." The EIS does not infer that the demonstrated reluctance of E. coli K-12 to colonize the human intestine renders it entirely harmless. If that were so, there would be no guidelines as we know them, where experiments using this attenuated DNA are classified over the whole range of containment possibilities.

Comment 3. "The possibility that an organism containing chimeric DNA could possess properties exhibited by neither the foreign donor nor the host organism is not considered. No response to this in the EIS. Appendix K65.

Response. Section IV-C-1 of the EIS, pages 23-31, describes the ways in which recombinant organisms might be hazardous. Under the subtitle "The effect of bacteria and viruses containing recombinant DNA on other forms of life, "there are sections explaining basic mechanisms whereby a resident microorganism is altered with regard to its pathogenicity or toxicity as a result of a resident recombinant. Foreign DNA inserted into a bacterial gene, "it is stated, "might so alter the microbial cell's properties that it becomes harmful to other organisms. This might happen, for example, through a change in the growth rate and competitive advantage of the recipient microbial cell, resulting in increased virulence of a mildy pathogenic bacterium." (EIS, p. 29) The statement and those following it are broad enough to include the possibility that "an organism containing chimeric DNA could possess properties exhibited by neither the host nor the organism", (which probably means "neither the foreign donor nor the host organism"). In other words, the EIS has nowhere denied this possibility and, indeed, addressed it in a general way by considering the various mechanisms through which hazards might arise.

Comment 4. "There is no adequate response to the criticism that the public rejection of the guidelines (as announced on March 6 in the Federal Register) under the sponsorship of the U.S. Department of Agriculture, the National Science Foundation, and the National Institutes of Health. The report of this workshop constitutes appendix C. It was presented to the Recombinant Advisory Committee at its meeting April 27-28, 1978, and was unanimously endorsed with certain minor amendments. The recommendations of the RAC have been adopted in the NIH Director's proposed revised guidelines (RG-NIH) with additional minor amendments to sections dealing with the use of plants and plant pathogens in recombinant DNA research.

Comment 5. "No response or correction of the lack of 'classification system for pests and pathogens of plants and animals' from transferring their hazards to agriculture such as exists for etiologic agents of disease on the basis of their hazard to humans." Correspondence between Drs. John W. Littlefield and Peter Day, April 14, 1977.

Response. The EIS does not address the guidelines' treatment of plant and animal sources of DNA on page 120, first paragraph. It explains that the analysis of potential hazards in the EIS is given in a general way that is equally applicable to persons, animals, and plants. The section of the guidelines on plants has been expanded in the proposed revision. Specifications for plant host-vector systems provide safeguards in greenhouses, growth chambers, etc., that meet the standards for experiments involving other life forms. As to a classification system, a workshop on risk assessment of agricultural pathogens was held in March 1978.

Comment 6. "No response to Dr. Peter Albersheim's concern over the use of the organism Agrobacterium tumefaciens in nitrogen-fixation work. Correspondence with Dr. Fredrickson.
The relatedness of different micro-organisms can be estimated by determining DNA-DNA homology between them or by studying the properties of different microorganisms in genetic crosses. As a general rule, organisms that show considerable homology of their nucleotide sequences under a standard set of experimental conditions have the capacity to mutually integrate chromosomal genes. For example, in the case of the Enterobacteriaceae family of bacteria (includes Inc P-1, K-12), there is both extensive DNA-DNA homology (1) and chromosomal gene exchange, (2) with a reasonable correlation between the degree of DNA-DNA homology and the capacity to mutually integrate chromosomal genes.

Genetic relatedness, as indicated by a high level of DNA-DNA homology between different microorganisms, is not, however, an absolute requirement for the exchange of chromosomal genes between bacteria. In fact, chromosomal gene transfer among diverse members of the Gram-negative group of bacteria has been demonstrated where the microorganisms involved show little or no DNA-DNA homology. In these cases the exchange of chromosomal genes is promoted by a broad-host-range plasmid of the Inc P-1 incompatibility type. These plasmids mobilize the chromosomes of a wide variety of Gram-negative bacteria, incorporate segments of these chromosomes, and are capable of establishing themselves along with covalently-linked chromosomal genes in a wide range of Gram-negative bacteria. (3)

Appendix A to the Guidelines contains a list of documented cases of chromosomal gene exchange between a variety of bacteria and E. coli K-12 where the gene exchange is promoted by Inc P-1 or other plasmids. The first ten entries in this table are members of the Enterobacteriaceae family of bacteria. The bacterial species in this family not only show chromosomal gene exchange but, as indicated above, exhibit extensive DNA-DNA homology. References listed at the end of this Appendix (4) provide documentation for the entries in Appendix A to the Guidelines. All entries in Appendix A exhibit R-prime transfer (R plasmid carrying chromosomal genes) to E. coli K-12 mediated by the Inc P-1 or other plasmids.

The Recombinant DNA Advisory Committee, at its 27 April 27-28, 1976, meeting proposed three possible alternative lists for consideration by the Director, NIH, to become Appendix A to the Guidelines. The first list with its criteria and entries was as follows:

The following genera and/or species possess R plasmids (including R plasmids of the IncP-1 group) transferable to E. coli K-12:

1. All members of the Enterobacteriaceae family
2. Vibrio species (except Vibrio para-hydrolyticus)
3. Pseudomonas species
4. Rhizobium species
5. Acinetobacter calcoaceticus
6. Agrobacterium tumefaciens
7. Rhodopseudomonas palustris
8. Aeromonas species
9. Proteus species
10. Achromobacter species
11. Aeromonas salmonicida
12. Alcaligenes faecalis
13. Bordetella bronchiseptica
14. Mycoplasma xanthus
15. Neisseria gonorrhoeae
16. Pasteurella hemolytica
17. Pasteurella multoctica
18. Terania species (excludes Y. pestis, since it is a Class 3 agent)
19. Xanthomonas species

In addition, recombinant DNA experiments between H. influenzae and H. parainfluenzae are exempt on the basis of extensive DNA homology.

References
NOTICES

APPENDIX E


Dr. Donald S. Fredrickson,
Director, National Institutes of Health, 3000 Rockville Pike, Bethesda, Md.

Dear Dr. Fredrickson:

On January 25-28, 1978, a joint U.S.-EMBO Workshop to Assess Risks for Recombinant DNA Experiments Involving Transgenic Animal, Plant, and Insect Viruses was held in Ascot, England. The workshop was sponsored by the NIH at your request. In response to discussions concerning viruses at the Director's Advisory Committee meeting of December 1977. The workshop was attended by 27 scientists from the United States, the United Kingdom, West Germany, Finland, France, Sweden, and Switzerland. The participants were invited because of their scientific expertise and not as representatives of any government or of any policymaking group.

The primary purpose of the meeting was to conduct an inter-laboratory analysis of possible risks associated with cloning eukaryotic viral DNA segments in E. coli K-12 host-vector systems and with the use of eukaryotic viruses as cloning vectors in animal, plant, and insect systems. In addition, there were general discussions of the public importance of recombinant DNA technology for the solution of problems in basic and applied virology and of the classification of viruses with respect to the hazard that laboratory research with them might pose to the laboratory worker or to the community.

A report of the discussions and conclusions of the workshop is transmitted to you along with this letter. A draft of this report was sent to the members for comment and revision, and this final version is based on the replies of all the participants. In view of the favorable responses, we feel that this report will receive the support of virologists in general. We hope that it will be useful to you and the various national committees that are considering containment levels for this type of recombinant DNA research.

Since this is the report of an international group, we generally avoided reference to any particular set of containment conditions. However, various national committees will use this report as the scientific basis for setting the containment conditions they feel appropriate.

Sincerely,

MALCOLM A. MARTIN,
Laboratory of Biology of Viruses, NIAID.

WALLACE W. BOOZE,
Laboratory of Viral Diseases, NIAID.

John Tooze,
Executive Secretary, European Molecular Biology Organization, Heidelberg.

Co-Chairmen.

REPORT OF U.S.-EMBO WORKSHOP TO ASSESS RISKS FOR RECOMBINANT DNA EXPERIMENTS INVOLVING THE GENOMES OF ANIMAL, PLANT, AND INSECT VIRUSES

This is the report of a joint U.S.-EMBO workshop held in Ascot, England, January 27-28, 1978, which was convened to discuss the possible risks of recombinant DNA experiments involving the DNAs of animal, plant, and insect viruses. The 27 scientists in attendance (see list) bringing their expertise in clinical infectious disease, public health, medical and diagnostic virology; the biology of virus infection; biochemical virology; and plant, insect, and veterinary viruses. Five of the participants are actively engaged in recombinant DNA experimentation. A consensus statement of the discussions in the areas of pathogenesis and epidemiology of viral diseases, potential benefits of recombinant DNA experiments involving eukaryotic viral DNA, viral hazard classifications, and cloning in prokaryotic and eukaryotic systems is presented below. The group's conclusions, with respect to possible risks of recombinant DNA experiments involving viruses are based on the best available scientific data derived from publications, knowledge of current activities in the field of virology, and first-hand experience in the virology laboratory.  

Introduction

Viral disease is a complex process that involves a series of critical steps; these include entry of the virus particle into the host, infection of specific cells at the portal of entry, replication of the virus in the infected cells, and usually, the spread of the progeny virus particles within the infected host to other susceptible cells. Depending upon the nature of the particular viral agent, the deleterious effects for the host, if any, may result from cytolytic activity, cellular transformation, chronic cellular dysfunction, or the provocation of an injurious immunological response. Viruses contain 5 to 150 or more genes and their coordinated functioning is required for viral growth and, consequently, for survival of the virus in nature. Even though we do not yet fully understand the precise role of each viral gene product, it seems clear that viral infection and disease production requires proper functioning of most, if not all, viral genes and, in general, is not a consequence of any single viral gene product. In the case of oncogenic papovaviruses, transforming retroviruses and possibly adenoviruses, individual viral genes are thought to be responsible for the transforming properties of the virus.

Recombinant DNA experiments have already yielded new information about the structure and control of expression of genes in higher organisms that could not have been obtained by conventional techniques. DNA cloning provides unparalleled opportunities to explore the basic biology of animal and plant viruses. Virologists will be able to probe more deeply into the control of viral gene expression and
discover phenomena of general cell biological significance; techniques will be more readily available to elucidate the sequence of viral nucleic acids, to shed light on the role of viral gene products in pathogenicity, and eventually, to understand the molecular biology of animal and plant viruses to the extent that some bacteriophages are now understood. It seems apparent that this new information will lead to a deeper understanding of viral diseases and to new ways of combating them. In the immediate future the ability to obtain useful amounts of pure viral genomes and subgenomic fragments that cannot be obtained by other means will provide scientists and physicians with invaluable and inexpensive diagnostic protein and nucleic acid reagents. In the more distant future it should be possible to use gene cloning techniques to obtain large amounts of viral proteins; one practical benefit from such developments might well be effective and safe vaccines for control of diseases caused by hepatitis viruses, herpesviruses and influenza viruses and many other viruses, both known and, as yet, unknown.

In addition to being able to clone viral genes in bacteria we are now able to envisage using certain animal viral vectors for the propagation of foreign genes in animal cells; a similar system for exploiting a plant virus, cauliflower mosaic virus, to clone for-system for exploiting a plant virus, foreign genes in animal cells; a similar to envisage using certain animal viruses. The cloning of viral DNA's and cDNA's in E. coli K-12 using EK1 and EK2 plasmid and lambda phage vectors was discussed in light of the conclusions of the Falmouth meeting that E. coli K-12 is not pathogenic and does not efficiently colonize the vertebrate digestive tract (Gorbach, 1978). Not for want of trying, the participants were unable to envisage a sequence of events which could occur with significant probability that would allow E. coli carrying either whole viral genomes of certain viruses or subgenomic fragments of virtually any virus to lead to disease. The question was also raised as to whether or not, in the extremely remote possibility that all of the biological and physical containment barriers were bypassed, extraintestinal bacteria carrying cloned whole viral genomes might bypass the natural barriers to infection by the virus particle. As summarized in the following section, the group concluded that the probability that K-12 organisms carrying viral DNA inserts could represent a significant hazard to the community was so small as to be of no practical consequence.

Risk assessment analysis for cloning viral DNA in E. coli K-12. The following is a summary of the workshop discussions dealing with possible mechanisms of risk resulting from the cloning of viral genetic material of eukaryotic viruses (i.e., viruses of animals, plants, or lower eukaryotes) in E. coli systems.

We started with the extremely unlikely “worst case” assumption that a recombinant molecule containing eukaryotic viral genome DNA could in some way become established in wild type E. coli and has thereby become disseminated throughout the bowel flora of vertebrates. Given this hypothetical set of conditions, what consequences might be envisaged? For the purposes of analysis the discussions focused on two issues. First: The mechanisms by which the viral nucleic acid might gain access to cells of the host; and Second: The nature of the inserted viral sequences.

Access of the viral genome to cells of the vertebrate host might conceivably result from virus particles formed in the bacterium or from release of viral nucleic acid into the proximity of, or into, host cells; this could occur either in the intestine or at the site of extraintestinal E. coli infection. Production of infectious virus particles by bacteria carrying recombinant DNA molecules was considered to be virtually impossible, regardless of the completeness of the viral genome or the nature of the eukaryotic virus from which it was derived. The value for this high degree of assurance is in large part our good understanding of the molecular biology of virus replication.

The nature of regulation of gene expression in prokaryotes is clearly different from that in eukaryotes as particularly exemplified by the absence in prokaryotes of RNA splicing mechanisms (Berget et al., 1977; Aloni et al., 1977; Lavi and Groner, 1977; Melina and Duesberg, 1977; Chow et al., 1977; Kissel, 1977; Dunn and Haswell, 1977), RNA capping (Moore, 1966; Stavis and August, 1970; Blattner and Dahlberg, 1972; Malzels, 1973; Wel and Moss, 1975; Furuchil et al., 1976; Kates and Beeson, 1972; Abraham et al., 1975; Furuchil et al., 1975b; Dubin and Taylor, 1975; Perry and Scherrer, 1975; Moss and Kocot, 1976) and differences in messenger RNA biogenesis, polyadenylation (Kates and Beeson, 1970; Darnell et al., 1971; Mendecki et al., 1972; Phillipson et al., 1971; Weinberg et al., 1972; Ehrenfeld and Summers, 1972; Fridgen and Kingsbury, 1972), and ribosomal binding sites (Shine and Dalgarno, 1971; Steitz and Jakes, 1975; Hagenbuchle et al., 1978). The expression of animal viral mRNA in E. coli translation systems is not accurate; in one well studied system, poliovirus, insertion of a single sequence has in result in premature chain termination (Rekosh et al., 1970). Thus neither the synthesis of proper mRNA nor its translation into viral protein is likely to occur in E. coli.

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Virus replication requires the regulated and coordinated function of multiple enzyme systems derived from both the host and the viral genomes; it seems most unlikely that any prokaryote contains the complement of enzymes required for the synthesis of an infecting virus. Animal viruses have evolved to be adapted to replication in eukaryotic cells; except for the instances where they have coevolved to replicate in insect vectors, animal and plant viruses show a high degree of specificity for cells of a particular class or species of host cell or even a particular differentiated cell type. Further, there is no verified example of the replication of a virus in eukaryotes in bacteria, or conversely, the replication of a bacterial virus in any eukaryote. Consequently, since it was not considered possible for recombinant DNA containing a viral chromosome to produce intact virus particles in E. coli, the group felt secure in focusing on models involving host cell exposure to viral nucleic acid rather than viral particles.

In a model in which recombinant DNA-containing organisms are confined to the lumen of the intestine, the possibility of viral RNA or DNA gaining access to mucosal cells is extremely remote. First: The large amounts of nucleases in the intestinal contents would rapidly destroy the recombinant molecules (Maturin and Curtiss, 1977). Second: The efficiency of infection of cells by viral nucleic acid molecules, even in the presence of chemical potentiators, is extremely low, both in vitro and in vivo (Ellemen and Colter, 1972; Amstey and Parkman, 1966; McCutchan and Fagan, 1965; Graham and van der Eb, 1973; Israeli et al., 1978a). Third: Since animal experiments indicate that poliovirus DNA cannot initiate infection when administered by the oral or nasal routes (Israeli et al., 1978a), it is likely that recombinant DNA will not infect across mucous membranes.

Consequently, the only model to which serious attention must be directed is one in which the hypothetical bacterial carrying the viral recombinant DNA gains access to the body tissues. Two cases can be considered. With minor transgressions of the intestinal mucosa that allow brief penetration of organisms into the intestinal wall, lymphatics, or the portal circulation, the bacteria would be ingested by phagocytes. In phagocytes, bacteria are lysed and their nucleic acid is released in the lysosomal-rich lysosomes; the effectiveness of the lysosomal enzymes is such that no nucleic acid could survive to cause infection (Bensch et al., 1984; Carrara and Bernardi, 1968; Arsenis et al., 1970).

The second case, extraintestinal infection such as urinary tract or surgical wound infection, deserves serious consideration, but it must be pointed out that this would occur in only a fraction of individuals. In this context the consequences of infection by the recombinant DNA would be a function of the nature of the viral DNA inserted in the recombinant DNA molecule. We considered the following classes of DNA inserts: (1) Subgenomic segments of nononcogenic viruses; (2) transforming segments of oncogenic viruses; (3) cDNA prepared from the genome of segmental RNA viruses; (4) cDNA copies containing the complete viral genome of nonsegmented RNA viruses and (5) complete DNA viral genomes. The workshop participants reached the conclusion that viral inserts should be thought in terms of three classes of risk: Those for which there was no risk of an oncogenic outcome, and those for which a possibility of harm, however remote, could be envisioned. The latter were then divided into those scenarios which may well in reality be impossible, and those which are felt to be possible.

Those inserts for which the group could not construct any realistic harmful scenario were: (1) Subgenomic segments of nontransforming RNA or DNA viruses; (2) cDNA copies from RNA viruses with segmental viral genomes and (3) cDNA's of the complete genome of negative strand RNA viruses.

(1) Subgenomic segments (meaning small portions of the viral genome lacking genes needed for replication of the virus) of nontransforming viruses are considered to be harmless because of the absence of any known example of an individual viral encoded protein which, if destroyed, would lead to cell damage from within.

(2) Reverse transcripts of RNA viruses with segmented genomes cannot be envisaged as carrying any risk of producing infectious virus even when the cDNA is made from unfragmented nucleic acid preparations. It would be virtually impossible to ligate together a complete DNA copy, and if this ever did occur, we cannot envisage any way that the proper length RNA genome segments could be transcribed therefrom.

(3) Cloning of reverse transcripts of negative strand RNA viruses is viewed as being free of risk. With these viruses, the consequences of the infection by viral genomic RNA synthesis is complex, and the Workshop participants could not envisage a set of circumstances in which RNA segments, transcribed from a DNA template, could eventuate in the synthesis of progeny virus. This is based on the fact that the nucleic acid of negative strand RNA viruses (either the plus or minus strand) has never been shown to be infectious for cells (Kingsbury, 1966; Baltimore et al., 1970; Wagner, 1975) presumably because of their unique molecular biology. Infection by negative strand viruses requires the activity of the virion associated transcriptase (Huang et al., 1970; Cormack et al., 1971; Szilagyi and Pringle, 1972); this enzyme catalyzes the synthesis of multiple (segmental) functional plus strand mRNA molecules from the input minus strand transcript, as well as properly terminated, segmented transcripts from the minus strand RNA. These are obviously extremely unlikely events.

There were two classes in which it was considered that a risk scenario might be constructed but which might indeed be impossible; these involve the cloning of the transforming segments of DNA viruses or of transforming RNA viruses, and the cloning of complete reverse transcripts of plus-strand RNA viruses. The model involving subgenomic transforming segments postulates release of recombinant DNA molecules by lysis of E. coli in the tissues, and integration of the transforming gene segment into the DNA of host cells. While this eventuality cannot be ruled out, it was considered to have a very low probability in view of the inefficacy of transforming cells with viral nucleic acid (Aaronson and Martin, 1970; Graham et al., 1974; Abrahams et al., 1975) and the fact that integration of transforming DNA would occur in only a few cells in any individual and, in the presence of competent immuno-surveillance, would be most unlikely to result in a tumor (Habel, 1981; Stjogren, 1985; Stjogren et al., 1987; Costa et al., 1977). Transplanta-
Jakes, would generate a leader sequence lacking infectious molecules; would be initiated either: There is no reason to believe that the DNA into 5' or eukaryotic cell would be the infectious RNA from the recombinant whole genome sequence, the likelihood of cloning the viral specific molecules the vast majority of recombinant ligation to prokaryotic select full-length cDNA molecules for production of viral genome DNA. Unless a deliberate attempt is made to generate infectious viral infection. Neither card entry into host cells with resultant productive viral infection. Neither carries a risk if the cDNA insert is not a complete copy of the RNA genome. Unless a deliberate attempt is made to select full-length cDNA molecules for ligation to prokaryotic DNA vectors, the vast majority of recombinant DNA molecules will contain only a segment of viral specific DNA and, as a consequence, the likelihood of cloning the whole genome will be low.

The major block to synthesis of infectious RNA from the recombinant DNA molecule either in the prokaryotic or eukaryotic cell would be the inaccurate initiation of transcription. There is no reason to believe that the 5' terminus of the viral genome would generate a binding site for either prokaryotic or eukaryotic DNA polymerases, following reverse transcriptase initiation into DNA. Rather, RNA synthesis would be initiated either:

(1) Internally, by a random initiation process which would yield noninfectious molecules; (2) Upstream, either at a prokaryotic promoter or at a random initiation site, in the eukaryotic cell which would generate a leader sequence lacking the appropriate recognition signals for binding to eukaryotic ribosomes (Sshine and Dalgarno, 1974; Steitz and Jakes, 1975; Hagenbuchle et al., 1978). To produce infectious RNA from such a primary transcript, a site-specific cleavage would have to occur; (3) At the 5' terminus by random initiation, but this undoubtedly would be an extremely rare event. Any full-length plus strand transcripts synthesized in E. coli would have to escape degradation by extracellular ribonucleases following release from bacteria and then initiate an infection in a sensitive cell, which, under the best conditions in the laboratory, is an extremely inefficient process (Zem and Colter, 1977).

Further studies of this type of viral DNA insert would clearly be desirable. The cloning of the complete genome of DNA viruses (including proviral forms of retroviruses) provides a scenario feared to carry a finite probability of risk, but this too is considered extremely low. Since viral DNA molecules are generally infectious, any situation in which the complete viral DNA without modification or substitution, is excised from the recombinant molecule could conceivably lead to infection. In particular, circular DNA genomes, cleaved with a single cut restriction enzyme and ligated to a prokaryotic vector, provide a scenario; however, for accurate excision one must postulate the unlikely evenuality of the recombinant molecule being brought in contact with the same restriction enzyme used during the insertion of the RNA segment into the vector. Complete viral genomes could also be generated from a recombinant molecule in the case of oligomers of viral DNA inserts, a complete copy of the viral DNA could then be generated by intramolecular recombination. Full length linear DNA molecules inserted into a vector by oligo dA-oligo dT tailing or by addition of other linker molecules would be unlikely to excise accurately terminating genomes.

Given that it is conceptually possible to generate infectious molecules from recombinant DNA containing the complete genome of DNA viruses, it is important to assess the factors that would result in such infectious DNA causing disease. The probability that the excised molecules would infect host cells is of course relatively low in view of the inefficiency of infection by naked DNA (Ito, 1960; Burnett and Harrington, 1968; McCutchan and Pagano, 1968; Mayne et al., 1971; Graham and van der Eb, 1973; and van der Noordaa, 1977). Another important factor in such a scenario is the susceptibility of neighboring cells to the virions produced by a cell infected with the infectious DNA. If the surrounding cells were not sensitive to the virus itself, the initially infected cell, producing virions, could not spread this infection to other cells or tissues; in the absence of virus spread there would be no risk other than the possible transformation of a small number of cells, in the case of oncogenic viruses, as discussed above. Only if the host was sensitive to the virus would spread occur; this would not be different from infection with the virus itself and would not generally represent a unique biohazard. Further study of this type of viral DNA insert would be extremely useful.

Recapitulation. It should be noted that these model scenarios were not constructed from an anthropocentric viewpoint, but apply generally to any model in which vertebrates are colonized by the E. coli carrying the recombinant molecule.

To recapitulate, even assuming a worst case situation, this analysis leads us to conclude that cloning the subgenomic segments of nononcogenic viruses, the complete genome of negative strand RNA viruses, and any part of the genome of segmented viruses carries no risk of generating a biohazard. Second: It is possible to construct conceivable but extremely unlikely biohazard from the cloning of the transforming segment of oncogenic viruses. And, third: It is possible to envisage feasible biohazard scenarios from cloning of the complete genome of DNA viruses or the entire genome of plus strand RNA viruses but even these carry little possibility of risk. When this analysis is combined with the immense unlikelihood of generating this worst case scenario in the first place, given good laboratory practice and the safety inherent in use of approved E. coli K-12 host-vector systems (Gorbach, 1978), the group felt strongly justified in concluding from available scientific information that viral genomes or fragments thereof, cloned in E. coli K-12 using approved plasmid or phage vectors pose no more risk than work with the infectious virus or its nucleic acid and in most, if not in all cases, clearly present less risk. In fact, the Workshop participants agreed that cloning of viral DNA in E. coli K-12 may provide a unique opportunity to study with greatly reduced risks the biology of extremely pathogenic and virulent viruses.

The group also agreed that the cloning of cDNA copies of viroids in E. coli K-12 should be postponed until more information is available about their molecular and cellular biology.

Recommendation. Based on these considerations the participants of the U.S.-EMBO Workshop concluded that the use of F2 (NIH guidelines) or CI (Williams report) containment measures, in conjunction with an EK1 host-vector system should provide adequate containment for cloning any viral genome or fragment thereof and recommended this as the minimum con-
tainment levels for recombinant DNA experiments involving eukaryotic viral DNA inserts. However, if the virus itself must be handled at higher levels of physical containment it seems prudent at the present time to use the more stringent containment conditions. It was emphasized that containment practices must include adequate training and the use of high quality microbiological technique.

**EXPERIMENTS WITH EUKARYOTIC HOST-VECTORS**

1. **Vertebrate host-vector systems in which viral DNA vectors are used to propagate recombinant DNA.**

The workshop participants endorsed the portion of the NIH guidelines that describes the features required for an animal virus to be used as a cloning vector (i.e., the first portion of section III.B.3.a. of the draft version, revised NIH guidelines for recombinant DNA research). The following is our recommended version of this section:

Because this work will be done almost exclusively in tissue culture cells, which have no capacity for propagation outside the laboratory, the primary focus for containment is the vector; it should be pointed out that the risk of laboratory acquired infection as a consequence of tissue culture manipulations is very low. Given good microbiological practices, the most likely mode of escape of recombinant DNAs from a physically contained laboratory is carriage by an infected human; thus the vector with an inserted DNA segment should have little or no ability to replicate or spread in humans. Further, a recombinant viral virus should not inadvertently pose a threat to any species.

For use as a vector in a vertebrate host cell system, an animal viral DNA molecule ideally should display the following properties:

(a) It should not consist of the whole genome of any agent that is infectious for humans or that replicates to a significant extent in human cells in tissue culture.

(b) It should be derived from a virus whose epidemiological behavior and biological properties are well understood.

(c) Its functional anatomy should be known—that is, there should be a clear idea of the location within the molecule of:

(i) The sites at which DNA synthesis originates and terminates;

(ii) The sites that are cleaved by restriction endonucleases;

(iii) The template regions for the major gene products.

(d) It should be defective when carrying an inserted DNA segment; that is, propagation of the recombinant DNA as a virus must be dependent upon the presence of a complementing helper genome. In almost all cases this condition would be achieved automatically by the manipulations used to construct and propagate the recombinants. In addition, the amount of DNA encapsidated in the particles of most animal viruses is defined within fairly close limits. The insertion of sizeable foreign DNA sequences, therefore, generally demands a compensatory deletion of viral sequences. It may be possible to introduce very short insertions (50-100 base pairs) without rendering the viral vector defective. In such a situation, the requirement that the viral vector be defective is not necessary. If possible the helper virus genome should:

(i) Be integrated into the genome of a stable line of host cells (a situation that would effectively limit the growth of the vector recombinant to such cell lines); or

(ii) Consist of a defective genome, or an appropriate conditional lethal mutant virus, making vector and helper dependent upon each other for propagation.

However, neither of these stipulations is a requirement.

The group discussed at length the possibility that use of eukaryotic vectors under these conditions could pose a threat to the community or environment, but could not envisage a plausible set of circumstances whereby a risk to the community could develop. Given the extent of the genetic deletion required to satisfy the conditions stated above and in table 2, and the constraints that encapsidation places on the size of an inserted gene segment, the workshop participants saw no way that the experiments could generate a competent virus containing new genetic information sufficient to code for a functional gene product. The group tried to conceive of ways by which a recombinantional event between the defective recombinant genome and the helper genome or the genome of an indigenous virus in an exposed laboratory worker might generate nondefective viral recombinants, but as mentioned, was unable to identify any.

The possibility that a defective recombinant genome might be maintained in nature through complementation by a helper virus was considered too unlikely to be a cause for concern, given the absence of any precedent in animal virology. The group considered the adenov-associated viruses, which are defective paroviruses maintained in nature, to be a unique case in that they are known to integrate into host cells and to have at least 33 different potential helpers (human adenoviruses) available.

Having considered the use of the genomes of different DNA animal viruses to propagate DNA sequences from different sources, the group proposed the following recommendations:

**TABLE 2**

Precaution Level Depending on Source of Foreign DNA

<table>
<thead>
<tr>
<th>Viral Vector DNA</th>
<th>prokaryotic</th>
<th>eukaryotic</th>
<th>viral</th>
</tr>
</thead>
<tbody>
<tr>
<td>polyoma virus — all or part</td>
<td>L or M</td>
<td>L</td>
<td>C/C</td>
</tr>
<tr>
<td>SV40 — unconditionally defective by deletion of all or part of the sequences of any of the genes</td>
<td>L or M</td>
<td>M</td>
<td>C/C</td>
</tr>
<tr>
<td>adenoviruses 2 and 5 — incapacitated by deletion of at least two capsid genes</td>
<td>L or M</td>
<td>L</td>
<td>C/C</td>
</tr>
<tr>
<td>murine adenovirus strain FL — all or part</td>
<td>L or M</td>
<td>L</td>
<td>C/C</td>
</tr>
<tr>
<td>Herpes simplex virus — incapacitated by a large deletion</td>
<td>C/C</td>
<td>C/C</td>
<td>C/C</td>
</tr>
</tbody>
</table>

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\[ L \text{ corresponds to a containment level approximately equivalent to P2.} \]

\[ M \text{ corresponds to a containment level approximately equivalent to P3.} \]

Prokaryotic sequences that are known not to contain toxic gene may be cloned in \( L \) conditions; otherwise \( M \) conditions should be used.

Before this viral DNA can be used as a vector, further information is required about its host-range, particularly its interaction with cultured primate cells.

C&c these experiments should be assessed by the appropriate committees on a “Case by Case” (C&C) basis.

The group recommended that further work on the biological properties of recombinant formed between the genomes of two animal viruses should be carried out as a matter of some importance. The workshop participants discussed the possibility that new viral agents might be created with novel biological properties (e.g. host range, tissue tropism, pathogenicity) not found in either parent. Several model experiments were proposed to test this possibility. The group recommended that research in this area proceed cautiously with each case being considered on its individual merits and even if the model experiments suggest little cause for concern, continued careful surveillance of new recombinants should be maintained.

2. Vertebrate host-vector systems in which recombinant DNAs are used to transform cells. In these types of experiments viral DNAs carrying a foreign DNA segment will be used to transform cells in culture and in the process, integrate the recombinant DNA into the host cell chromosome. Some transformation systems are non-permissive for progeny virus production and pose no possibility of producing laboratory infections. Other transformation systems are semi-permissive and, in addition to the appearance of transformed cells, allow the production of low titers of infectious virus.

When recombinant DNAs are used to transform cells which do not yield significant quantities of infectious virus (e.g. SV40 in murine cells, polyoma virus in rat or hamster cells, adenovirus 2 and 5 in rat cells) \( L \) conditions are generally sufficient; for viruses which do not infect humans, there need be no requirement that the vector be disabled. \( M \) conditions should be used if the system is semi-permissive (i.e., virus is produced, in low titer) and the virus is capable of infecting humans (e.g. SV40 in human cell cultures). It was agreed that the DNA to be cloned must not be derived from another animal virus.

The use of viral genes as selectable markers offers exciting and important possibilities for experiments involving cloning in eukaryotic cells. Possibly the best of such markers would be the herpes simplex virus thymidine kinase gene. We recommend that special emphasis be given to cloning in prokaryotic systems a small fragment (<5KB) of herpes viral DNA which contains the sequences of this gene. Once available, the purified segment could be ligated to any chosen piece of DNA and cells transformed by the recombinant could easily be selected by virtue of the presence of thymidine kinase.

3. Bacterial viruses as vectors. The group discussed the use of bacteriophages (large DNA-containing insect viruses) for cloning genes in invertebrate cells and concluded that our knowledge of the molecular and cellular biology of these viruses is too limited to allow any general recommendations. Proposals to use these viruses should be considered case by case. The group also recommended, however, that because of the potential exploitation of these viruses as biological pesticides (two have already been licensed for this purpose) and as vectors in recombinant DNA experimentation, high priority should be given to studies of their basic virology, genetics, and molecular biology.

4. Cauliflower Mosaic Virus as a vector for cloning genes in plant cells. The only known plant viruses which could serve as vectors for cloning genes in plants and plant cell protoplasts are Cauliflower Mosaic Virus (CaMV) and its close relatives, which have relaxed circular double stranded DNA genomes with a molecular weight of \( 5 \times 10^6 \). The genomes of these viruses are not known to integrate into host chromosomes, or to pick up cellular genes. CaMV is spread in nature by aphids, in which it survives for a few hours. Spontaneous mutants of CaMV that are not transmitted by aphids arise frequently; these mutants fail to make a transmission factor essential for aphid transmission.

The viruses in the CaMV group have narrow host ranges and are relatively difficult to transmit mechanically to plants. For this reason, they are most unlikely to be accidentally transmitted from spillage of purified preparations of the virus.

The workshop participants recommended that for use as a vector with intact plants, a strain should be selected which is not transmitted by aphids. The ability to produce local lesions in an appropriate host would be an advantage in maintaining the integrity of the strain. The plants should be grown in either a greenhouse or plant growth cabinet which is insect-proof. Soil, plant pots and unwanted infected plant materials should be removed from the greenhouse or cabinet in sealed insect proof containers and sterilized. It is not necessary to sterilize run-off water from the infected plants as this is not a plausible route for secondary infections. Infected plant materials to be used for further research, which has to be removed from the greenhouse or cabinet, should be maintained under insect proof conditions. These measures provide an entirely adequate degree of containment and are similar to those required in many countries for licensed handling of “exotic” plant viruses.

CaMV or its DNA may also be useful as a vector to introduce genes into plant protoplasts. The fragility of plant protoplasts combined with the properties of CaMV mentioned above provides adequate safety. Since the group envisaged no risks to the environment from use of the CaMV protoplast system, no special containment was recommended.
## Appendix E

### TABLE 1

<table>
<thead>
<tr>
<th>Agent</th>
<th>Genome</th>
<th>Severity of Disease in Adult Mice</th>
<th>Risk of Laboratory Infection</th>
<th>Transmission Into Community or Environment</th>
<th>Community or Environmental Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lassa Fever Virus</td>
<td>RNA - Negative strand, segmented</td>
<td>4*</td>
<td>H</td>
<td>L - H</td>
<td>H</td>
</tr>
<tr>
<td>Varicella Virus</td>
<td>DNA - Linear, double stranded</td>
<td>4*</td>
<td>H (if not vaccinated)</td>
<td>L - H</td>
<td>H</td>
</tr>
<tr>
<td><em>Yersinia pestis</em> (Plague bacterium)</td>
<td>RNA - Positive strand</td>
<td>3*</td>
<td>H (if not vaccinated)</td>
<td>L - H</td>
<td>L - H</td>
</tr>
<tr>
<td><em>Yersinia pestis</em> (bubonic type)</td>
<td>RNA - Positive strand</td>
<td>3*</td>
<td>H (if not vaccinated)</td>
<td>L - H</td>
<td>L - H</td>
</tr>
<tr>
<td><em>Anticom parasitii</em> (Typhus agent)</td>
<td>DNA - Circular, partially single stranded</td>
<td>3*</td>
<td>L to H</td>
<td>L</td>
<td>0 to L</td>
</tr>
<tr>
<td><em>Tulane comma</em> (Chlorera bacterium)</td>
<td>DNA - Circular, partially single stranded</td>
<td>3*</td>
<td>L to H</td>
<td>L</td>
<td>0 to L</td>
</tr>
<tr>
<td><em>Yersinia comma</em></td>
<td>DNA - Linear, single stranded</td>
<td>1*</td>
<td>L</td>
<td>L</td>
<td>0 to L</td>
</tr>
<tr>
<td><em>Vesicular stomatitis virus</em></td>
<td>DNA - Negative strand</td>
<td>1*</td>
<td>L</td>
<td>L</td>
<td>0 to L</td>
</tr>
<tr>
<td><em>Ahsinovirus 2 or 5</em></td>
<td>DNA - Linear, double stranded</td>
<td>0 - 1*</td>
<td>0 - L</td>
<td>0</td>
<td>0 to L</td>
</tr>
<tr>
<td><em>Geno-SEC hybrid Viruses</em> (landfocative)</td>
<td>DNA - Linear, double stranded</td>
<td>0 - 1*</td>
<td>0 - L</td>
<td>0</td>
<td>0 to L</td>
</tr>
<tr>
<td>Yersinia virus</td>
<td>DNA - Linear, single stranded</td>
<td>1*</td>
<td>L</td>
<td>L</td>
<td>L to 0</td>
</tr>
<tr>
<td><em>Sasa papilloma virus</em></td>
<td>DNA - Circular, double stranded</td>
<td>1*</td>
<td>L</td>
<td>L</td>
<td>L to 0</td>
</tr>
<tr>
<td><em>Yersinia pestis</em> (RFE)*</td>
<td>DNA - Negative strand, segmented</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0 to L</td>
</tr>
<tr>
<td><em>Ipiuscom&amp;</em></td>
<td>DNA - Linear, single stranded</td>
<td>0</td>
<td>L</td>
<td>L</td>
<td>0 to L</td>
</tr>
<tr>
<td><em>Le</em> Virus</td>
<td>DNA - Circular, double stranded</td>
<td>0</td>
<td>L to H (1)</td>
<td>0 to L(1)</td>
<td>0 to L</td>
</tr>
<tr>
<td><em>Simian Virus</em></td>
<td>DNA - Circular, double stranded</td>
<td>0</td>
<td>0 to H (1)</td>
<td>0 to L(1)</td>
<td>0 to L</td>
</tr>
<tr>
<td><em>Shubella virus</em> (lab. adapted)</td>
<td>DNA - Negative strand**</td>
<td>0 - 1*</td>
<td>0</td>
<td>0 to H (1)</td>
<td>0 to L(1)</td>
</tr>
<tr>
<td><em>Similaki Forest Virus</em></td>
<td>DNA - Negative strand**</td>
<td>0 - 1*</td>
<td>0</td>
<td>0 to H (1)</td>
<td>0 to L(1)</td>
</tr>
<tr>
<td><em>Reoviruses</em></td>
<td>RNA - Double stranded, segmented</td>
<td>0</td>
<td>0 to H (1)</td>
<td>0 to L(1)</td>
<td>0 to L</td>
</tr>
<tr>
<td><em>Bovine sarcoma virus</em></td>
<td>RNA (M낫rais)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0 to L</td>
</tr>
<tr>
<td><em>Horse leukoencephalitis</em></td>
<td>DNA</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0 to L</td>
</tr>
<tr>
<td><em>Filoviruses</em></td>
<td>DNA</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0 to L</td>
</tr>
<tr>
<td><em>Potyca virus</em></td>
<td>DNA - Circular, double stranded</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0 to L</td>
</tr>
</tbody>
</table>

* Non-viral agents.
** Ed. note: This should read "RNA-Positive strand."

H = High probability; L = Low probability.

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Kissig, D. F. (1977) Two adenovirus mRNAs have a common 5' terminal leader and a 10 kb upstream from their main coding regions. Cell 13, 9-22.


Mendenick, J., Lee, S. Y. and Braewman, G. (1972) Characteristics of the polyadeny-
REVIEW OF THE U.S.-EMBO WORKSHOP REPORT

The working group discussed the U.S.-EMBO workshop report section by section and recommended the following amendments:

(1) Page 16, line 17—delete "then modify" and insert "is thought to modify."

(2) Page 16, lines 6-8—The working group did not understand the scientific basis behind this short paragraph which singled out viroids from RNA plant viruses and which would postpone work in this area. Deletion of these three lines was recommended following a discussion about the potential risks attending the cloning of cDNA copies of viroids in E. coli K12.

(3) Table I.

(a) Yellow fever virus—Add "L" (if vaccinated) under Risk of Laboratory Infection and change "(H)" to "(L-H)" under Community or Environmental Impact.

(b) Epstein-Barr Virus—Change "+" to "0-+" under Severity of Human Disease.

After reviewing the U.S.-EMBO report the working group unanimously endorsed: (1) The classification of viruses with respect to their ability to cause disease in laboratory workers and their impact on the environment; (2) The analysis and recommendations for cloning viral DNA's in E. coli K12; and (3) The analysis and recommendations for the use of viral DNA's as vectors in eukaryotic cells.

IMPLEMENTATION OF THE U.S.-EMBO REPORT

A. Cloning Eukaryotic Viral DNA in E. coli K12 Host-Vector Systems.

After considerable discussion, the working group recommended physical and biological containment conditions for experiments involving the cloning of viral DNA in E. coli K12 as shown in table 1. The group classified the viral DNA experiments in three categories: (1) Virion DNA of DNA viruses; (2) cDNA copies of virion RNA of RNA viruses; and (3) Intracellular forms of viral DNA including integrated genomes and DNA from productively infected cells. The viral DNA to be cloned was then subclassified into whether it represented the entire viral genome or a purified subgenomic segment thereof. Subgenomic segments were further subdivided on the basis of whether they contained intact transforming genes or not (see table 1). In addition, the working group also assigned physical and biological containment levels for cDNA copies of cellular mRNA's for each class of viral DNA insert (see table 1).

1. In its deliberations, the working group was impressed with the safeguards afforded by a ban on mouth-pipetting for recombinant DNA experiments involving E. coli K12 host-vectors. The group felt that the only plausible way E. coli K12 could gain entry into laboratory workers was by mouth-pipetting. The virus working group recommended on the remote possibility that E. coli K12, containing eukaryotic viral DNA, would be swallowed and the viral DNA insert would be delivered to tissue in the body which ordinarily would be inaccessible to the virus. A prohibition of mouth pipetting would clearly prevent this sequence of events from even beginning. The working group therefore recommended that no mouth pipetting be allowed at any level of physical containment (including PI) when working with E. coli K12.

2. The group was struck by the inherent safety afforded by nonmobility of plasmids and felt they represented an additional level of containment when used with E. coli K12. Accordingly, the working group recommended that E. coli K12 should be considered as vectors for these plasmid vectors (referred to in table 1 as EK1NM) for several categories of experiments.

3. The virus working group extensively discussed the use of class III nononcogenic viral DNA's (NCI) as vectors, referred to as Class III nonmobility (NCI) viral DNA's in E. coli K12 host vector systems. The group concluded that vesicular stomatitis virus (VSV), which is a widely studied negative-strand RNA virus, is classified as a class III agent because of its ability to produce disease in animals; VSV is not an important human pathogen (see table 1 of U.S.-EMBO report). The working group agreed that VSV possessed all of the safety features of other negative-strand RNA viruses (see U.S.-EMBO report) and strongly recommended that cloning of VSV cDNA be permitted because of its importance as a model virus in studies of the propagation of the viruses themselves during the preparation of reagents/substrates for use in recombinant DNA experiments. None of these agents produces human disease or has been associated with human malignancy. The virus working group endorsed the inclusion of these agents as sources of eukaryotic viral DNA for cloning in E. coli K12 and recommended that NCI guidelines be followed for work involving the viruses themselves.

B. Viral DNA Vectors in Eukaryotic Cells.

The working group discussed the physical containment levels appropriate for different eukaryotic viral DNA vectors and prepared a list of four animal viruses and two plant viruses as candidate vectors. In each case the group made recommendations regarding physical containment conditions for productive or nonproductive cell infections. The virus working group, like the participants of the U.S.-EMBO workshop, were concerned about alterations in host range and tissue tropism that might occur following the insertion of foreign viral DNA sequences into eukaryotic viral DNA vectors and were unable to specify containment levels for this type of DNA recombinant. The group agreed that experiments of this type could yield useful information about viral pathogenesis and recommended that each be evaluated by the recombinant DNA Molecule Program Advisory Committee on a "case-by-case" basis.

The virus working group regarded the use of DNA vectors prepared from CaMV and BGMV as posing virtually no biohazard to plants or the ecosystem and recommended a minimum of physical containment. The group extensively discussed the use of baculovirus DNA as vectors, and, despite their certification as registered pesticides, considered the available information about their host range, persistence, and basic biology to be too rudimentary at the present time. A "case-by-case" evaluation was therefore recommended.

The virus working group unanimously endorsed the elimination of the requirement pertaining to the functional anatomy of viral DNA vectors (page 49602, third column, (iii)) since these features are related in no way to the inherent safety of the agent used. These criteria for candidate vectors were retained in the final recommendations, however, as desirable, although not required features.

It should be noted that the recommendations of the virus working group impact on two other sections of the Revised Guidelines for Recombinant DNA Research.

(1) Section III B 1a(1)(g) can be eliminated because it is now covered in section III B 1b(1).

(2) Section III A should be amended to read "pathogenic organisms in classes 3, 4, and 5 except vesicular stomatitis virus," the prohibition of moderate oncogenic viruses should be deleted.

The recommendations made by the virus working group were based on the best and most current available scientific considerations. The containment levels proposed for cloning eukaryotic
viral DNA inserts in prokaryotic systems pertain only to E. coli K12 and its derivatives. The working group agreed with the participants of the U.S.-EMBO Workshop that eukaryotic viral genomes cloned in E. coli K12 posed less risk in nearly all cases than work with the infectious virus itself.


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### TABLE 1. Type of Viral DNA Segment to be Cloned

<table>
<thead>
<tr>
<th>Virus Class</th>
<th>Subgenomic 1</th>
<th>Genomic 2</th>
<th>CDNA from cellular mRNA 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Non-transforming Segments</td>
<td>Genes containing an entire transforming gene</td>
<td>Non-segmented genome</td>
</tr>
<tr>
<td>DNA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-transforming viruses</td>
<td>A1<strong>P</strong>1+EK1</td>
<td>A1<strong>P</strong>2+EK1N9</td>
<td>P1+EK1</td>
</tr>
<tr>
<td>AAV, MVM, Mouse Adeno</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Transforming viruses</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Herpes salmiri and H. ateles</td>
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<tr>
<td>Other</td>
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<td></td>
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<tr>
<td>RNA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Retroviruses</td>
<td>A1<strong>P</strong>1+EK1</td>
<td>A1<strong>P</strong>2+EK1N9</td>
<td>P2+EK2 or P3+EK1</td>
</tr>
<tr>
<td>Gibbon and woolly monkey</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Negative strand RNA</td>
<td>P1+EK1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Plus strand RNA</td>
<td>P1+EK1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Type 1 and 2 Sabin polio, 17D</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yellow fever vaccine strains</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Double stranded RNA</td>
<td>P1+EK1</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1. > 99% pure (i.e., less than 1% of the DNA consists of intact viral genomes), otherwise as for whole genomes.
2. Integrated genomes to be cloned at containment as for shotgun experiments on uninfected cells.
3. > 99% pure, otherwise as for shotgun with uninfected cells.
4. For the purposes of this chart, P1 is defined as including a ban on mouth pipetting.
5. EK1N9 means K-12 with non-mobilizable plasmid vectors.
6. These viruses have been classified by NCI as "moderate risk oncogenic viruses," and NCI recommends that the viruses be handled under the equivalent of P3 containment.
### Table 2. Recommended Containment for Recombinant DNA Research Using Eukaryotic Viral Vectors

<table>
<thead>
<tr>
<th>Vector DNA</th>
<th>Productive Virus-Cell Interactions</th>
<th>Non-Productive Virus-Cell Interactions</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Type of DNA Insert</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Prokaryotic</td>
<td>Eukaryotic</td>
</tr>
<tr>
<td></td>
<td>Shotgun Purified</td>
<td>Shotgun Natural Host</td>
</tr>
<tr>
<td>1. Polyoma</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intact Genome</td>
<td>P2  P2</td>
<td>P2</td>
</tr>
<tr>
<td>Deleted Genome</td>
<td>P2  P2</td>
<td>P2</td>
</tr>
<tr>
<td>2. SV40</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intact Genome</td>
<td>--  --</td>
<td>--</td>
</tr>
<tr>
<td>Deleted Genome</td>
<td>P2  P2</td>
<td>P2</td>
</tr>
<tr>
<td>3. Human Ad2+Ad5</td>
<td>P3  P3</td>
<td>P3</td>
</tr>
<tr>
<td>Deleted Genome</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Mouse Adenovirus (Strain FL)</td>
<td>CBC  CBC</td>
<td>CBC</td>
</tr>
<tr>
<td>Intact Genome</td>
<td>P2  P2</td>
<td>P2</td>
</tr>
<tr>
<td>Deleted Genome</td>
<td>P2  P2</td>
<td>P2</td>
</tr>
<tr>
<td>5. Insect Viruses</td>
<td>CBC  CBC</td>
<td>CBC</td>
</tr>
<tr>
<td>6. Plant Viruses (CoVH and OGV)</td>
<td>P1  P1</td>
<td>P1</td>
</tr>
<tr>
<td>7. All other potential Viral Vectors</td>
<td>CBC  CBC</td>
<td>CBC</td>
</tr>
</tbody>
</table>

*CBC - Case by case to be decided by RAC*
(1) Viruses of Eukaryotes.
   (a) DNA viruses.
      1. Nontransforming viruses.
         (a) Adeno-associated viruses, minute virus of mice, and mouse adenovirus strain F1.—P1 physical containment including no mouth pipetting + an EK1 host-vector shall be used for DNA recombinants produced with the whole genome, subgenomic DNA segments, or cDNA copies of cellular mRNA.*
         (b) Other viruses.
            (i) P1 physical containment including no mouth pipetting + an EK1 host-vector shall be used for DNA recombinants produced with purified subgenomic DNA segments or cDNA copies of cellular mRNA.
            (ii) P1 physical containment including no mouth pipetting + an EK2 host-vector shall be used for DNA recombinants produced with the whole genome.

2. Transforming viruses.
   (a) Herpes saimiri and herpes atelis.
      (i) P1 physical containment including no mouth pipetting + an EK1 host vector shall be used for DNA recombinants produced with purified non-transforming subgenomic DNA segments or cDNA copies of cellular mRNA.
      (ii) P2 physical containment + an EK1 host vector which, in the case of a plasmid, must be non-mobilizable, shall be used for DNA recombinants produced with the whole genome.
      (iii) P3 physical containment + an EK1 host-vector or P2 + EK2 shall be used for DNA recombinants produced with the whole genome.

3. RNA viruses.
   (a) Gibbon ape and woolly monkey viruses.
      (i) P1 physical containment including no mouth pipetting + an EK1 host-vector shall be used for DNA recombinants produced with the whole genome or purified subgenomic DNA segments or cDNA copies of cellular mRNA.
      (ii) P2 physical containment + an EK1 host-vector which, in the case of a plasmid, must be non-mobilizable, shall be used for DNA recombinants produced with purified subgenomic DNA segments containing an entire transforming gene, the whole genome, or cDNA copies of cellular mRNA.*
      (b) Other viruses.
         (i) P1 physical containment including no mouth pipetting + an EK1 host-vector shall be used for DNA recombinants produced with purified subgenomic DNA segments containing an entire transforming gene, the whole genome, or cDNA copies of cellular mRNA.*
         (ii) P2 physical containment + an EK1 host-vector which, in the case of a plasmid, must be non-mobilizable, shall be used for DNA recombinants produced with purified subgenomic DNA segments containing an entire transforming gene, the whole genome, or cDNA copies of cellular mRNA.*

4. Double-stranded segmented RNA viruses.—P1 physical containment including no mouth pipetting + an EK1 host-vector shall be used for DNA recombinants produced with the whole genome, subgenomic DNA segments or purified cDNA copies of cellular mRNA.*

5. Viruses.—P1 physical containment including no mouth pipetting + an EK1 host-vector shall be used for DNA recombinants produced with the whole genome, subgenomic DNA segments or cDNA copies of cellular mRNA.*

*The cDNA copy of cellular mRNA must be 99 percent pure; otherwise, physical and biological containment specified for shotgun experiments involving infected eukaryotic cellular DNA (see B.l.a.)(1) shall be used for DNA recombinants produced with integrated viral DNA or viral genomes present in infected cells.

3. Experiments with Eukaryotic host-vectors.
   a. Vertebrate host-vector systems.—Because this work will be done almost exclusively in tissue culture cells, which have no capacity for propagation outside the laboratory, the primary focus for containment is the vector; i.e., it should be pointed out that risk of laboratory acquired infection as a consequence of tissue culture manipulations is very low. Given good microbiological practices, the most likely mode of escape of recombinant DNAs from a physically contained laboratory is carriage by an infected human; thus the vector with an integrated DNA segment should have little or no ability to replicate or spread in humans. Further, a recombinant virus should not inadvertently pose a threat to any species. For use as a vector in a host cell system, any viral DNA molecule should display the following properties:
   (b) It should not consist of the whole genome of any agent that is infectious for humans or that replicates to a significant extent in human cells in tissue culture. If the recombinant molecule is used to transform non-permissive cells (i.e. cells which do not produce infectious virus particles), this is not a requirement.
   (b) It should be derived from a virus whose epidemiological behavior and host range are well understood.
   (c) In nonpermissive cells, it should be defective when carrying an inserted DNA segment; i.e. propagation of the recombinant DNA as a virus must be dependent upon the presence of a complementing helper genome. In almost all cases this condition would be achieved automatically by the manipulations used to construct and propagate the recombinants. In addition, the amount of DNA encapsidated in the particles of most animal viruses is defined within fairly close limits. The insertion of sizeable foreign DNA sequences, therefore, generally demands a compulsory deleterious effect on viral sequences. It may be possible to introduce very short insertions (50-100 base pairs) without rendering the viral vector defective. In such a situation, the requirement that the viral vector be defective is not necessary except in those cases in which the inserted DNA encodes a biologically active polypeptide.

It is desired but not required that the functional anatomy of the vector be known—that is, there should be a
clear idea of the location within the molecule of:
(a) The sites at which DNA synthesis originates and terminates.
(b) The sites that are cleaved by restriction endonucleases.
(c) The template regions for the major gene products.
If possible the helper virus genome should:
(i) Be integrated into the genome of a stable line of host cells (a situation that would effectively limit the growth of the vector recombinant to such cell lines), or
(ii) Consist of a defective genome, or an appropriate conditional lethal mutant virus, making vector and helper dependent upon each other for propagation.

However, neither of these stipulations is a requirement.

(1) Polyoma virus.
(a) **Productive virus-cell interactions.**
1. Defective or intact polyoma virus genomes, with appropriate helper, if necessary, can be used in P2 conditions to propagate DNA sequences from:
   (a) Bacteria of class 1 or class 2 (see appendix B), or their phages or plasmids, except for species of bacteria that produce potent polypeptide toxins.
   (b) From mice.
   (c) From other eukaryotic organisms that do not produce potent polypeptide toxins, provided the DNA segment is purified.
2. Defective or intact virus genomes with appropriate helper, if necessary, can be used in P3 conditions for shotgun experiments to propagate DNA sequences from eukaryotic organisms, provided the DNA is obtained from uninfected cells such as embryonic or tissue culture cells.
3. Experiments involving the use of defective polyoma virus genomes to propagate DNA sequences from eukaryotic viruses will be evaluated by the Recombinant DNA Molecule Program Advisory Committee on a case-by-case basis and will be conducted under physical containment conditions recommended by that committee.

(b) **Non-productive virus-cell interactions.**—Defective or intact SV40 genomes can be used as vectors in P2 conditions to transform nonpermissive cells in culture.

(3) Human adenoviruses 2 and 5.
(a) **Productive virus-cell interactions.**
1. Human adenoviruses 2 and 5, rendered unconditionally defective by deletion of at least 2 capsid genes, with appropriate helper(s), if necessary, can be used in P3 conditions to propagate DNA sequences from:
   (a) Bacteria of class 1 or class 2 (see appendix B), or their phages or plasmids except for species of bacteria that produce potent polypeptide toxins.
   (b) Eukaryotic organisms (shotgun experiments or purified DNA) provided the DNA is obtained from uninfected cells such as embryonic or tissue culture cells.
2. Experiments involving the use of human adenoviruses 2 and 5, rendered unconditionally defective by deletion of at least 2 capsid genes, with appropriate helper(s), if necessary, can be used in P2 conditions to transform nonpermissive cells in culture.

(b) **Non-productive virus-cell interactions.**—Defective or intact human adenovirus strain FL or genomes can be used as vectors in P2 conditions to transform non-permissive cells in culture.

(5) **All other potential viral vectors.**
(a) Experiments involving the use of DNA vectors consisting of 25 percent or less of the viral genome shall be used:
1. In P2 conditions to transform non-permissive cells in culture.
2. Under physical containment conditions to be determined by the Recombinant DNA Molecule Program Advisory Committee to propagate DNA sequences from prokaryotic or eukaryotic organisms.

(b) Experiments involving the use of other intact or defective virus genomes to propagate DNA sequences from prokaryotic or eukaryotic viruses (and viruses) or as vectors to transform non-permissive cells will be evaluated by the Recombinant DNA Molecule Program Advisory Committee on a case-by-case basis and will be conducted under physical containment conditions recommended by that committee.

The Recombinant DNA Molecule Program Advisory Committee will also review all experiments involving the use of virus vectors in animals and the physical containment conditions appropriate for such studies.

b. **Invertebrate host-vector systems in which insect viruses are used to propagate other DNA segments.**—As soon as information concerning the nature of the host range, infectivity, persistence and integration in vertebrate and invertebrate cells becomes available, experiments involving the use of baculoviruses to propagate...
The viruses or their DNA may also be useful as a vector to introduce genes into plant protoplasts. The fragility of plant protoplasts combined with the properties of the viruses mentioned above provide adequate safety. Since no risks exist from the use of the DNA plant virus/protoplast system is envisaged, no special containment is recommended.

Experiments involving the use of plant virus genomes to propagate DNA sequences from eukaryotic viruses will be evaluated by the Recombinant DNA Molecule Program Advisory Committee on a case-by-case basis and will be conducted under containment conditions recommended by that committee.

APPENDIX G.—REPORT OF A WORKSHOP ON RISK ASSESSMENT OF AGRICULTURAL PATHOGENS

Conducted by: Recombinant DNA Molecule Program Advisory Committee.


Contents

Introduction.
Hazard classification of plant pathogens.
Table 1—Survival data of plant protoplasts.
Table 2—Available evidence for exchange among bacterial plant pathogens and symbionts.
References.
Participants.
Liaison representatives.

INTRODUCTION

An assessment of risk involved in recombinant DNA research on plant and insect pathogens necessarily entails consideration of different concerns than those applied to risk assessment of research with pathogens of man and animals. This fundamental difference provides the basis on which the recommendations of our committee were formulated.

There was a consensus amongst the committee members that working with plant pathogens and baculoviruses in recombinant DNA studies presents no more hazard than that which exists in current laboratory studies with the pathogens themselves. It is significant that to the best of our knowledge there have been no cases recorded in which laboratory studies with cultures of plant pathogens have resulted in illness in man or animals exposed to these organisms. Neither is there a documented case in which laboratory studies with cultures have resulted in an escape resulting in an outbreak of disease in plants growing under natural conditions.

We believe that any potential risk that might arise from studies involving plant pathogens is now adequately covered by existing federal and state quarantine regulations. These have evolved to enable government to deal with the practicalities of plant disease control (Gram, E., 1960, Chapter 5, pp. 514-555 in "Plant Pathology, An Advanced Treatise", J. G. Horsfall and A. E. Dimond, eds., vol. 3, Acad. Press., New York). They take precedence over any other regulations since they determine whether or not an investigator has access to a particular pathogen.

With plants, resistance to disease is the rule, susceptibility is the exception. Thus, the common occurrence of resistance poses an important barrier to the successful establishment of potential pathogens. There is no pathogen that is highly virulent on all plant species. Rather, the majority of pathogens are restricted to a relatively small number of host plants and within these specific susceptible hosts variable variation in resistance is usually present. Breeding for disease resistance has provided a means for effecting relatively rapid changes in varieties. In the United States today, approximately 95 percent of the acreage in crops of economic importance is planted to varieties that carry resistance to one or more major diseases. This is one of the key factors in the productivity of American agriculture. Even when a particularly destructive new race or strain of a plant pathogen arises, it is possible to change the available varieties and to reduce or minimize the threat within the space of two or three years. This was the case when a virulent strain of the pathogen that causes Helminthosporium leaf blight spread throughout the corn growing area of the United States in 1970 and it was necessary to discontinue the growing of those hybrids that carried the factor for male sterility which also conferred susceptibility to the disease (Ullstrup, A. J., 1972, Ann. Rev. Phytopath. 10:37-50).

Virulent plant pathogens commonly are maintained in nature because for their very survival and dissemination within a region, or for an epidemic to develop, they require specific environmental factors (Colhoun, J., 1973, Ann. Rev. Phytopath. 11:93-106). For example, bacterial wilt caused by Pseudomonas solanacearum rarely occurs north of the Mason-Dixon line. The causal bacterium is sensitive to low temperatures and has a relatively high optimum temperature for growth. Even when introduced inadvertently into Northern states it does not overwinter in the soil or affect susceptible crops the following year (Kelman, A., 1953, N. Carolina Agr. Exp. Station Bull. 509, 1953).

In considering hypothetical risks of recombinant DNA research on plant pathogenic organisms our committee considered the following questions:
1. Will the introduction of recombinant DNA from a specific plant pathogen in E. coli K12 lead to the development of strains with enhanced virulence to man or animals?

2. Will strains of E. coli be converted into plant pathogens?

3. Will the use of plant pathogens as HV systems result in hazards to plants?

With the relatively minor reservations documented below, the committee agreed that the answer to all three questions was "No". First we would point out that there is no evidence that genetic information transferred from plant pathogenic organisms would enhance the capability of strains of E. coli to harm man, animals, or plants. There are a very small number of possible exceptions to this generalization. These include a few species of bacteria which have been found in association with plants or 

plants or have been described as weak or minor plant pathogens and which may be closely related to forms causing disease in man. Also, plant pathogens such as the ergot fungus, and certain molds that produce aflatoxins on stored plant products are likely to be banned on the grounds that they produce potent, albeit non-polypeptide, toxins.

Provided that the use of plant pathogens as HV systems is not undertaken with the objective of deliberately creating forms with increased virulence and host range beyond that which occurs by natural genetic exchange (these are expressly prohibited by the guidelines) we see no hazard from such systems to plants.

1. Without dissent, the committee agreed on a classification of plant pathogens on the basis of hazard to agriculture.

We have placed all plant pathogens into a single class with two subgroups. This reflects our opinion that recombinant DNA research with plant pathogens has a negligible risk. The two subgroups take account of existing federal and state quarantine regulations. We propose that this classification be appended C in the guidelines.

HAZARD CLASSIFICATION OF PLANT PATHOGENS

Class 1A—Plant pathogens not in class 1B.

Class 1B—All organisms that are subject to quarantine restrictions for any of the following reasons:

(i) Plant pathogens not known to occur in the United States.

(ii) Plant pathogens that are not widely distributed throughout the ecological range of their hosts.

(iii) Plant pathogens subject to federal or state eradication or suppression programs.

All plant pathogens require state and federal (USDA) permits for shipment across state lines.

2. Spectroscopic Considerations. The lack of an accepted definition of exchangers caused us some difficulty in our discussions. A majority of the committee favored a definition that would exclude all gram negative bacteria from the guidelines. However, since this decision has still to be made by the RAC and Dr. Fredrickson some of our recommendations had to reflect two alternatives: (i) On the basis that most gram negative forms would be excluded we present rationale for including gram negative plant pathogens in this exclusion; (ii) On the basis that prokaryotic exchangers might be defined in a less liberal fashion, or that there might be a long lag period before plant pathologists can present evidence satisfying whatever exchange criteria are established, we present rationale for adopting minimal containment levels for all phytopathogenic bacteria namely Pl+EK2 or P2+EK1.

III B 1a. Shots using the E. coli K12 host-vector systems.

1. (2) Prokaryotic DNA recombinants. (p. 49602 FR 42 No. 187, Sept. 27, 1977). We propose that the minimum containment levels adopted for other bacteria be applicable to phytopathogenic bacteria, namely Pl+EK2 or P2+EK1.

1. (i) Modify line 7 to read: "biochemical, genetic, and/or pathogenic properties.

1. (ii) Delete the words "and plant pathogens" from line 5 of the second paragraph.

Rationale: Plant pathogenic bacteria include diverse organisms principally in the genera Agrobacterium, Corynebacterium, Erwinia, Pseudomonas, and Xanthomonas. A number of the plant pathogenic species are soil-inhabitants and are widely distributed throughout the United States. Generally they cause economic loss only when environmental conditions are favorable and available control practices are not used. A number of bacteria that cause foliage diseases can exist as epiphytes on a variety of non-host plants as well as on their susceptible hosts. Other bacteria such as the pathogen that causes halo blight of beans are seed-transmitted, do not survive in soil for long periods of time and can be controlled by the use of pathogen-free seed. The mechanisms by which plant pathogenic bacteria produce disease in plants may involve enzymes which attack substrates in plants such as pectic compounds. Such enzymes would not be harmful to man or animals. Similarly certain growth promoting compounds associated with bacteria with specific physiological functions in plants, e.g. polysaccharides that block movement of water, are not known to cause injury to man.

Certain bacteria which are not known to cause disease in plants but which are commonly present as epiphytes on leaves (Leben, C., 1965 Ann. Rev. Phytopath. 3:209-230) have been associated with diseases of man, i.e. Erwinia herbicola also designated as Enterobacter agglomerans (Starr, M. P. and Chatterjee, A. R., 1972, Ann. Rev. Microbiol. 26:389-426). However, there is a diversity of strains that have been obtained from plants and there is no conclusive evidence that the types widespread in plants are the same strains associated with certain infections in man.

Similarly it has been reported that a bacterium similar to a pathogen of onions (Pseudomonas cepacia) has been associated with a disease of man (Ederer, G. M. & Matzen, J. M., 1972, J. Infect. Dis. 125:613-616; Snell, J. J., Hill, L. R., LaPare, S. F. & Curtis, M. A., 1972 Internat. Symp. System. may not have useable vectors.

III B 3c. Plant host-vector systems.

(i) Delete second paragraph. "Whole plants or plant * * * at this time".

Rationale: This paragraph is confusing. Its intent was to define practical size or scale limits to physical containment rather than limits to biological containment. The committee concluded that the discussion of physical containment in the preceding paragraph makes this redundant.

(ii) Delete last sentence of fourth paragraph "However, if the source of the DNA is itself pathogenic * * * shall be carried out under P2 conditions" and substitute: "If the vector is an unmodified virus the experiments shall also be carried out under P2 conditions".

Rationale: This committee has reassessed the risk to man, animals, and plants from plant pathogenic agents. In this context we are concerned principally with the risk of DNA from plant pathogens to plants. This paragraph now reflects our lowered assessment of these risks.

(iii) Delete paragraph five. Experiments on * * * are not met.

Rationale: As for (ii).

(iv) Modify final paragraphs to read "* * * permit a decrease of one step in the physical containment to Pl."

Rationale: The survival of plant protoplasts (see table 1) and undifferentiated cultured plant cells outside their laboratory environment is possible because of their extremely exacting growth requirements and fragility.
NOTICES

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This committee proposes that the Recombinant Advisory Committee consider allowing the construction of modified HV-1 systems with conjugation proficient plasmids in addition to other recombinant molecules of prokaryotic origin under one step higher physical containment providing that all the DNA segments in the cell are derived from organisms which exchange DNA by natural physio-Lower Eukaryotes (p. 8601)(e)2. Insert the words—The remainder of the species in this class, including plant pathogenic or symbiotic fungi that do not produce potent toxins: P2+EK1 or P1+EK2.
Rationale: There is no demonstrable risk either to man or plants from cloning such DNA in E. coli. Also the present wording which refers to disease causing microorganisms could be interpreted to call for an unreasonably high containment level for these plant pathogens.
(f) Plants. (p. 4601). Delete the words “carries a known pathogenic micro-organism or”
Rationale: The risk to man or plants from DNA of a plant pathogen is not comparable to the risk of cloning DNA which codes for a potent polypeptide toxin. We have covered this risk elsewhere.
I.I.D. Biological containment—Host vector systems. a.2. Other prokaryotes (p. 48500).
We endorse the La Jolla Working Group Draft: (Insert III-3). “Experiments that are exempt from these guidelines”. In the event that sections (iii) and (iv) are not adopted we propose the following:
Self-cloning of bacterial plant pathogens and symbionts:
(i) The use of an indigenous plasmid or bacteriophage shall be exempt from the guidelines.
(ii) The use of a foreign vector (a non-indigenous plasmid or bacteriophage) from an organism which exchanges DNA by natural physiological processes shall require P2 containment.
Rationale: Many self-cloning experiments with agriculturally significant gram-negative bacteria could be more readily and safely carried out by using well characterized E. coli plasmid vectors. Some plant pathogens and symbionts Bacteriol., 22-138). Pseudomonas aeruginosa, a pathogen of man, conversely, has been reported to cause a leaf-spot of tobacco but is considered a minor and inconsequential pathogen of plants (Chao, J. J., Schroth, M., Mason, M. N., Komine, S. D. and Green, S. K., 1975 Phytopath, 65:425-431). These three bacteria should be governed by regulations applicable to human pathogens.
(ii) Our opinion it is a mistake to equate prokaryotic plant pathogens with Class 2 human pathogens as is done in the revised guidelines. The minimum containment level for those that have been extensively characterized as to pathogenic and other properties should be consistent with that adopted for other prokaryotes namely, P1+EK2 or P2+EK1.
III B1b(1)(d) Viruses of plants (p. 49602). Change to P2+EK1 or P1+EK2.
Rationale: Because of their fastidious modes of transmission and restrictive host ranges, DNA plant viruses were considered to present a minimal risk to animals or agriculture when used in shotgun experiments with the E. coli K-12 host vector systems.
III B 3b Pesticide baculoviruses (p. 49603).
(1) Remove sentences “Two viruses are presently registered *** tussock moth”.
Rationale: Footnote No. 7 in the September, 1977, draft describes the baculovirus pesticides that have been registered to date. The second sentence of the September, 1977, draft is therefore repetitive. Also, it should be made clear that any baculovirus that is registered by the EPA may be used as a vector since EPA registration is an ongoing process and other baculoviruses may eventually be registered which could be more useful for vector work.
(2) Remove the sentence “However, much still needs to be learned” and rewrite the final sentence of first paragraph to read “However, information is needed on the nature of the host range specificity, particularly the infectivity and persistence of the viral DNA in invertebrate and vertebrate cell cultures.”
Rationale: The original sentence, “However much still needs to be learned,” introduces ambiguity. The background information that was agreed to be essential in 1977 was information on the host specificity, particularly infectivity of viral DNA in vertebrate cell cultures.
(3) Substitute for the last paragraph in this section: When such background information is available, and if it confirms the narrow host range specificity, a baculovirus vector may be used for cloning DNA segments derived from the host insect, from another Environmental Protection Agency registered baculovirus, from an EK1 bacterium of from DNAs cloned in an EK1 bacterium (with the exception of any cloned DNA derived from an animal virus other than an EPA registered baculovirus), using P2 physical containment. Cloning of other classes of DNA is not envisioned for the exploratory phases of this work, but may be considered on a case-by-case basis in the future.
Rationale: The term “EK1 bacterium” was originally meant to include any DNA cloned in an EK1 bacterium, not simply E. coli K-12 DNA. Of particular interest in this category are Lepidopteran genes already cloned in E. coli K-12 such as the B. mori silk gene and the chorion genes of A. polyphemus. Also, it would be of interest to extract baculovirus DNA cloned in EK1 with a plasmid vector and test infectivity and/or effects in insect cell cultures. Such experimentation is also relevant to safety assessment of EK1 hosts.
Rationale: The revised guidelines explicitly prohibit conjugative plasmids and generalized transducing phages in EK-1 and HV-1 Systems. It is implicit that these elements shall not be introduced subsequent to cloning. This precludes host range tests unless they are carried out under more stringent physical containment. It also prevents plasmid promoted mobilization to introduce recombinant molecules back to the original DNA source organism or its mutants. Plant pathogens and Rhizobia are often non-transformable. This will effectively preclude complementation tests for traits not expressed in the cloning host such as plant pathogenicity in EK hosts. In effect, this creates a dilemma. In the proposed revisions of the drafted guidelines self-cloning in plasmids will be excluded even though the recombinant DNA can be mobilized out of the host strain into other prokaryotes. On the other hand, DNA cloned from the donor prokaryotes into a different recipient prokaryote cannot be mobilized by a conjugative plasmid back into the original donor, despite the fact that it is receiving its own DNA by this procedure. If the “exchanger” list is based on plasmid exchange these arguments are irrelevant.
We have listed in table 2 our suggestions for prokaryotic exchangers that are either plant pathogens or symbionts (Rhizobium) together with evidence for such exchange.
TABLE 1
Survival Data of Plant Protoplasts
(E.T. Lui, S.N. Fernandes, H. Scholthamer, G.I. Kado. Department of Plant Pathology, University of California Davis, CA 95616 - March 16, 1978)

<table>
<thead>
<tr>
<th>Source (Plant)</th>
<th>Medium</th>
<th>Supplemented phytohormones</th>
<th>Temp. (°C)</th>
<th>Cell wall density (μg)</th>
<th>Cell survival (%)</th>
<th>Fraction of surviving (cell)</th>
</tr>
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<tbody>
<tr>
<td>自来</td>
<td>CD</td>
<td>Yes</td>
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<td>&gt;10^6</td>
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1Greczyn, P. and C. Day (1972) Planta 107, 301-170
2Dried completely in 24 hours
3Dried completely in 3 hours
42C period in 24 hours
8Protoplasts first allowed to regenerate cell walls before plating on media indicated

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REFERENCES

30. Recommends DNA Molecule Program Advisory Committee, Workshop on Risk Assessment of Agriculture Pathogen.

31. Zaitlin, D. Milton (Chairman), Department of Plant Pathology, Cornell University, Ithaca, N.Y.
32. Zaitlin, D. Milton (Chairman), Department of Plant Pathology, Cornell University, Ithaca, N.Y.
33. Day, Dr. Peter A. (Co-Chairman), Connecticut Agricultural Experiment Station, New Haven, Conn. 06510.
34. Ausubel, Dr. Frederick M., Department of Biology, Harvard University, Cambridge, Mass. 02138.
35. Chilton, Dr. Mary D., Department of Microbiology and Immunology, University of Washington, Seattle, Wash. 98195.
36. Dropkin, Dr. Victor, Department of Plant Pathology, University of Missouri, Columbia, Mo. 65201.
37. Giles, Dr. Kenneth L., Department of Genetics, College of Agriculture, Iowa State University, Ames, Iowa 50011.
38. Kado, Dr. Clarence, L., Department of Plant Pathology, University of California, Davis, Calif. 95616.
39. Kelman, Dr. Arthur, Department of Plant Pathology, University of Wisconsin, Madison, Wis. 53706.
40. Millar, Dr. Roy, Department of Plant Pathology, Cornell University, Ithaca, N.Y. 14853.
41. Miller, Dr. Lois K., Department of Bacteriology and Biochemistry, University of Idaho, Moscow, Idaho 83843.
42. Panopoulos, Dr. Nicholas J., Department of Plant Pathology, University of California, Berkeley, Calif. 94703.
43. Vidaver, Dr. Anne, Department of Plant Pathology, University of Nebraska, Lincoln, Neb. 68503.
DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

EXEMPTION FROM PREEMPTION OF STATE AND LOCAL HEARING AID REQUIREMENTS

Applications
EXEMPTION FROM PREEMPTION OF STATE AND LOCAL HEARING AID REQUIREMENTS

Applications for Exemption

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: In response to applications from several States, this proposal would exempt certain State and local hearing aid device requirements from Federal preemption. The Federal Food, Drug, and Cosmetic Act preempts State and local medical device requirements that are different from or in addition to Federal requirements.

DATES: Comments by September 28, 1978. The Commissioner proposes that the final regulation based on this proposal shall be effective 30 days after its publication in the Register.

FOR FURTHER INFORMATION CONTACT:

Joseph M. Sheehan, Bureau of Medical Devices (HFX-79), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

SUPPLEMENTARY INFORMATION: The Commissioner of Foods and Drugs, in a final regulation published in the Federal Register of February 15, 1977 (42 FR 9226), established professional and patient labeling and conditions for sale of hearing aids. Since this regulation became effective on August 25, 1977, any State and local hearing aid requirement that is different from or in addition to the requirements established by the FDA regulations is preempted under section 521(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360k(a)).

The Food and Drug Administration issued final regulations, published in the Federal Register of May 2, 1978 (43 FR 18681), establishing procedures for considering applications for exemption from preemption. In these regulations, the Commissioner announced his determination that section 521 of the act does not preempt certain types of State and local requirements. The following requirements relating specifically to hearing aids are not preempted: (1) Requirements with respect to the licensing of hearing aid dispensers, audiologists, and physicians: (2) Requirements that are substantially identical to the FDA requirements governing the labeling and conditions for sale of hearing aids; and (3) requirements established by Federal, State, or local agencies to control the expenditures of public funds for purchasing hearing aids and hearing health care services for the hearing impaired.

These regulations also established procedures for applications filed under section 521(b) of the act. Section 521(b) provides that FDA may, by regulation issued after notice and an opportunity for an oral hearing, exempt a State or local medical device requirement applicable under the act. The agency must comply with both State and Federal law.

THE FDA HEARING AID REGULATIONS

For more information, the Commissioner has compared each of the State requirements to FDA hearing aid requirements and exemptions in §801.420 and §801.421 (21 CFR 801.420, 801.421).

Section 801.420 requires a manufacturer or distributor of a hearing aid to provide a user instructional brochure to accompany each hearing aid. This brochure must contain certain information for the hearing aid dispenser and instructions for use of the hearing aid. If an exemption is granted, these State or local requirements are in addition to and not in lieu of the FDA requirements. Therefore, a person engaged in the sale or distribution of hearing aids must comply with both sets of requirements to be in compliance with both State and Federal law.

The Commissioner also notes that many State requirements do not apply to all sales of hearing aids, as the FDA requirements do. For example, some State requirements apply only to sales to minors; other State requirements specifically do not apply to sales of replacement hearing aids. If such requirements are more stringent than the FDA requirements, they may be exempted from preemption. If an exemption is granted, these State or local requirements are in addition to and not in lieu of the FDA requirements. Therefore, a person engaged in the sale or distribution of hearing aids must comply with both sets of requirements to be in compliance with both State and Federal law.

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GENERAL ISSUES

Many of the State requirements are similar and involve a number of recurring issues. Later sections of this preamble will address individual State or local requirements. The following dis-
cussion of the recurring issues and the Commissioner's reasons for their resolution generally will not be repeated in the discussion of the individual State laws.

1. Medical evaluation. The Commissioner has determined that good hearing health care practice requires that any person who is being considered for the purchase of a hearing aid have a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid. A medical evaluation by a physician is necessary to determine the cause and the pathology associated with a patient's hearing loss. Because a medical evaluation often includes an interpretation of a medical history, a physical examination, and laboratory tests, an examination by other than a licensed physician will not satisfy this need. Therefore, the Commissioner is proposing to deny exemption from preemption for any State or local requirements that do not require a medical evaluation by a licensed physician.

2. Audiological evaluation. In the final FDA regulation on labeling and conditions for sale of hearing aids, the Commissioner rejected suggestions that an audiological evaluation be made a condition to the sale of a hearing aid. The Commissioner concluded that the public record did not justify requiring an audiological evaluation to determine hearing aid candidacy. The Commissioner also noted that such a requirement would create an additional barrier to the receipt of a hearing aid. Therefore, he is proposing to grant an exemption from preemption for those State requirements that do not require an audiological evaluation for adults, but does not require an audiological evaluation for children, the Commissioner believes that State requirements for audiological evaluation for children are more stringent than, and consistent with, the Federal requirement. Therefore, the Commissioner is proposing to grant the exemption from preemption for such requirements.

3. Waiver of medical evaluation. The Federal regulation permits a prospective hearing aid user 18 years of age or older to waive the medical evaluation requirement. Therefore, the hearing aid dispenser: (1) Informs the prospective user that exercise of the waiver is not in the user's best health interest; (2) does not actively encourage the user to waive; and (3) affords the user the opportunity to sign a waiver. This waiver provision acknowledges that some persons have religious or personal beliefs against a medical evaluation. The provision also allows for the rare case in which an individual would have great difficulty in obtaining a medical evaluation because of the lack of a physician in the area. The FDA regulation (§ 801.420(c)(2)) also requires that the User Instructional Brochure contain a statement warning hearing aid dispenser to advise the prospective user to consult promptly with a licensed physician if the dispenser determines that the prospective user has any of the eight conditions. A prospective user may waive medical evaluation whether or not any one of the eight conditions is present. The Commissioner, however, expects hearing aid dispensers to urge prospective users exhibiting any of these conditions to consult a physician.

The Commissioner believes that, in general, an informed adult who has religious or personal objections to medical examination should be permitted to waive the medical evaluation requirement. Therefore, he is proposing to deny exemption from preemption for those State and local requirements that do not permit a waiver of a medical evaluation requirement, or permit a waiver only for religious reasons. However, the Commissioner strongly believes that a medical examination should be an integral part of the hearing aid selection process for most adults and an absolute requirement, as provided in § 801.421(a)(2), for persons who are less than 18 years of age. Therefore, he is proposing to grant exemptions from preemption for those State and local requirements that do not permit a waiver when certain medical conditions are found to exist in the prospective purchaser. Such a requirement is more stringent than the FDA requirement and is consistent with the FDA policy of encouraging a medical evaluation as a condition to the purchase of a hearing aid. The Commissioner generally agrees with the State laws that permit a waiver when certain medical conditions are found to exist in the prospective user's medical condition.

Some States have requested an exemption for requirements which provide that a medical evaluation must take place less than 6 months before the sale of a hearing aid. These States argue that, in their jurisdictions, hearing health care services are readily available and, therefore, it is reasonable to require an examination within a shorter period of time. The Commissioner generally agrees with these States that, in their jurisdictions, hearing health care services are readily available and, therefore, he is proposing to grant an exemption from preemption for those State requirements that provide that the medical evaluation must take place, less than 6 months before the sale of a hearing aid; the basis for the exemption is that such requirements are more stringent than the FDA requirement.

Other States do not establish any time period within which a medical examination must take place. These States argue that, in their jurisdictions, hearing health care services are not scarce in their jurisdictions. These States also claim that the cost of audiological evaluation is generally covered by medical insurance so as not to represent a direct additional cost to the patient.

Although audiological examinations may be covered by insurance as a number of States claim, the Commissioner is not persuaded that this provides a basis for granting an exemption from preemption. The consumer ultimately pays for these examinations, if not directly, then through increased insurance premiums. Furthermore, the Commissioner has not seen any additional information which would justify requiring an audiological evaluation to determine hearing aid candidacy. Therefore, the Commissioner is proposing to deny exemption from preemption for State laws requiring audiological evaluation for adults before the sale of a hearing aid.

4. Six-month requirement. The FDA regulation in § 801.421(a)(1) requires that a medical evaluation be made no more than 6 months before the purchase of a hearing aid. These States assert that, in their jurisdictions, hearing health care services are readily available and, therefore, it is reasonable to require an examination within a shorter period of time. The Commissioner generally agrees with these States that, in their jurisdictions, hearing health care services are readily available and, therefore, he is proposing to grant an exemption from preemption for those State requirements that provide that the medical evaluation must take place, less than 6 months before the purchase of a hearing aid; the basis for the exemption is that such requirements are more stringent than the FDA requirement.
grants an exemption for a State law that establishes a shorter time period, then under State law the shorter time period is a valid State requirement.

5. Sales receipt. Many State laws require a hearing aid dispenser to provide the purchaser with a receipt containing certain information. Most of the required information concerns the terms of sale. Such requirements are not preempted by section 521(a) of the act because they do not relate to the safety and effectiveness of hearing aids. Therefore, they are not candidates for exemption from preemption.

Some State laws, however, require that the receipt contain certain information with respect to the safety or effectiveness of the hearing aids. For such requirements, the Commissioner is proposing to grant exemption from preemption provided that the requirement does not conflict with any requirement under FDA regulation.

Many State laws also require that the receipt include a statement as to whether the hearing aid is new, used, or reconditioned. Section 801.420(a)(6) requires that, if a hearing aid is "used" (as defined in §801.420(a)(6)), or rebuilt, this fact shall be declared on the container in which the hearing aid is packaged and on a tag physically attached to the hearing aid. Most of the State laws, however, do not define the term "used hearing aid." The Commissioner is proposing to exempt from preemption State laws that require a sales receipt to state whether the hearing aid is new, used, or reconditioned, provided that the State applies the Federal definition of "used hearing aid" when enforcing the requirement. Such requirements will be exempted on the basis that they impose an additional and more stringent requirement.

6. Recordkeeping. Section 801.421(d) requires a hearing aid dispenser to maintain a medical evaluation statement or the signed waiver for at least 3 years from the date of sale. The Commissioner is proposing to exempt from preemption those more State requirements that provide that these records must be kept for a longer period, because such requirements may assist the States in enforcing the medical evaluation requirements.

INDIVIDUAL STATE OR LOCAL REQUIREMENTS

Following are discussions of the sections of State hearing aid laws and regulations that are subject 521(a) of the act:

ARIZONA

Arizona Revised Statute 36-1001.7. This section provides that unethical conduct for a hearing aid dealer includes:

(c) Fitting and dispensing of a hearing aid when dealing with a child 14 years of age or under, without first ascertaining whether the child has been examined by an otolaryngologist, including an otologic and audiological examination, for his recommendation within 90 days prior to the fitting. If such not be the case, a recommendation to do so must be made and this fact shall be recorded as provided by regulation. The provisions of this subdivision shall not apply to the replacement of a hearing aid within 1 year of its purchase.

(d) Fitting and dispensing of a hearing aid to any individual who has a significant air bone gap or an apparent unilateral sensorineural hearing loss without first ascertaining that the individual has been examined by an otolaryngologist and received an otologic and audiological examination within the preceding 6-month period. If such not be the case, the individual shall sign an agreement as provided by regulation, stating the person has been informed of possible correction of his hearing loss by surgical or medical means, and that a hearing loss of this nature could be caused by serious and life threatening disease. The provisions of this subdivision shall not apply to the replacement of any hearing aid within 1 year of its purchase.

Subsection (e) and its implementing regulation (A.C.R.R. R9-16-303) are less stringent than the FDA requirements because they would allow the parent or guardian of a child 14 years of age or under to give the child a medical evaluation requirement for the child. These provisions would allow the dispensing of a hearing aid to a child without any medical examination. Therefore, the Commissioner is proposing to deny exemption from preemption for these requirements.

Subsection (f) and its implementing regulation (A.C.R.R. R9-16-304) require that a prospective hearing aid user with a significant air bone gap or apparent unilateral sensorineural hearing loss be examined by an otolaryngologist and receive an otologic and audiological examination within 6 months before the sale of a hearing aid. An informed adult may sign a written waiver of these requirements. As stated above in the discussion of general issues, the Commissioner is proposing to deny exemption from preemption for audiological evaluation requirements for adults. However, because the Arizona statute permits a waiver of this requirement, the Commissioner believes that the reasoning given above does not apply. The Commissioner is proposing to exempt these requirements from preemption because they are more stringent than the FDA requirements.

CALIFORNIA

California Business and Professions Code §3365.6:

No hearing aid shall be sold by an individual licensed under this chapter, to a person 16 years of age or younger, unless within the preceding 6 months a recommendation for a hearing aid has been made by both a board-certified, or a board-eligible physician specializing in otolaryngology, and an audiologist certified by the American Speech and Hearing Association. A replacement of an identical hearing aid within one year shall be an exception to this requirement.

This section is more stringent than the FDA regulation because it requires that a prospective hearing aid user 16 years of age or younger be examined by an otolaryngologist and an audiologist before the sale of a hearing aid. Therefore, the Commissioner is proposing that this section be exempted from preemption. The Commissioner advises, however, that in order for a sale to be in compliance with Federal law, it must meet all the requirements of the FDA regulation. Thus, with specific reference to the "replacement" provision in the final sentence of §3365.6, if a "replacement" constitutes a new sale, and is not simply a warranty-type substitution of one hearing aid for another, all requirements of the FDA regulation must be met including a medical examination within the preceding 6 months.

The Commissioner is also proposing to exempt from preemption California’s Health and Safety Code, section 26463(m), which prohibits the advertising of any device represented to have any effect in diseases or disorders of the ear. The Commissioner especially seeks comments on this provision because to the extent that it relates to the safety and effectiveness of a hearing aid, it is more stringent than the FDA requirements. However, if the provision is not related to safety or effectiveness, but rather relates to other forms of consumer protection, it may not be preempted by section 521(a) of the act.

The Commissioner notes that the proposal here is independent of an earlier application for exemption of similar provisions of California law (see Federal Register of February 15, 1977, 42 FR 9186, 9226). That matter is pending. When the proposed regulation was issued on the earlier application for the FDA hearing aid regulation had not yet gone into effect and, therefore, California laws relating to hearing aids were not preempted. Because California laws relating to labeling and conditions of sale of hearing aids that are in addition to or different from the FDA requirements are now preempted, it is necessary to include these provisions in the current proceeding.

CONNECTICUT

Connecticut General Statutes 20-403:

Anyone who has a history of (1) Visible congenital or traumatic deformity of the ear; (2) Active drainage from the ear within the previous 90 days; (3) Sudden, or rapidly

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provides, That the prospective hearing aid user signs the following statement, printed in ten (10-point) type:

“My religious beliefs require that I waive the medical examination and the hearing aid evaluation. I understand such waiver and will not hold the Hearing Aid Dealer and Consumers Act of 1977 for the purchase of a hearing aid. I voluntarily waive the medical examination, notwithstanding the fact that I have been advised by

Hearing Aid Dispenser’s Name

that my best health interest would be served if I had a medical evaluation by a physician who is an ear specialist.”

No registrant shall seek to induce a prospective hearing aid user to execute such a waiver.

This section is more stringent than the FDA requirements in several respects. First, it requires that the prospective purchaser be examined by an otorhinolaryngologist and not just a licensed physician. Second, it requires that the prospective purchaser receive a hearing test evaluation in addition to a medical examination. Third, this section requires the prospective purchaser to obtain a medical examination and hearing test evaluation within 30 days of the date of purchase. Finally, this section allows for the waiver of the medical examination requirement only for a person who has a bona fide religious belief which precludes a medical examination.

As stated above in the discussion of general issues, the Commissioner is proposing to exempt this section from preemption to the extent that it requires a medical examination by an otorhinolaryngologist with 3 months before the sale of the hearing aid. However, as also stated above, the Commissioner is proposing to deny exemption for the requirement of a hearing test (audiological) evaluation before the sale of a hearing aid.

The provision that the prospective purchaser may waive the medical examination requirement only for a bona fide religious belief is also more stringent than the FDA regulation, which permits a waiver for personal or religious reasons. Moreover, the provision does not require any medical examination for the purchase of a hearing aid. However, because it substantially narrows the grounds under which an adult may waive a medical examination, the Commissioner is proposing to deny exemption from preemption for the District of Columbia provision that a purchaser may waive the medical examination requirement only for religious reasons. As a result, the Federal waiver provision will apply in the District of Columbia; that is, any informed adult, 18 or over, may waive the medical examination requirement.

The Commissioner notes that section 5(c) of the District of Columbia act exempts from the coverage of sections 5(a) and 5(b) the “purchase of an identical hearing aid within two (2) years” of the original purchase. To be in compliance with Federal law, however, the waiver may not satisfy all the requirements of the FDA regulation including a medical examination within the preceding 6 months. Where there is simply a warranty-type substitution of one hearing aid for another and not a new purchase, the basic requirements relating to conditions of sale do not apply.

FLORIDA

Florida Statutes § 488.135(5):

Medical Clearance: If, upon inspection of the ear canal with an otoscope, in the course of a proper procedure of a hearing aid fitter, and upon interrogation of the client, there is any recent history of infection or any observable anomaly, the client shall be instructed to see a physician, and a hearing aid shall not be fitted until medical clearance is obtained for the condition noted. A history with a significant difference between bone-conduction and air-conduction hearing must be informed of the possibility of medical correction.

Florida Administrative Code § 16D-48.25(23): The registrant shall not fit or sell a hearing aid to any individual when any of the following conditions are found to exist, either from observation by the registrant, or on the basis of information furnished by the prospective hearing aid user, without first receiving a written medical clearance for the condition noted. Such written statement shall be attached to the buyer's sale contract. A copy of such statement shall be retained by the registrant at his place of business for no less than three (3) years:

(a) Visible congenital or traumatic deformity of the ear
(b) History of, or active drainage from the ear within the previous ninety (90) days;
(c) History of otitis media, or acute or otogenital or chronic hearing loss within the previous ninety (90) days;
(d) Acute or chronic disease
(e) Unilateral hearing loss of sudden or recent onset within the previous ninety (90) days;
(f) Any hearing loss in which there is a 15 db or greater difference between the air-conduction threshold and the bone-conduction threshold at 500 hertz (Hz), 1,000 Hz, and 2,000 Hz;
(g) Visible evidence of cerumen accumulation or foreign body in the ear canal;
(h) Pain or discomfort in the ear.

The statute and its implementing regulation are more stringent than the FDA regulation because of the requirements that a prospective user exhibiting one of several medical conditions obtain a written medical clearance. Moreover, the section does not contain a waiver provision, whereas the FDA regulation allows for a waiver. The Commissioner notes, however, that Florida law does not specify
PROPOSED RULES

MAINE

Maine Revised Statutes Annotated 1655-D, 1658-E

1658-E Medical or audiological examination. 1. Minors. No dealer may sell or furnish a hearing aid to a person of 18 years of age or less without a written statement, signed by a licensed physician or an audiologist, that such person has had an ear or hearing examination within 90 days of the purchase of a hearing aid and that the hearing aid is recommended for such person.

2. Adults. The department shall by regulation list and define certain medical conditions affecting hearing. If a dealer has notice of the existence of any one or more of such conditions in the case of a prospective purchaser of a hearing aid, whether by the dealer's observation of the prospective purchaser or by information furnished by the prospective purchaser, fitting of the hearing aid shall be delayed until the purchaser has had an ear or hearing examination administered by a physician with specialized training in the field of otorhinolaryngology or by an audiologist who, as a result of such examination, recommends in writing a hearing aid for the prospective purchaser.

1658-E Persons and practices not affected. This chapter is not intended to prevent anyone from engaging in the practice of measuring human hearing, provided that such person does not intend to sell hearing aids and accessories unless under the direct supervision of a licensee.

This chapter does not apply to a person who is a physician or osteopath duly licensed under the laws of the State of Maine.

Persons holding a master's or doctoral degree from an accredited university program which includes at least 24 credits in audiology at the graduate level and 150 supervised clinical hours in clinical audiology may test or measure human hearing but shall not demonstrate, with the intent to sell, hearing aids and accessories, except ear molds.

Nothing in this chapter shall be construed to require an ear or hearing examination by a physician or audiologist of a person who objects therefor on the ground that such examination conflicts with the tenets and practices of a church or religious denomination of which he is a member or adherent.

Section 1658-D is less stringent than the FDA regulation in its requirements for both minors and adults because it permits the sale of a hearing aid on the recommendation of an audiologist without a medical examination by a licensed physician. Although the last sentence of section 1658-E may be more stringent than the FDA waiver provision because it applies only to those who object to examination by a physician or audiologist for religious reasons, the effect of this provision is to require that only those persons who do not object for religious reasons be examined by a licensed physician or an audiologist. Therefore, the Commissioner is proposing to deny exemption from preemption for section 1658-D and the last sentence of section 1658-E.

The Commissioner has determined that the first three sentences of section 1658-E are not preempted because they are licensing provisions, and therefore, not requirements with respect to a device within the meaning of section 521 of the act.

Maine also requests an exemption from preemption for section 1658-C, which requires a hearing aid dispenser to give a notice containing certain information to the prospective purchaser at the time of sale. Most of the provisions of this section are not requirements with respect to a device within the meaning of section 521 of the act, and, therefore, are not preempted. Section 1658-C(3)(a), however, requires that the notice contain a statement as to whether the hearing aid is new, used, or reconditioned. This provision is preempted because it is different from the requirements of the FDA regulation.

In the final analysis, after reviewing the foregoing discussion above, the Commissioner is proposing to exempt from preemption this portion of section 1658-C. As a result, if the exemption is granted, none of the section will be preempted.

MINNESOTA

Minnesota Statutes §§ 145.43 and 145.44: 145.43 Hearing aid; restrictions on sale. Subdivision 1. Definition. "Hearing aid" means any instrument or device designed for or represented as aiding defective human hearing, and its parts, attachments, or accessories, including but not limited to ear molds. Batteries and cords shall not be considered parts, attachments, or accessories of a hearing aid.

Subdivision 2. Prescription or written recommendation required. No hearing aid shall be sold by any person in this State except upon the prescription or other written and signed recommendation of an authorized person who is neither employed by, or in a business relationship with, the hearing aid dispenser or seller of hearing aids. For purposes of this section, "authorized person" means an audiologist, otorhinolaryngologist, otologist, or licensed medical doctor. "Audiologist" means an individual who holds a master's degree or doctor's degree in audiology from a college or university that is fully accredited by the North Central Association of Colleges and Secondary Schools or an equivalent accrediting association. Any person selling a hearing aid as provided in this section shall maintain for not less than one year, in a file under the name of the person to whom the hearing aid was sold, a true copy of the prescription or other written recommendation, as provided herein, upon which such sale was made. Nothing in this section shall apply to a sale solely limited to either repair services or replacement parts, or both, for a hearing aid already owned by a consumer or to the sale of a replacement hearing aid to an aid already owned by a consumer.

145.44 Conditions requiring consultation of doctor or audiologist; waiver of sale restrictions. Subdivision 1. When a hearing aid vendor finds the following conditions in any person either by observation or being told by said person, said vendor shall not fit or sell a hearing aid until that person has a time period before a sale during which the medical examination must have taken place. Therefore, the Commissioner is proposing that the Florida statute and the implementing regulation be exempted from preemption. The Commissioner advises, however, that the medical examination must take place within 6 months before the sale of the hearing aid in order for the sale to be in compliance with the FDA regulation.
consulted with a licensed medical doctor or audiologist;
(1) Visible congenital or traumatic deformity of the ear;
(2) History of, or active drainage from the ear within the previous 90 days,
(3) History of sudden or rapidly progressive hearing loss within the previous 90 days,
(4) Acute or chronic dizziness,
(5) The loss of sudden or recent onset within the previous 90 days.

Section 145.43 is less stringent than the FDA requirements because it allows the dispensing of a hearing aid upon the recommendation of an audiologist alone. Therefore, the Commissioner is proposing to deny exemption from preemption for this section.

Similarly, subdivision 1 of §145.44 will allow the sale of a hearing aid upon the recommendation of an audiologist alone. Although the waiver provisions of subdivision 2 of §145.44 is limited to adults under 60 years of age, the effect of this provision is merely to require that children and adults 60 years of age and older be examined by a physician or an audiologist. Therefore, §145.44 is less stringent than the FDA requirements because it does not require examination by a physician. The Commissioner is proposing to deny exemption from preemption for this section.

MISSISSIPPI
Mississippi Code 73-14-3(g). This section defines “unethical conduct” for hearing aid dealers. Included in this definition is the following:
(9) Dispensing and selling a hearing aid to a child under the age of ten (10) years who has not been examined and cleared for hearing aid use by a board of eligible or certified otolaryngologists or evaluated by an audiologist certified by the American Speech and Hearing Association unless stated as unnecessary for further evaluation by either within a ninety-day period.

This requirement is less stringent than the FDA regulation because it would allow the sale of a hearing aid to a child under the age of 10 upon the recommendation of an audiologist alone. Therefore, the Commissioner is proposing to deny exemption from preemption for this section.

NEBRASKA
Nebraska Rev. Statutes 71-4712(2)(e). This section prohibits unethical conduct in hearing aid dealers including:
(vi) Fitting and selling a hearing aid to a child under the age of sixteen who has not been examined and cleared for hearing aid use within a six-month period by an otolaryngologist. The provisions of this subdivision shall not apply to the replacement with an identical model of any hearing aid within one year of its purchase.
(vii) Selling a hearing aid to any individual who has a significant air bone gap or a unilateral sensorineural hearing loss unless that individual has been examined by an otolaryngologist within a six-month period or has signed a statement in duplicate, also signed by the retailer, that he has been informed that he may have a medically or surgically remediable hearing loss and should seek the advice of an otolaryngologist. One copy of such statement shall be filed with the department. The provisions of this subdivision shall not apply to the replacement with an identical model of any hearing aid within one year of its purchase.

Subdivision (vii) is more stringent than the FDA requirement because it requires examination and clearance by an otolaryngologist while the FDA regulation requires examination and clearance by any licensed physician. Similarly, subdivision (vii) is more stringent than the FDA requirement because it requires that an individual with a significant air bone gap or a unilateral sensorineural hearing loss be examined by an otolaryngologist or sign a waiver of that requirement. Therefore, the Commissioner is proposing to exempt these requirements from preemption.

The Commissioner advises, however, that in order for a sale to be in compliance with Federal law, it must also meet all the requirements of the FDA regulation. Thus, with specific references to the replacement provision in the final sentences of subdivisions (vi) and (vii), if a “replacement” constitutes a new sale and not simply a warranty-type substitution of one hearing aid for another, all requirements of the FDA regulation must be met, including a medical examination within the preceding 6 months.

NEW JERSEY
Whenever any of the following conditions are found to exist either from observations by the licensee or on the basis of information furnished by the prospective hearing aid user, a license shall not issue to fitting and selling a hearing aid to any individual, suggest to that individual in writing that his best interests would be served if he would consult a licensed physician specializing in diseases of the ear or if no such licensed physician is available in the community then to a duly licensed physician.
(A) Visible congenital or traumatic deformity of the ear.
(b) History of, or active drainage from the ear within the previous 90 days,
(c) History of sudden or rapidly progressive hearing loss within the previous 90 days,
(d) Acute or chronic dizziness,
(e) Unilateral hearing loss of sudden or recent onset within the previous 90 days,
(f) Significant air-bone gap.
If a prospective hearing aid user would have received the written recommendation to purchase a hearing aid shall sign a receipt for the same.

The licensee shall provide the prospective hearing aid user with a list of at least three physicians specializing in diseases of the ear, practicing in the area, and their addresses. If none are practicing in the area, then a list of at least three physicians and their addresses.

45:9A-24. Sale of hearing aid to person under 18. No hearing aid shall be sold by an individual licensed under this chapter, to a person less than 18 years of age unless within the preceding 6 months a recommendation for a hearing aid has been made by a board-certified, or a board-eligible physician specializing in otolaryngology, or by an audiologist certified by the American Speech and Hearing Association after examination and diagnosis by a board-certified or board-eligible otolaryngologist. A replacement or an identical hearing aid within one year shall be an exception to this requirement.

Section 45:9A-24 is more stringent than the FDA regulation because it requires the hearing aid dispenser to advise the prospective hearing aid user to consult an otolaryngologist or other licensed physician if any of the listed conditions is found to exist. The Federal regulation requires only that the User Instructional Brochure contain a statement warning hearing aid dispensers to advise a prospective hearing aid user to consult a physician if certain medical conditions are found to exist. Therefore, the Commissioner is proposing to exempt this section from preemption.

Section 45:9A-25 is more stringent than the FDA regulation because it prohibits the sale of a hearing aid to a person under the age of 18 without a receipt signed by an otolaryngologist or an audiologist or by an audiologist after the prospective user has been examined by an otolaryngologist, while the Federal regulation only requires, examination by a licensed physician. Therefore, the Commissioner is proposing to exempt this section from preemption.

The Commissioner notes that the New Jersey requirement does not apply to the sale of a replacement or identical hearing aid within 1 year. The Commissioner reiterates that if a “substitution” in reality a new sale, all requirements of the FDA regulation, including the medical examination provisions, must be met.

New Jersey also requests an exemption from preemption for section 45:9A-23, which requires the dispenser to make certain statements to the purchaser and to give to the purchaser a receipt containing certain information. Most of the provisions of this section are not requirements with respect to a device within the meaning of section 521 of the act and therefore are not preempted. Section 45:9A-23(b)(4), however, requires that the receipt...
This provision is less stringent than the FDA regulation because it allows the sale of a hearing aid on the recommendation of an audiologist alone. Therefore, the Commissioner is proposing to exempt this provision from preemption for this provision and its implementing regulations.

New York also requests exemption from preemption for section 785-a(3) and its implementing regulations, which require the dispenser to give the purchaser an itemized receipt containing certain information. Most of the provisions of this section are not requirements with respect to a device within the meaning of section 521 of the act and therefore are not preempted. Sections 785-a(3) and 191.11(a) of the implementing regulations, however, require that this receipt contain a statement as to whether the hearing aid is new, used, or reconditioned. This provision is preempted because it is different from the Federal requirements.

This provision is more stringent than the FDA regulation because it requires examination and clearance by both an otorhinolaryngologist and an audiologist. Therefore, the Commissioner is proposing to exempt this provision from preemption. As a result, the entire section will not be preempted.

New Mexico

New Mexico Statutes Annotated 67-36-16F prohibits: F. Selling or fitting of the first hearing aid of any child under sixteen (16) years of age, who has not been examined and cleared for the aid by both an otorhinolaryngologist and an audiologist, certified competent by the American Speech and Hearing Association.

This provision is more stringent than the FDA regulation for the situations to which it applies because it requires examination and clearance by both an otorhinolaryngologist and an audiologist. Therefore, the Commissioner is proposing to exempt this provision from preemption. As a result, the entire section will not be preempted.

New York

New York General Business Law Article 37, § 801.421 of the FDA regulations.

Each licensed hearing aid dealer or fitter shall furnish each person supplied with a hearing aid a receipt showing the licensee's signature, the number of his license certificate, the complete address of his place of business, a complete description of the make and model of hearing aid furnished, the full terms of sale, including the terms of guarantee, if any, and a statement as to whether the hearing aid is new, used, or reconditioned. The receipt shall also be clearly marked "used" or "reconditioned," whichever is applicable.

Each receipt shall bear, in type no smaller than that used in the body of the receipt, the following legend: "the purchaser is advised that any examination, fitting, recommendation, or representation made by a licensed hearing aid dealer or fitter in connection with the sale of this hearing aid is not an examination, diagnosis, or prescription made by a person licensed to practice medicine in this state and therefore must not be regarded as medical opinion or advice."

This provision is less stringent than the FDA requirements because it requires only that the hearing aid dispenser advise the parent or guardian that the child should be examined by an otorhinolaryngologist and apparently allows the parent or guardian to waive this examination for the child. Therefore, the Commissioner is proposing to deny exemption from preemption for this section.

The first two sentences of this section require the dispenser to give to each purchaser a receipt containing certain information. Most of the information required does not relate to the safety or effectiveness of personal aids and therefore the requirements are not requirements with respect to a device within the meaning of section 521 of the act and are not preempted. The requirement, however, that the receipt be clearly marked "used" or "reconditioned" is preempted because it is different from the Federal requirements. As indicated in the discussion of general issues above, the Commissioner is proposing to exempt this section from preemption. As a result, all of the provisions with respect to the receipt will not be preempted.

Oregon

Oregon Revised Statute § 694.136 provides that a person registered to deal in hearing aids may have the certificate of registration revoked for several reasons including the following:

(6) Fitting or dispensing a hearing aid for use by any person without first determining through direct observation or referral for medical opinion, to in any manner whatsoever disparage or discourage a prospective hearing aid user from seeking medical opinion prior to the fitting
and dispensing of a hearing aid. Nothing re-
quired to be performed by a person dealing
in hearing aids under this subsection means
that the person is engaged in the diagnosis
of illness or the practice of medicine or any
other activity prohibited by the provisions
of ORS 694.038, 694.039 and this section.
(7) Fitting or dispensing a hearing aid for
use by a person 18 years of age or younger,
unless within 90 days of such sale the child
has been referred:
(a) To an otorhinolaryngologist for ex-
amination and for a recommendation of cor-
rective measures which may be required; or
(b) To a properly licensed medical physi-
cian for like examination and recommenda-
tion; or
(c) To an audiologist licensed by the State
of Oregon for an evaluation of the child’s
hearing and for a recommendation of cor-
rective measures which may be required:
Provided, That the child is also examined
by a properly licensed medical physician
who gives approval for possible hearing aid
use.
If the parents or guardian of such person
refuse for good cause to seek medical opin-
on, the person dealing in hearing aids shall
obtain from such parents or guardian a cer-
tificate to that effect in a form prescribed
by the commission. The replacement of an identical hearing aid within one year is not subject to this subsection.

Subsection (6) is less stringent than
the FDA regulation because it appar-
ently permits the parent or guardian
of a minor 18 years of age or younger to
waive the medical examination re-
quirement for the child. Therefore,
the Commissioner is proposing to deny
exemption from preemption for this
subsection.

Subsection (7) also provides that the
parent or guardian of the child may
waive the medical evaluation require-
ment for the child. To this extent,
subsection (7) is less stringent than
the FDA requirement. The Commis-
sioner is proposing to deny exemption
from preemption for this subsection.

Oregon also requests exemption
from preemption for section 694.038
which requires the dispenser to give
the purchaser a receipt containing cer-
tain information. Most of the provi-
sions of this section are not require-
ments with respect to a device within the
meaning of section 521 of the act.
However, section 694.038(6) requires
that this receipt contain a statement as
to whether the hearing aid is new,
used, or reconditioned. This provision
is preempted because it is different from
the Federal requirements. As in-
dicated in the discussion of general
issues above, the Commissioner is pro-
specting to exempt this section from
preemption. As a result, none of sec-
tion 694.038 will be preempted.

Pennsylvania
35 Purdon’s Statutes § 6700:
Section 402. Referral to physician.
Whenever any of the following conditions
are found, either by observation or upon
the basis of information furnished by the
prospective hearing aid user, a registrant shall,
under these conditions, require a written recom-
nendation from a licensed physician before
selling a hearing aid to any individual, suggest to that individual in writing that his
best interests would be served if he would
consult a licensed physician specializing in
diseases of the ear. If the physician
is available, then a duly
licensed physician:
(1) Waive congenital or traumatic defor-
mity of the ear.
(2) Active drainage from the ear within
the previous 90 days or history of this symp-
tom.
(3) Sudden or rapidly progressive hearing
loss within the previous 90 days.
(4) Acute or chronic disizziness.
(5) Unilateral hearing loss of sudden or
recent onset within the previous 90 days.
(6) Visible evidence of cerumen accumula-
tion or foreign body in the ear canal.
(7) Significant air-bone gap, when general-
ly acceptable standards have been estab-
lished.
(8) Pain in the ear within the previous 90
days.
Whenever any of the aforementioned con-
ditions are found, the registrant shall not
waive the medical examination require-
ment. The commissioner is proposing to exempt this section.

Section 606. Sale to Minors. No hearing
aid shall be sold to any individual aged
6 years or younger, unless within the preceding 6
months a recommendation for a hearing aid
has been made by a physician specializing in
to an otolaryngologist or otologist.
A replacement of an identical hearing aid within 6 months
shall be an exception to this requirement.

This section is less stringent than
the FDA requirements because it re-
quires only that the hearing aid disp-
enser recommend that the child be
examined by an otorhinolaryngologist,
and that the child be examined
by a physician specializing in
to an otolaryngologist or otologist.
A replacement of an identical hearing aid within 6 months
shall be an exception to this requirement.

Section 402 is more stringent than
the FDA requirement because it pro-
hibits the hearing aid dispenser from
selling a hearing aid when certain
medical conditions are found, unless
the prospective user receives a
written recommendation from a
licensed physician; no waiver of this re-
quirement is permitted. The Commis-
sioner is proposing to exempt this sec-
tion.

Section 403 is not preempted because
it is substantially identical in
most respects to the FDA require-
ments in that it requires that the pro-
spective user obtain medical clearance
within 6 months before the sale of
a hearing aid and permits an informed
adult to waive this requirement.

The Commissioner advises, however,
that in order for a sale to be in compli-
ance with Federal law, it must also
meet all the requirements of the FDA
regulation. Thus, with specific refer-
ence to the replacement provision in
the first sentence of the second para-
graph of section 403, if a “replacement
of parts or accessories or of a worn out
or damaged hearing aid” constitutes a
new sale and not simply a warranty-
type replacement of parts or substitu-
tion of one hearing aid for another, all
requirements of the FDA regulation
must be met including a medical exami-
nation within the preceding six
months.

The requirement in section 506 that
a prospective hearing aid user 18 years
of age or younger must be examined
by an otolaryngologist or otologist
is more stringent than the FDA require-
ment of examination by any licensed
physician. Also, section 506 does not
permit anyone 18 years of age to waive
the requirement while the FDA regu-
lations permits a waiver for those 18
years of age or older. The Commis-
sioner is proposing to exempt section 506
from preemption because it is more
stringent than the Federal regulation.

Texas
Vernon’s Civil Statutes. Article 4568, Sec-
tion 33187.
(c) Every license must, when dealing with
a child 10 years of age or under, ascertain
whether the child has been examined by an
otolaryngologist or otologist within
90 days prior to the fitting. If such is
not the case, a recommendation by the
licensure to do so must be made and this
fact noted on the bill of sale required in subsec-
tion (b) of this section.

This section is less stringent than
the FDA requirements because it re-
quires only that the hearing aid dis-
enser recommend that the child be
examined by an otolaryngologist.
Applying to an otologist would appar-
tly allow the dispenser to sell the hearing aid even though
the child has not been medically ex-
amined. The Commissioner is propos-
ing to deny exemption from preemp-
tion from preemption.

Texas also seeks exemption from
preemption for section 14(b), which re-
quires the dispenser to give to the pur-
chaser a bill of sale containing certain information. Most of the information required by this section does not relate to the safety or effectiveness of hearing aids and therefore these provisions are not preempted. However, section 14(b) requires that the bill of sale include a statement as to whether the hearing aid is new, used, or rebuilt. This provision is preempted because it is different from the Federal requirements. As indicated in the discussion of general issues above, the Commissioner is proposing to exempt this provision from preemption. As a result, none of section 14(b) will be preempted.

WASHINGTON

Revised Code of Washington 18.35.110: §18.35.110 Grounds for suspension of license. Any person licensed under this chapter may have his license suspended for a fixed period or be placed on probation by the department for any of the following causes:

- (2)(e)(i) Whenever any of the following conditions are found or should be found to exist either from observations by the licensee or on the basis of information furnished by the prospective hearing aid user, prior to fitting and dispensing a hearing aid to any such prospective hearing aid user:
  (A) Visible congenital or traumatic deformity of the ear;
  (B) History of, or active drainage from the ear within the previous ninety days;
  (C) History of sudden or rapidly progressive hearing loss within the previous ninety days;
  (D) Acute or chronic dizziness;
  (E) Unilateral hearing loss of sudden or recent onset within ninety days;
  (F) Significant air-bone gap (when generally acceptable standards have been established);
  (G) Any other conditions that the department may by rule establish: Provided, That it shall be a violation of this subsection for any licensee or his employees and putative agents upon making such required referral for medical opinion to in any manner whatsoever disparage or discourage a prospective hearing aid user from seeking such medical opinion prior to the fitting and dispensing of a hearing aid: and provided further, That no such referral for medical opinion need be made if the licensee has no reason to believe that a dispensing of a hearing aid which has been lost or damaged beyond repair within one year of the date of purchase: Provided further, That nothing in this section required to be performed by a licensee shall mean that the licensee is engaged in the diagnosis of illness or the practice of medicine or any other activity prohibited by the provisions of this code;
  (ii) Fitting and dispensing a hearing aid to any person under eighteen years of age who has not been examined and cleared for hearing aid use within the previous six months by a physician specializing in otolaryngology except in the case of replacement instruments or except in the case of the parents or guardian of such person refusing, for good cause, to seek medical opinion: Provided, That if the parents or guardians of such person refuse, for good cause, to seek medical opinion, the licensee shall obtain from such parents or guardian a certificate to that effect in a form as prescribed by the department;
  (iii) Fitting and dispensing a hearing aid to any person under eighteen years of age who has not been examined by a clinical audiologist for his recommendations during the previous six months, without first advising such person or his parents or guardian in writing that he should first consult a clinical audiologist.

Subsection (2)(e)(i) is less stringent than the FDA regulation because it requires only that the hearing aid dispenser advise the prospective user to consult an otolaryngologist or other licensed physician if one of the listed conditions is found to exist and apparently allows the sale of the hearing aid without a medical evaluation or a written waiver of a medical evaluation. Therefore, the Commissioner is proposing to deny exemption from preemption for this requirement.

Subsection (2)(e)(iii) is less stringent than the FDA regulation because it allows the parent or guardian of a child under the age of 18 to waive the medical evaluation requirement for the child. Therefore, the Commissioner is proposing to deny exemption from preemption for this requirement.

Subsection (2)(e)(iii), if it is considered to be in addition to the FDA medical evaluation requirement, is more stringent than the FDA requirement because it imposes an additional requirement of examination by an audiologist for a prospective hearing aid user under the age of 18. The Commissioner is proposing to exempt subsection (2)(e)(iii) from preemption.

WEST VIRGINIA

West Virginia Code § 30-28-14: Section 30-26-14 Fitting and dispensing a hearing aid. (a) Every licensee engaged in the practice of dealing in or fitting of hearing aids shall, prior to the sale or fitting of a hearing aid intended to be worn or used by any person, first ascertain whether such person has within the preceding six months been examined by a physician: Provided further, That nothing in this section required to be performed by a licensee shall mean that the licensee is engaged in the diagnosis of illness or the practice of medicine or any other activity prohibited by the provisions of this code;

(b) Prior to the sale of a hearing aid, every licensee shall be required to advise in writing, in the presence of the prospective hearing aid user, the person to whom he intends to sell or fit such hearing aid that such person’s best interest would be served by consulting an otolaryngologist or other physician specializing in diseases of the ears or any other physician duly licensed to practice medicine in this State, if any of the following conditions are found upon examination of such person:
  (1) Visible congenital or traumatic deformity of the ear;
  (2) History of active ear discharge within the previous ninety days;
  (3) History of a sudden or rapidly progressive hearing loss within the previous ninety days;
  (4) Acute or chronic dizziness;
  (5) Unilateral hearing loss of sudden or recent onset; within the previous ninety days; or
  (6) Significant air-bone gap.

(c) A copy of any writing or form required to be given to a prospective purchaser or other person by the terms of this section shall be retained in the records of the licensee for a period of seven years following the issuance of each writing.

Subsection (a) is more stringent than the Federal regulation because it does not permit the prospective user to waive the medical evaluation requirement. However, as stated above, the Commissioner believes that informed adults should be permitted to waive the medical evaluation requirement if the prospective user has religious or personal objections to a medical evaluation. Therefore, the Commissioner is proposing to deny exemption from preemption for this subsection. As a result, the Federal waiver provision will apply in West Virginia.

Subsection (b) of this section is more stringent than the Federal regulation because it requires the hearing aid dispenser to consult a physician if one of six warning signs is present. The Federal regulation (§801.420(e)(2)) requires that the user instructional brochure contain a statement warning hearing dispensers to advise the prospective user to consult promptly a physician if one of eight conditions is observed in the prospective user. Since the West Virginia statute requires the dispenser to consult a physician in writing, it is more stringent than the Federal requirement and the Commissioner is proposing to exempt it from preemption.

Subsection (c) of this section is more stringent than the Federal requirement because it requires the hearing aid dispenser to maintain for 7 years copies of the physician’s clearance statement and the written warnings required by subsection (b), while the Federal regulation requires the dispensers to maintain copies of medical clearance statements and waivers for only 3 years. Therefore the Commissioner is proposing to exempt subsection (c) from preemption.
The Commissioner has made his decisions on these applications based on the plain meaning of the language of the requirements. The Commissioner invites comments on whether he has interpreted these requirements correctly and on whether these requirements are interpreted or applied differently by the States. The Commissioner also invites comments on those State statutes that require mandatory audiological evaluation and those that also limit waiver of the medical evaluation requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 521, 701, 52 Stat. 1055-1056 as amended, 90 Stat. 574 (21 U.S.C. 360k, 371I) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes that part 808 be amended as follows:

1. In §808.1 by adding a new paragraph (f) as follows:

§808.1 Scope.

(f) The Federal requirement will apply at all times regardless of whether the State or local requirement is preempted or exempted from preemption. As a result, if a State or local requirement exempted from preemption is not as broad in its application as the Federal requirement, the Federal requirement will apply to those circumstances not covered by the State or local requirement.

2. In §808.55 California by adding new paragraphs (a) (13) and (14) as follows:

§808.55 California.

(a) Business and Professions Code, sections 3365 and 3365.6.

(14) Health and Safety Code, section 25643(m).

3. In subpart C by adding new §§808.53, 808.57, 808.59, 808.67, 808.69, 808.73, 808.74, 808.77, 808.80, 808.81, 808.82, 808.85, 808.87, 808.88, 808.89, 808.97, 808.98, and 808.101 as follows:

§808.53 Arizona.

(a) The following Arizona medical device requirements are enforceable notwithstanding section 521 of the act because the Commissioner of Food and Drugs has granted an exemption from preemption under section 521(b) of the act:

(1) Arizona Revised Statutes, chapter 17, §36-1901.7(F).

(2) Arizona Code of Revised Regulations, title 9, article 3, section R9-16-304.

(b) The following Arizona medical device requirements are preempted by section 521 of the act and have been denied an exemption from preemption:

(1) Arizona Revised Statutes, chapter 17, §36-1901.7(F).

(2) Arizona Code of Revised Regulations, title 9, article 3, section R9-16-303.

§808.57 Connecticut.

The following Connecticut medical device requirements are enforceable notwithstanding section 521 of the act because the Commissioner of Food and Drugs has granted an exemption from preemption under section 521(b) of the act:

§808.59 Florida.

The following Florida medical device requirements are enforceable notwithstanding section 521 of the act because the Commissioner of Food and Drugs has granted an exemption from preemption under section 521(b) of the act:

§808.67 Kentucky.

The following Kentucky medical device requirement is enforceable notwithstanding section 521 of the act because the Commissioner of Food and Drugs has granted an exemption from preemption under section 521(b) of the act:

§808.69 Maine.

(a) The following Maine medical device requirement is enforceable notwithstanding section 521 of the act because the Commissioner of Food and Drugs has granted an exemption from preemption under section 521(b) of the act:

§808.73 Minnesota.

The following Minnesota medical device requirements are preempted by section 521 of the act and the Commissioner of Food and Drugs has denied an exemption from preemption for these requirements: Minnesota Statutes, §§145.43 and 145.44.

§808.74 Mississippi.

The following Mississippi requirement is preempted by section 521 of the act because the Commissioner of Food and Drugs has granted an exemption from preemption for this requirement: Mississippi Code, section 73-14-3(g)(9).

§808.77 Nebraska.

The following Nebraska medical device requirements are enforceable notwithstanding section 521 of the act because the Commissioner of Food and Drugs has granted an exemption from preemption under section 521(b) of the act:

§808.80 New Jersey.

The following New Jersey medical device requirements are enforceable notwithstanding section 521 of the act because the Commissioner of Food and Drugs has granted an exemption from preemption under section 521(b) of the act:

§808.81 New Mexico.

The following New Mexico medical device requirement is enforceable notwithstanding section 521 of the act because the Commissioner of Food and Drugs has granted an exemption from preemption under section 521(b) of the act:

§808.82 New York.

(a) The following New York medical device requirements are enforceable notwithstanding section 521 of the act because the Commissioner of Food and Drugs has granted an exemption from preemption under section 521(b) of the act:

| (1) General business law, article 9, section 783-913.

(2) Official Compilation of codes, rules and regulations of the State of New York, chapter V, title 19, subchapter G, §§191.10 and 191.11, on the condition that New York, in enforcing this requirement, applies the definition of "used hearing aid" in §801.420(a)(6) of this chapter.

| (b) The following New York medical device requirements are preempted by section 521(a) of the act and the Commissioner of Food and Drugs has denied an exemption from preemption:

| (1) General business law, article 19, subchapter G, §§191.10 and 191.11, on the condition that New York, in enforcing this requirement, applies the definition of "used hearing aid" in §801.420(a)(6) of this chapter.

| (b) The following New York medical device requirements are preempted by section 521(a) of the act and the Commissioner of Food and Drugs has denied an exemption from preemption:

§33189
§ 801.420 (a)(6) of this chapter. Dated: July 20, 1978.

DONALD KENNEDY,
Commissioner of Food and Drugs.

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DEPARTMENT OF AGRICULTURE
Agricultural Marketing Service

MILK IN TEXAS AND CERTAIN OTHER MARKETING AREAS
Decision on Proposed Amendments to Marketing Agreements and Orders
PROPOSED RULES


PRELIMINARY STATEMENT

A public hearing was held upon proposed amendments to the marketing agreements and to the orders regulating the handling of milk in the aforementioned market areas. The hearing was held pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended 7 U.S.C. 1001 et seq., and the applicable rules of practice (7 CFR 800), at Irving, Tex., on April 5–8, 1977, pursuant to notices thereof.

Upon the basis of the evidence introduced at the hearing and the record thereof, the Deputy Administrator, Program Operations, on December 20, 1977, filled with the Hearing Clerk, U.S. Department of Agriculture, his recommended decision containing findings of the opportunity to file written exceptions thereto.

The material issues on the record of the hearing relate to:

1. The need for a common base-excess plan in the 11 markets, and
2. Order provisions implementing the base-excess plan.

FINDINGS AND CONCLUSIONS

The following findings and conclusions on the material issues are based on evidence presented at the hearing and the record thereof:

1. The need for a common base-excess plan in the 11 markets. A common base and excess plan for distributing returns for milk among producers should be provided under each of the 11 orders included in this proceeding. The plan should be made effective on October 1, 1978.

2. A base-excess plan is a means of apportioning among producers on the basis of their deliveries of milk to handlers the money due them from such handlers. The plan in no way affects the cost of milk purchased by handlers. Producers in total receive the same amount of money under a base-excess plan as they would receive under a blend price payment procedure. The plan is designed to encourage production in the fall months of seasonally low production and to discourage excess production in the spring months of seasonally high production.

Except for the initial base-making period in 1978, the base-excess plan adopted herein would provide that each producer under the 11 orders would receive a daily base equal to the average of his daily deliveries of milk to all handlers under such orders.

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during the 4-month period of September through December. The daily base of a producer who delivered less than 90 days' production to all handlers under one of the orders during the 4-month period would be computed by dividing his total deliveries during such period by 90. This base would then be used during the following months of March through July to determine how much of the producer's milk is to be priced at the base and excess prices. The quantity of milk which a producers delivers during each of the months of March through July which is in excess of his base milk for the month would be paid for at the excess price, which would be the Class III price for the month. The quantity of milk not in excess of the producer's base milk would be paid for at the base price.

For the initial base-making period in 1978, a base for each producer would be established by adding the pounds of producer milk delivered by him under each of the 11 orders during the months of September through December and dividing such total amount by the number of days' production represented by such producer milk or by 60, whichever is greater.

The quantity of milk which a producer delivers during each of the months of March through July which is in excess of his base milk for the month would be paid for at the excess price, which would be the Class III price for the month. The quantity of milk not in excess of the producer's base milk would be paid for at the base price.

The base price for each market using marketwide pooling would be determined by subtracting the total value of all excess milk in the market from the total pool obligation of all handlers and dividing the resulting amount by the pounds of base milk.

The base prices for milk received by individual handlers during the 4-month period would be computed by dividing the total deliveries of such producer to handlers regulated under the three orders by the number of days in such period beginning with the first day in the month of delivery of milk. The resulting amount would be multiplied by the number of days in the month to obtain a monthly base, which is used to determine how much of the producer's deliveries is base milk and excess milk.

The producer's base and excess milk is apportioned among producers, and ultimately among the three orders, according to the percentage that the producer's deliveries to each handler is of his total deliveries to handlers regulated under the three orders.

The value of a producer's milk under the Central Arkansas, Fort Smith, and Memphis orders is computed by assigning excess milk in series, beginning with Class III milk, to the producer's milk in that order and multiplying the quantities of milk delivered by such producer for each class by the respective class prices. The total value of the excess milk is divided by the total pounds of excess milk and the answer is rounded to the nearest cent.

Under the Central Arkansas order, 4 cents per hundredweight is deducted to maintain a reserve in the producer-settlement fund.

Under the Fort Smith and Memphis orders, which are individual handler pooling orders, the base price for each handler is determined by subtracting the value of the excess milk received by the handler from his total obligation to producers and dividing such amount by the quantity of base milk.

It should be noted that in computing the base and excess prices, adjustments are made for purposes of applying location adjustments and funding the advertising and promotion programs. These adjustments to the prices received by producers are necessary during all months and do not affect the operation of the base-excess plan.

The Southern Region Division of Associated Milk Producers, Inc. (AMPI), proposed a base plan for the 11 orders applicable for the period September 1, 1977. The Southern Region Division markets the milk of its members to handlers located in a seven-state area who are regulated under the 11 orders under consideration. The cooperative proposed a base plan patterned after the provisions of the base plan in the Central Arkansas order. Under its proposal, milk from an individual producer that is received as producer milk during the base-forming months by handlers fully regulated under any of the 11 orders would be used to compute a base for such producer. The producer's base would be computed by dividing the total pounds of milk delivered during all months of the base-forming period by the number of days in such period beginning with the first day on which milk was first received from such producer, but not less than 90.

Proponent proposed that producers receive base and excess prices for their deliveries during the months of February through July. The excess price would be the Class III price for the month. The value of base milk would be determined by subtracting from the total obligation of pool handlers the value of the excess milk. To determine the base price, the value of the base milk would be divided by the quantity of base milk, and the resulting amount would be reduced between 4 and 5 cents to provide a reserve in the producer-settlement fund.

AMPI contended that a common base plan should be adopted in each of the 11 markets to provide an incentive for all producers in these markets to bring their seasonal milk production pattern more in line with the fluid milk needs of handlers. Proponent pointed out that since August 1968 it had been using a somewhat different type of base plan as a means of making payment to its members producers under the 11 orders. The cooperative indicated that the objective of its payment plan was to provide its members with an incentive to gear their production to the demand of handlers for Class I milk, including a pricing plan.

AMPI claimed that its plan was reasonably successful for a number of years during which the "majority" of producers in the 11 markets were members of AMPI. The cooperative contended, however, that the effectiveness of its payment plan in terms of meeting the needs of the markets had declined in recent years as a result of the cooperative's position that a production incentive plan could be applied equitably to its members only if the plan were to apply on a marketwide basis. Accordingly, AMPI requested that the orders be amended to provide all producers under the 11 orders with the incentive to improve the seasonal pattern of their milk production.

Proponent claimed that a sufficient supply of milk is not available in the 11 markets during the fall months to meet the Class I requirements of han-
The cooperative stated that because supplies are inadequate in the fall it has been necessary for it to acquire milk from outside the 11-market area in supplying the fluid milk needs of handlers. Proponent indicated, however, that it has not been able to procure sufficient milk from outside sources and thus has been forced to allocate its available supply among the handlers supplied by the cooperative.

Proponent contends that it has the primary burden of maintaining a reserve milk supply for the 11 markets and of allocating the available milk supplies to handlers for Class I and Class II uses. AMPI alleges that it bears a disproportionate share of the costs of maintaining a reserve milk supply. It pointed out that some producers in the 11 markets have none of the expenses of maintaining the reserve milk supply because of the milk procurement practices of certain handlers. These handlers buy milk from producers who deliver all of their milk production to such handlers on six or seven days during the week. These same handlers then buy supplemental milk supplies from AMPI on only those days of the week when their plants bottle milk. The cooperative then has the responsibility of marketing on the remaining days of the week the milk production of the cooperative's members who deliver to such handlers.

Proponent indicated that because of the cooperative's role in handling the reserve milk supply its members have had their pay prices for milk reduced to cover the cost of such operations. During the fall months the cooperative pointed out, its members have had to bear the costs of shifting milk from market to market to meet the fluid milk requirements of handlers. During the spring months the cooperative's members have had the expense of moving to manufacturing plants that milk which is surplus to the fluid milk requirements of handlers.

Proponent contended that the proposed plan would be adopted in each of the 11 orders because the procurement area of the handlers regulated by such orders constitutes one area of reserve milk supply for the 11 markets. Proponent indicated that most, if not all, of its member milk associated with its Southern Region Division is disposed of in the 11 markets and that 1,307 of its 4,895 members associated with the 11-market area were pooled during October 1976 under more than one of the 11 orders. Because of this intermingling of producers among the 11 markets, proponent contended that the plan should be adopted on a common basis under all 11 orders so that the milk delivered by a producer to any one of the markets is taken into account in the computation of his base and in the payment for base and excess milk.

A cooperative association opposed the adoption of a base-excess plan on the basis that such plans do not level production during the year. Opponent claimed instead that the plan would provide an incentive for producers to expand production annually. The cooperative argued that additional quantities of milk are not needed in these 11 markets because Class I utilization in 1976 ranged from a low of 58 percent in the Wichita market to a high of 64 percent in the Arkansas market. It contended that the plan would cause dairy farmers to participate in a "race for base," i.e., make an extra effort to increase milk production during the base-forming months. It alleged that such efforts would result in too much production in the fall months and add to the excess reserve milk supplies in other months.

The cooperative's representative contended that dairy farmers located on the fringe of the production areas might shift to another market if the base-excess payment plan resulted in a lower per hundredweight return than the blend price received by neighboring dairy farmers shipping to other Federal order markets. Thus, the cooperative was concerned that the proposed payment plan might result in disorderly marketing conditions.

The cooperative contended further that the plan would preclude the movement of producers from one market to another. It indicated that a producer would not want his milk moved to a market outside the 11 markets during the spring months since he would not earn a base for that production. During the spring months it would not be feasible for producers to shift to the 11 markets from other markets since they would not have a base and, thus, would not be eligible to receive the base price for their milk. The cooperative also stated that the plan would present administrative and enforcement problems for the market administrator. It suggested that, in order to obtain additional base, dairy farmers would add water to milk, borrow milk cows from a dairy farmer shipping to a manufacturing plant, or exchange milk with another dairy farmer.

Several proprietary plant operators, cooperatives, and producers expressed opposition to a common base-excess plan on the basis that such plan would restrain outside milk supplies from entering the 11 markets. They contended that, because only dairy farmers who begin delivering milk to one of the 11 markets in either August or September would be able to earn a base reflecting their average daily production during the fall months, the proposed plan would preclude other dairy farmers from entering the markets during other months of the year. Several also were concerned that cooperatives that deliver to handlers regulated by an order other than the 11 under consideration could tend to keep their members from joining cooperative's supplying the 11 markets by having them sign membership contracts expiring in months other than August or September.

A large number of producers testified individually in opposition to a base-excess plan, indicating that the plan should not be adopted for various reasons, including the following:

a. The plan is sought by AMPI to increase milk production so the cooperative can operate its manufacturing facilities throughout the year.

b. The plan is a means of restricting entry of new producers to the market, or forcing independent producers to join AMPI.

c. More producer milk is not needed during the fall months because producers currently receive the Class III price for a portion of their milk during the fall.

d. Cows calving in September and October will produce more milk in the spring months relative to the preceding fall months if good pasture is available for grazing during the spring.

It takes from 3 to 5 years to change the milk production pattern of a herd through breeding practices.

e. Moving a cow from one herd to another herd to build base would decrease the yearly milk production of that cow by 2,000 pounds.

f. The Dairy Herd Improvement Association claims that a cow calving in the fall will yield $110-$114 more net return than a cow calving in the spring months. In which case such a return in itself provides sufficient incentive for fall production.

h. The base plan would be an extreme hardship on those producers whose dairy herd is or has been affected by Bang's or other diseases affecting milk production.

i. July and August are not good months for a cow to have a calf due to high daytime temperatures and an infestation of flies.

The proposed blend price, which is usually higher in the fall months than in the spring months, provides sufficient incentive to produce additional milk in the fall months.
Several handlers opposed the adoption of a base-excess plan in the 11 markets. One handler stated that his seasonal pattern of Class I sales in the Corpus Christi area is contrary to that of other handlers in other markets. He indicated that his Class I sales are greater in the spring than in the fall because of the tourist trade and that the proposed base-excess plan would not be compatible with this sales pattern. The handler claimed that such a plan would discourage new dairy farmers from entering the market, that it would decrease the local producer milk supply and force a greater reliance on milk supplies from the northern part of the United States, and that consumers would be forced to pay a higher price for milk. The handler also argued that a base-excess plan would help the proponent cooperative gain additional market control.

Another handler opposed the adoption of a base-excess plan on the basis that the seasonal fluctuation in milk production in the 11 markets is not significant, pointing out that in the spring of 1975 and 1976 milk production was 114 and 110 percent, respectively, of production in the immediately following fall months. The handler also noted that a base-excess plan terminated in the North Texas order in 1963 because milk production had increased 85 percent in a 10-year period of time while Class I sales had increased only 41 percent.

Several handlers with own-farm production opposed the application of the proposed base-excess plan to their own-farm production and suggested the following alternatives if such a plan is adopted: (1) delay the effective date of the plan for 2 years, (2) exempt own-farm production from the base-excess plan, and (3) exempt from the base plan that portion of own-farm production equivalent to the amount of packaged milk sold to consumers.

A common base-excess plan should be included in each of the 11 markets under consideration. The base plans will provide a means of encouraging a more level seasonal production pattern in the 11 markets so that there will be a better seasonal coordination of milk supplies with the Class I demand.

Milk production in the 11-market area fluctuates seasonally, with supplies increasing in the spring and declining in the fall. Such changes are portrayed, for example, in the producer delivery data for 1975 and 1976 that were included in the record. In the spring of 1975, average daily deliveries of producer milk reached 109 percent of the average daily deliveries for 1975 and 1976 combined. For 1976, this figure was 108 percent. Similar downward swings occurred in the fall, with average daily deliveries dropping to 92 percent in 1975 and 95 percent in 1976 of the 2-year daily average.

Although it was argued by some that such seasonal fluctuations in production are not severe, such changes are much more meaningful when viewed in terms of the somewhat opposite swings in Class I sales. When supplies were lower in the fall, average daily Class I sales fluctuated upward to 107 percent in 1975 and 105 percent in 1976 of the average daily Class I sales for the 2-year period. During the heavy production months, sales dropped off considerably. In 1975, average daily Class I sales in the 11-market area were only 50 percent of the 2-year daily sales average. In 1976, the amount was 92 percent.

When the production and sales data are put together, it is quite evident that producers' needs for Class I sales fluctuate in seasonal balance with the Class I sales of regular handlers. In 1975, the relationship of average daily producer deliveries to the 2-year average of daily Class I sales ranged from a low of 121 percent in April to a high of 144 percent in May. Similarly, in 1976, this relationship ranged from 125 percent in November to 142 percent in April.

It is recognized that the production-sales data do not portray the same seasonal relationship for each of the 11 markets individually. However, the producer delivery data for each market do not necessarily reflect the seasonal production patterns of individual producers. This is because producers are shifted extensively from market to market by the proponent cooperative in balancing the fluid milk needs of handlers throughout the entire 11-market area in seasonal balance. For this reason, the only meaningful analysis of producer delivery data is that which is based on producer deliveries for all 11 markets combined.

A number of producers contended in their exceptions to the recommended decision that there is no seasonal shortage of milk in the 11 markets but merely daily shortages of milk resulting from the 4- and 5-day bottling schedules of handlers. It is true that daily variations in the quantity of milk demanded by handlers tend to accentuate milk shortages during the fall months. However, there is little reason to expect that the bottling schedules of handlers will change significantly, and the milk shortages that result from such bottling schedules pose a supply problem for those cooperatives committed to supplying the fluid milk needs of handlers.

Because of the seasonal changes in production and Class I sales, it has been necessary for the proponent cooperative to take various actions in response to the marketing problems that arise from such seasonal changes. Such actions have centered on obtaining adequate supplies of milk for handlers' fluid needs during the fall and disposing of excess supplies during the spring months.

For example, in the fall of 1976 the cooperative found it necessary to acquire substantial quantities of milk from outside the 11-market area. About 22 million pounds of supplemental milk were obtained from the Central Arizona Federal order market, for instance. Most of this was needed to meet the fluid milk requirements of handlers in the Dallas/Fort Worth, Houston, and San Angelo areas of the Texas market. Also, supplemental milk was moved into the 11-market area from Missouri, primarily for use by handlers in the Memphis market. In most cases, the supplemental supplies moved into the 11-market area were not moved directly to the shortage areas but instead were used to supply handlers nearest the out-of-area source in order to minimize transportation costs. Supplies regularly associated with the 11-market area were then redirected (in what proponent referred to as a "stairstepping" arrangement) to the shortage areas. Even with the acquisition of out-of-area milk supplies, the cooperative was not always able to fulfill the needs of handlers and was forced to allocate its limited supplies to its regular buyers.

Additional efforts by the proponent cooperative to balance the Class I needs of handlers include the shifting of producers from one market to another within the 11-market area. Such efforts are directed primarily toward having sufficient supplies available for the Texas market. Relative to the number of producers on the Texas market in February 1977, the following numbers of additional producers were associated with the Texas market in the immediate past: 539 in September, 551 in October, 458 in November, 669 in December and 492 in January. Such additional numbers resulted largely from the proponent cooperative's shifting of producers, which was done in part to implement the "stairstepping" arrangement referred to earlier in connection with the out-of-area supplies and also to redirect the movement of milk supplies within the 11-market area to the areas of greatest need.

In addition to its balancing activities necessitated by seasonal shortages in milk production, the proponent cooperative also handles much of the excess milk that results from the seasonal increases in milk production. The major outlets in the 11-market area for reserve milk supplies are manufacturing plants operated by proponent. Such plants are located at Sulphur Springs and Muenster, Tex.;
Tulsa and Oklahoma City, Okla.; and Hillsboro, Kans. Milk supplies not needed at distributing plants are redirected to these plants for surplus disposal. At times, the cooperative assumes the handling of a somewhat greater proportion of the surplus in the 11-market area than would normally be associated with its share of the area's total producer milk. It is not unusual for some handlers to buy milk on a regular basis from producers not belonging to a cooperative association and then obtain supplemental milk from the cooperative on heavy bottling days. Also some handlers purchase milk from the cooperative only during the fall months when the supplies of milk are traditionally short in these 11 markets.

In his exceptions, a party held that there is no evidence on the record that AMP! bears the "burden" of surplus disposition. The record reveals, however, that proponent cooperative handles the reserve requirements and the related sales for nonmembers who receive milk produced by nonmembers on 7 days a week and rely on the cooperative to supply milk on a lesser number of days. To the extent that the cooperative handles a disproportionate share of the market surplus, it bears the "burden" of surplus disposition in the market.

In carrying out the various balancing activities associated with the seasonal fluctuations in milk production, the proponent cooperative incurs operating costs that are passed on to its members through reduced returns from the sale of their milk. As a marketing organization attempting to obtain the highest possible returns for its members, the cooperative has sought to reduce such costs. For a number of years, the cooperative has operated a type of base plan among its own members, for the purpose of tailoring production on the part of these producers to meet the fluid needs of the 11 markets. The effectiveness of the plan in reducing balancing costs has been limited, however, because the cooperative's balancing activities are affected also by the production pattern of other producers in the 11-market area. Also, there has been some reluctance on the part of the cooperative members to impose an effective production incentive plan on themselves when other producers in the 11 markets are not operating under a similar plan. As an aid to minimizing the costs of marketing the milk of its members, the cooperative is seeking the adoption of a common base-excess plan under the 11 orders.

It is in the interest of orderly marketing that a base-excess plan be applicable under each of the 11 orders under consideration. Such plans are specifically authorized by the act as a marketing arrangement that producers may use under a Federal order. It is recognized that not all producers who would be affected by the adopted plan favor it. Nevertheless, considerable weight must be given to the fact that a very significant number of producers in each of the markets believe that such a plan can materially aid in the marketing of their milk. The proponent cooperative alone represents roughly three-fourths of the producer milk in the 11 markets combined, and about 85 percent or more of the producer milk in 8 of the 11 individual markets. In the other three markets—Wichita, Rio Grande Valley, and Texas—the proponent cooperative markets at least two-thirds or more of the milk in each market. In view of the seasonal fluctuations in milk production and the attendant marketing problems for these producers, the adoption of a common base-excess plan for the 11 markets is appropriate.

Opposition to the proposed base plan was limited primarily to the Texas market, which has about half of the milk in the 11-market area. It is in the Texas market, however, where the proponent cooperative is heavily engaged in balancing activities associated with the seasonal swings in production, and where it is significantly affected by the fluctuations in production of producers outside its membership. The fact that there was opposition to the base plan should not be an over-riding consideration in this case in determining whether or not the proposed plan should be adopted.

The base plan for each order should permit the interchange of producers among all 11 markets without affecting their establishment of base or payments for base milk. Such an arrangement is not applicable under the central Arkansas, Fort Smith, and Memphis orders. A similar arrangement is needed for the 11-market area because of the extensive and continuing shifting of producers among the individually regulated markets. Such shifts occur largely in connection with the proponent cooperative's balancing activities referred to earlier. Under the "stairstepping" arrangement, for example, producers associated with the Rio Grande Valley market may be redirected to the Texas Panhandle and Lubbock-Plainview markets. Producers associated with the latter two markets might then be redirected to the Texas markets. Producers may be shifted from the Wichita market to the Oklahoma metropolitan market, and then from the latter market to the Texas market. In October 1976, for example, 1,307 of the proponent cooperative's producers on the 11 markets that month were producers under more than one of the 11 orders.

A producer representative and a handler regulated under the Memphis order permitted deliveries by producers to central Arkansas, Fort Smith, and Memphis markets to be used in the computation of a producer's base, opposed a comparable provision for the 11 markets. Both stated that such a provision is not authorized in the Act.

There is nothing in the Act stating that a base-excess plan in a market cannot include deliveries by producers to plants regulated under another Federal order in determining the quantities of base milk of an individual producer. As indicated, the Memphis, central Arkansas, and Fort Smith orders all presently contain such provisions.

The handler also opposed the inclusion of the central Arkansas, Fort Smith, and Memphis orders in the proposed 11-market base plan. He was not opposed, however, to the continuation of the present base plan in each of the three orders or in an order merging the three orders. He was of the position that the three markets receive their milk supply from a common production area. Opposing testimony at the hearing argued that the Lubbock-Plainview market should not be included since that market is a growth area and additional class I milk is needed from one year to the next.

These arguments are not persuasive. These markets are an integral part of the area being supplied by the proponent cooperative. For the reasons already set forth, recognition should be given to the cooperative's request that a base plan be adopted in these and nearby markets for the purpose of aiding it in the marketing of its members' milk.

Various parties suggested that it would not be appropriate to limit the computation of a producer's base to deliveries only within the 11 markets. They noted that one or more of the 11 markets may be milk from a production area that also serves markets outside these 11 markets. They pointed out that a dairy farmer residing in such common production area would be disadvantaged unless his total production is used in computing his average daily base.

Producers in the 11 markets who are not members of a cooperative usually deliver their milk to the same handler throughout the month. Consequently, their total production for the month would be used in computing their base. Producers who are members of a cooperative association which markets the milk of its members under one of the 11 orders and a market outside of the 11 markets could be affected. Such
producer would not be disadvantaged in the computation of his base if at least three-fourths of his production were delivered during the 11-month period to one of the 11 markets. The plan provides that a producer who delivers milk at least 90 days out of the 122 days during September through December would receive a base equal to his average daily production. This provision will permit a limited interchange of producers between the 11 markets and other Federal order markets.

Several parties noted that climatic conditions and production patterns vary throughout the 11 markets. For that reason, they suggested that whatever months are used as the basemaking and basepaying months for the 11-market area might not be appropriate for each of the individual orders.

The production area of each of the 11 orders is in reality a part of a common production area used to supply all 11 markets. It is for this reason that the 11 markets must be considered on a combined basis in establishing the basemaking and basepaying months.

In their exceptions to the recommended decision, several parties argued that if the 11-market area is in fact a common production area the 11 orders should be combined into one order. This proceeding does not provide the forum for deciding whether there should be only one order or 11 orders. Such a decision would have to be made on the basis of a hearing held for that purpose.

A number of those who testified were concerned that the adoption of a base plan would result in a “race for base.” They contended that the adoption of the plan would result in excessive fall production, thereby reducing the level of the blend price in the fall months. Also, they argued that a plan would increase milk production during the flush months and thus increase total milk production rather than level milk production throughout the year.

There is no means of foretelling how producers will react to a common base plan in the 11 markets. If a “race for base” occurs and results in excess fall production or in a large increase in milk production annually, marketing conditions can be reviewed at such time.

Several parties filed exceptions to the finding in the recommended decision that “there is no means of foretelling how producers will react to a common base plan in the 11 markets.” They pointed out that the experience that the Department has had with base plans in other markets, particularly in Texas, should have caused the Department to conclude that adoption of the plans would lead to chaotic marketing conditions. They also held that the decline in the number of base plans under Federal orders during the period from 1967-1977 was further evidence of the failure of base-excess plans as a feasible marketing tool.

It is true that there has been a decline in the number of orders with base-excess plans, however, the base plans were terminated because they resulted in an increase in yearly milk production. These past events, however, provide no conclusive evidence that producers within the 11-market area will react in a similar manner to the adoption of the proposed base-excess plans.

In this regard, parties excepting to the recommended decision held that base plans in the 11 markets will increase rather than decrease reserve milk supplies during the spring and summer months. If producers attempt to increase fall milk production by expanding base-excess plans during the basepaying months, then it is likely that milk production will increase during the spring and summer months. However, if producers change the production of their current herds to conform with the production pattern during the basepaying months, the increase in reserve milk supplies that excess producers anticipate should not result during the spring and summer months.

Several parties claimed that the proposed base-excess plans could result in only nonmember producers receiving base and excess prices. They contended that because a cooperative association has the privilege of rebending its proceeds, the association would not be required to pay its members upon the basis of their deliveries of base milk and excess milk. They argued that the cooperative would use the proceeds, the association would not be required to pay its members upon the basis of their deliveries of base milk and excess milk.

Proponent cooperative indicated that it intends to pay its members using the base-excess payment plan. It was not revealed on the record what payment procedures other cooperatives would use. Irrespective of the payment procedures utilized by cooperatives during the months when base and excess prices are paid, the payment that the cooperative association receives from the producer-settlement fund for all of its member producer milk will reflect the respective quantities of its member producer milk that is base milk and excess milk. For that reason members of a cooperative who are to supply milk that is advanta-

It appears instead that a cooperative’s milk received from the cooperatives would not have a base and would receive only the excess price for their milk. It was claimed that such restrictiveness was a restraint of trade in violation of §608c(5)(G) of the act.

It is recognized that any base-excess plan will tend to provide a disincentive at certain times of the year for producers to come onto the market, either as new producers who have just started dairying or as producers who have been shipping to other markets outside the 11-market area. This is why it is necessary to establish a common base plan for the 11 markets that permits the interchange of producers within this area. Nevertheless, the time when producers just coming onto the 11 markets would be adversely affected the most would be during the basepaying months. If supplies are customarily in excess of the class I requirements of handlers and handlers normally would not be seeking new producers. The influx of new producers at this time would be expected to be minimal.

The use of a base-excess plan under the order is not in violation of §608c(5)(G) of the act. The latter provision specifies that an order shall not prohibit or in any manner limit the marketing in a Federal order area of milk produced in any production area in the United States. Congress, in providing specific authorization in the act for base-excess plans, did not intend that their use be nullified by §608c(5)(G) of the act.

Exceptors reiterated claims made at the hearing and in post-hearing briefs that the proposed base plan is in violation of §608c(5)(G) of the act. For the reasons already indicated, such claims are not valid and do not warrant a denial of the proposal for base plans in the 11 markets.

Exceptors held that the adoption of the base plans would allow AMPI to “manipulate” an order through “pool loading” i.e., shifting unneeded milk supplies from one market to another for the purpose of depressing the returns to producers in the second market who are not members of the cooperative. Neither the exceptions nor the record provide a basis, however, for concluding that base plans would facilitate socalled pool loading. It appears instead that a cooperative’s milk received from the producer-settlement fund would not have a base and would receive only the excess price for their milk. It was claimed that such restrictiveness was a restraint of trade in violation of §608c(5)(G) of the act.

Exceptors reiterated claims made at the hearing and in post-hearing briefs that the proposed base plan is in violation of §608c(5)(G) of the act. For the reasons already indicated, such claims are not valid and do not warrant a denial of the proposal for base plans in the 11 markets.
ers would receive only the excess price for their milk. Thus, it seems likely that a base plan would deter a cooperative from loading a pool rather than facilitating marketing.

As outlined earlier, producers testifying against a base-excess plan raised numerous reasons as to why such a plan should not be adopted. Much of the opposition centered on the difficulties and additional expense that producers would experience in adjusting their production operations under a base plan.

In their exceptions, certain parties held that the base plans would insulate AMPF from competition for membership by making it more difficult for a producer to switch cooperatives while at the same time qualifying for a full base. As the recommended decision pointed out, there are other incentives under a base plan which might deter a new producer from entering the 11 markets under consideration during certain months of the year. To the extent that these disincentives exist, a dairy farmer who markets his milk outside the 11 markets might be deterred from joining a cooperative that markets its milk entirely within the 11 markets. However, a producer who is a member of a cooperative could transfer to any other cooperative in the area during any month of the year and continue to market his milk under one of the 11 orders without any loss of base as a result of such a transfer. This would be possible since a base is earned by the producer and not by the cooperative of which the producer is a member. Thus, the transfer of a producer from one cooperative to another would not affect the ability of the producer to earn a full base, as suggested in the exceptions.

In other exceptions, it was contended that the Department was insensitive to "consideration of the proposals of the producers" by adopting the base plans. This is not the case. Consideration has been given to the extent to which the base plans might tend to limit a cooperative's ability to compete for members and market outlets for milk. The claims are without merit.

Also, approximately 200 individuals, primarily dairy farmers, submitted comments to the Department opposing the base-excess plans. For the most part, the individuals reiterated the same objections voiced by dairy farmers at the hearing. Some of the 200 individuals also signed the exceptions filed by Concerned Dairymen, a group of dairy farmers opposed to the adoption of uniform base-excess plans. Approximately 500 individuals signed such exceptions.

It is recognized that producers may need to make some added expenditures and special adjustments in their operations under the adopted base-excess plan if they desire to maximize their returns under the plan. As indicated, the purpose of the plan is to encourage a more level seasonal pattern of production. Seasonal variations in production occur because this production pattern is normally the least costly and most natural production pattern for farmers. Any change in this normal production pattern comes about only through the collective efforts of farmers, which usually entails added costs and operating difficulties. Farmers are not inclined to change their production pattern in the absence of any special incentive. The purpose of the base plan is to provide this incentive.

Questions arose at the hearing concerning the application of an 11-market uniform base-excess plan under the Texas order in conjunction with that order's "dairy farmer for other markets" provision. The "dairy farmer for other markets" provision provides that a cooperative or pool plant operator caused milk from the same dairy farmer to be marketed under another market any time during the immediately preceding months of September through November. The provision is intended to preclude the association of reserve supplies of surrounding Federal order markets with the Texas market during the months of February through July if the cooperative association or pool plant operator caused milk to be marketed during any part of these months.

The application of the "dairy farmer for other markets" provision in conjunction with the base-excess plan could impose a dairy farmer who earned base during the months of September through December not to receive the base price on any of his milk delivered to the Texas market during the base-paying months of March through July. Under that provision a dairy farmer who is a "dairy farmer for other markets" could not qualify as a producer. As a consequence, the dairy farmer would not be eligible to have his milk priced under the order and thus would have no assurance of what price he would receive for his milk. If the order required such dairy farmer to be paid the base price on any of his deliveries to the Texas market, such payment would conflict with the "dairy farmer for other markets" provision and defeat the purpose of that provision. The "dairy farmer for other markets" provision, however, would not preclude producers delivering to a plant which was a nonpool plant under the Texas order during the months of September-November but which is a pool plant during the next March-July period from benefiting under the base-excess plan. Also, an individual dairy farmer could shift to the Texas market from any of the 10 markets during March-July and retain his earned base provided that he does not deliver milk at a plant operated by the same handler to whom he shipped milk during the preceding September-November period.

The operators of pool plants with own-farm production and dairy farmers whose herds consist solely of registered dairy animals should note that a record of the exceptions filed by Concerned Dairymen who opposed the adoption of a base-excess plan on the basis that plan would impose an incentive from loading a pool rather than facilitate marketing conditions for the Texas market.

Whether or not base-excess plans should be applicable in the 11 markets under consideration must be based on the record evidence of the current hearing as it relates to present marketing conditions in these markets. As described previously in this decision, the record evidence in this proceeding justifies the use of a base-excess plan in each of the 11 markets.

A cooperative association and a handler opposed the adoption of a base-excess plan on the basis that proponent did not develop studies on the impact of the proposed plan on the markets involved and thus provided for the record only limited evidence regarding its proposal. The relevant point here is not the extent to which proponent studied the issue at hand but rather whether or not the evidence in the record adequately supports the adoption of the proposal. As already indicated, the record does justify the use of a common base-excess plan for the 11-market area.

Exceptors reiterated previous contentions that AMPF presented no studies or data which would indicate that a
One cooperative association maintained that the "economic incentive to obtain base creates a major administrative burden in policing the plan." Its representative alleged that many farmers threatened to terminate their production during the fall months by adding water to milk, borrowing cows from dairymen shipping to grade B manufacturers, and exchanging milk with someone who is not pooled in the market, for example. In support of his argument that the plan would be an administrative burden, the cooperative's representative indicated that the decline in the number of base plans under Federal orders was the best evidence of the deficiencies of such plans.

Speculation by the cooperative's representative that the base plan provisions would create an administrative burden is not sufficient reason for denying implementation of the proposed plan. Furthermore, none of the potential problems cited would be an administrative burden for the market administrator in computing bases. The market administrator would rely on the handlers to determine the producers' milk to report the amount of milk pooled by each producer during the month. Additionally, none of the reasons set forth by opponent for terminating base plans were related to the administration of such plans. The need for the base plan in the 11 markets as a means of leveling production throughout the year overrides any potential administrative problem noted at the hearing that might arise in the operation of the base plan.

Several cooperative associations alleged they would not be able to obtain as members dairy farmers who are members of other cooperatives operating outside the 11-market area unless the members' contracts expired in either August or September. They indicated that, if the members' contracts expired at any other time, a dairy farmer would be reluctant to change cooperatives since he would be at a disadvantage in becoming a producer on one of the 11 markets. They noted that if the dairy farmer entered the market in October-December, he would not be able to obtain a base equal to his average daily deliveries in the base-making period. If he entered the market during March-July, he would receive the excess price for his milk during such period of time.

The representative of one cooperative was concerned that, if a base-excess plan were adopted, a cooperative which presently has a 30-day contract with its members would begin signing its members to 1-year contracts expiring in months other than August or September to discourage any shifting of members to other cooperatives. It is not pertinent whether a proposed base plan could be a disincentive for dairy farmers in other areas to become producers under 1 of the 11 orders, and that dairy cooperatives supplying the 11 markets could have some difficulty in obtaining new members. Furthermore, this presumably would be a limited problem since dairy farmers usually maintain their membership in a cooperative over a period of years and do not switch membership from one cooperative to another. In any event, the inability of a cooperative to obtain new members readily should not be an overriding consideration in deciding whether a base-excess plan should be adopted.

Counsel for 30 dairy farmers contended that the proposed base-excess plans should not be adopted because present marketing conditions in the markets are in conformity with § 602(4) of the act. He contended that the proposed plans would result in conditions that are contrary to this section. Section 602(4) is the declared policy of Congress for the Secretary to establish and maintain such orderly marketing conditions as will provide an orderly flow of the supply to market throughout its normal marketing season to avoid unreasonable fluctuations in supplies and prices. As one of the means of obtaining this objective, the act specifically provides for the adoption of base-excess plans in Federal order markets. The record of this proceeding indicates that the use of base-excess plans in the 11 markets would, in fact, foster orderly marketing as contemplated under § 602(4) of the act.

This representative for 30 dairy farmers also claimed that the hearing was improperly called. He contended that § 608c (3) and (17) of the act permits hearings to be called only under two conditions: (1) The Secretary may call a hearing if he has reason to believe that the issuance of an order will tend to effectuate the declared policy of the act; and (2) the Secretary is required to call a hearing under specified conditions when one-third or more of the producers as defined in an order apply as individuals and in writing for a hearing stating that it is a cooperative association. As the representative thus concluded that a hearing could not be called to consider a proposal submitted by a cooperative association on behalf of producers.

This is not the case. The act does not preclude parties in the industry, such as a cooperative association, from petitioning for a hearing. The Secretary may call a hearing either on his own volition or at the request of other parties if he concludes that the proposed change would tend to effectuate the declared policy of the act.

Moreover, the Department's "Rules of Practice and Procedure Governing Proceedings to Formulate Marketing Agreements and Marketing Orders" (7 CFR part 900) specifically provide for the submission of proposals by persons other than the Secretary. Section 900.3 states that "a base-excess plan or a marketing order may be proposed by the Secretary or by any other person."

The motion by a cooperative association to render the entire hearing void and the motion by another cooperative association to reconvene the hearing at a later date because proponent altered provisions of its proposal at the hearing are denied. No statutory or administrative rules preclude appropriate modifications thereof. Thus, interested parties were given the opportunity to modify the proposed base-excess plan during the course of the hearing to the extent that no new issue outside the scope of the hearing was raised. In fact, as described elsewhere in this decision, several handler witnesses did propose certain modifications.

Exceptions reiterated claims made at the hearing and in post-hearing briefs that a modification at the hearing of a provision contained in the notice of hearing did not allow sufficient time to introduce testimony in opposition to the proposed amendments and any appropriate modifications thereof. Thus, interested parties were given the opportunity to modify the proposed base-excess plan during the course of the hearing to the extent that no new issue outside the scope of the hearing was raised. In fact, as described elsewhere in this decision, several handler witnesses did propose certain modifications.

Two cooperative associations claimed that the administrative law judge erred in not dismissing the hearing on the proposed base-excess plans. These cooperatives maintained that because proponent had submitted a revision to its original proposal and the Department had issued a revised notice of hearing reflecting the revision, proponent and the Department were involved in new party communication which is prohibited by the "Government in the Sunshine Act."

The communications which took place between proponent and Department officials in this instance involved the receipt of revisions from proponent to previously submitted proposals and the Department's acknowledgement of the receipt of such revisions. The initial proposals had been accepted by the Department for considera-
tion at a hearing and had been set forth in a hearing notice. The revised proposals represented modifications of the initial proposals that could have been made during the course of the hearing. However, the communications which were made available to the Department prior to the hearing, it was possible to provide the industry with advance notice of the modifications intended to be supported at the hearing. In the absence of the communications which took place, interested parties would have had to wait until the hearing to be made aware of the modifications. The communications involved were made a part of the record evidence, would be considered at the hearing that, disclosure, however, is not required.

An excess plan would tend to effectuate the purposes of the act. Such letters and oppositions to the base plan and from Department officials from persons have been made a part of the official record for viewing by the public.

One of the exceptions further stated that all ex parte communications between any party and the Department in its initial proposals. This afforded all interested parties the opportunity to safeguard their interests, through full participation in all aspects of the rulemaking proceeding, which is the very thrust of the regulations on ex parte communications.

Exceptors reiterated their contention that the presiding officer's rejection of a motion to require AMPFI to show cause why the plan should not be dismissed under "Government in the Sunshine Act" was in error. The views expressed by exceptions were fully considered in the recommended decision and, as noted, are without merit.

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Counsel for the cooperative association alleged also that § 554(d) of the Administrative Procedure Act precludes an employee of the Department from participating in the hearing from being involved in the subsequent decisionmaking process. This is not the case. There is no requirement that those employees involved in the decisionmaking process in the proceeding must not have participated in other activities related to the proceeding.

In his exceptions, counsel restated his previous contention. However, he provided no additional basis for such contention in renewing his objection. As indicated, Counsel's claim is without foundation.

Two cooperative associations and a party who investigated the initial proposal, produced no additional basis for such a demonstration. Accordingly, the request to reopen the hearing is denied.

In his exceptions, a party requested that the Department inform each producer prior to his voting on a base plan of how it intends to curb abuses of the base plan. Exception did not specify, however, any particular abuse that he believed might occur. Any abuses of the base plan can be reviewed, of course, through the hearing procedure.

This exception also requested a listing of all producers who might be voting on a base plan so that those proposed uniform base-excess plans would tend to effectuate the purposes of the act. Such disclosure, however, is not required.

Following a public hearing, the Secretary may adopt only those proposals considered at the hearing that, if supported by the record evidence, would tend to effectuate the purposes of the act. It would be useless, then, to include in the hearing notice proposals that obviously would not be consistent with the act and thus could not be adopted. For this reason, the Department must make a preliminary evaluation of all proposals submitted to it for consideration at a hearing to determine if the proposals would carry out the purposes of the act. The Department is not required to reveal publicly the various considerations involved in making an affirmative determination on the proposals. It should be emphasized, though, that the inclusion of a hearing notice to the point means that the proposal will be adopted. The adoption of a proposal by the Secretary must be based solely on the evidence presented at the hearing.

In his exceptions, counsel reiterated his objection to the Department's failure to disclose the basis for its prehearing conclusion that the uniform base-excess plans would tend to effectuate the purposes of the act. For the renderd just noted, the objection is not valid.

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This exception also requested a listing of all producers who might be voting on a base plan so that those opposed to the base-excess plan could ascertain the eligibility under the Act of each potential voter. The task of determining the eligibility of voters in this circumstance is delegated to the referendum agent whom the Secretary selects to conduct the vote among producers. Such voting eligibility is determined in accordance with the Department's rules as set forth in 7 CFR Part 900.
Counsel for a cooperative which was opposed to the adoption of the proposed uniform base plans requested in his exceptions that official notice be taken of the following items:

1. The Texas Milk Market Report of December 1977 which was published by the Market Administrator of the Texas order.


The request for official notice of the three items is denied. The rules governing this proceeding specify that “interested persons shall be given adequate notice, at the hearing or subsequent thereto, of matters so noticed and shall be given adequate opportunity to show that such facts are inaccurate or are erroneously noticed.” Taking official notice of the above items in this final decision would preclude interested parties from having an opportunity to comment through exceptions on any of the information contained in these several items.

Counsel for this cooperative also requested rulings on 18 proposed findings of fact which he set forth in his post-hearing brief and which in his opinion were not ruled upon in the recommended decision. The proposed findings and the Department’s rulings are as follows:

(1) “The base-excess plans in the North Texas, Red River, Lubbock-Plainview, Northern Louisiana, and New Orleans order are not market oriented because of excessive production depressing the blend price to the farmer in a ‘race for base’.”

(2) “The base-excess plans in the 11 market area were discontinued in the five orders with the final decision or termination order relative to the discontinuance of such plans in the respective orders. In some cases, a ‘race for base’ was indicated as a partial reason for discontinuing the base plan.”

(3) “The AMPI base-excess plan for 11 federal market orders covers precisely an area where AMPI holds oligopolistic control of milk supply.”

(4) “The 11-market area has an adequate reserve supply of fluid milk over Class I sales is 15 to 20 percent.”

(5) “The 11-market area as a whole, in 1976, seasonality of production of 9.5 percent, spring over fall production, and 13.8 percent in 1975, which seasonality is well within reasonable and achievable limits of effective management.”

(6) “It is not probable that a base-excess plan would materially improve upon the present seasonality of production.”

(7) “The 11-market area has an adequate reserve supply of fluid milk to accommodate plants, receiving milk four or five days a week only, occasion a 14 percent reserve for each day of non-receipt. The cost of this reserve is not a cost of marketing properly to be borne by producers through a diminution of their blend price.”

(8) “Reserves of fluid milk to accommodate plants, receiving milk four or five days a week only, occasion a 14 percent reserve for each day of non-receipt. The cost of this reserve is not a cost of marketing properly to be borne by producers through a diminution of their blend price.”

(9) “The 11-market area is an adequate reserve supply of fluid milk to meet the reasonable needs of handlers in the market.”

This finding is contrary to the record evidence, which indicates that milk supplies during the fall are not adequate to meet the Class I demand of handlers.
(10) "AMPI does not disproportionately bear the burden of carrying the reserve supply for the 11-market area. In fact, many of the markets dominated by AMPI draw upon reserves pooled upon the Texas and Wichita markets thereby depressing the blend price to no longer imposing the burden of reserves for markets monopolized by AMPI on the nonmembers serving the Texas and Wichita markets."

The manner in which AMPI bears a disproportionate share of the reserve milk for the Texas market was discussed earlier in this decision. With respect to the other point in the proposed finding, it is noted that the "dairy farmer for other markets" provision of the Texas order was adopted specifically to assure that the Texas market would not carry the reserve milk supplies for other markets.

(11) "The base-excess plan would stimulate a 'race for base' in the fall base-forming period."

This proposed finding was discussed earlier in this decision.

(12) "Added production stimulated in the fall would depress the blend price and cause loss of income to the farmers."

If it is assumed that the only variable in this instance is the quantity of milk produced, it is true that an increase in production would lower the average blend price. However, this presumably would be offset by an improvement in producer pay prices in the spring and summer months as a result of less production (in response to the base plan incentive).

(13) "Increased production will stimulate increased spring production because baseholders will strive to obtain full payment for the base acquired in the fall and because of natural factors of breeding and pasturage, thereby depressing the blend price to the farmers in the spring."

To obtain full payment in the spring months for base earned during the fall months, a producer would need to produce only as much milk in the spring months as he produced in the fall months. The base plan would provide a disincentive (through the payment of the surplus price) for any production in excess of a producer's base. It does not follow, therefore, that an increase in fall production will necessarily result in a proportionate increase in spring production.

(14) "The proposed base-excess plan would create an economic barrier to the entry of new producers except for entry during the months of August and September."

As indicated earlier, it is recognized that any base-excess plan will tend to provide a disincentive at certain times of the year for producers to come onto the market.

(15) "The fall of the year is the most expensive time for a new producer to enter into dairy farming."

Several producers testified that this was true in the areas in which they were located. In such areas, a dairy farmer who began operations in the fall would need to make a large cash outlay to purchase feed for his cows until such time as they could be placed on pasture the next spring and until he could raise his own feed grains. In a "dry lot" operation, it does not seem likely that the cost of the beginning operations in the fall months would differ materially from beginning operations at any other time of the year.

(16) "The base-excess plan would make it difficult for new and young dairy farmers to enter the dairy business in the 11-market area."

As noted earlier, there may be a disincentive for producers to come onto the market at certain times of the year. Those disincentives apply to all producers whether they are new or experienced and whether they are young or old.

(17) "The base-excess plan may lend itself to manipulation to strengthen the oligopolistic control of the market by AMPI."

The provisions of an order are intended to promote the orderly marketing of milk and must carry out the intent of the act. If it is believed at any time that such provisions, including the base plans adopted herein, are not meeting these requirements, a review of such provisions at a hearing may be sought.

(18) "In a free vote by individual dairy farmers, the base-excess plan would probably not be adopted."

There is no basis on the record for establishing that a base plan would be more acceptable than the base-excess plan. The base-excess plan adopted in this decision would probably not be adopted.

2. Order provisions implementing the base-excess plan. Except for the interim provisions established for 1978 that are described later, the base-excess plan adopted in this decision would establish a base for each producer by adding the pounds of producer milk delivered by him under each of the 11 orders during September through December (the base-forming period) and dividing such amount by the number of days' production represented by each producer milk or by 90, whichever is greater. Under usual conditions, a producer would deliver milk throughout the base-forming period (122 days). It is possible that a producer would not deliver milk to any of the 11 markets for a limited number of days during the base-forming period (perhaps because of a temporary suspension of a health permit, or shipments to a market other than the 11 markets). The 32-day grace period provided herein should accommodate most situations in which a producer's milk would be withheld from delivery to one of the 11 markets.

Requiring a producer to supply one or more of the 11 markets in the base-forming months in order to earn a full base provides an incentive for him to ship to these markets instead of other markets. This will tend to assure that sufficient milk is available to supply handlers in the 11 markets during the fall months when production is lowest relative to the demand for Class I milk. A producer who delivers at least 90 days' production during the one month base-forming period to the 11 markets can be considered as being primarily associated with this 11-market area. A producer who delivers less than 90 days' production may have his base determined by dividing his total producer milk in the base-forming period by 90. This will assure that a producer who may have been supplying the Class I needs of a market for a limited number of days during the base-forming period to receive a base that reflects his contribution as a producer supplying the needs of the 11 markets in such period.

Dairy farmers who deliver to a plant that becomes a pool plant under one of the 11 orders after the beginning of the base-forming period should be assigned bases in the same manner as if they had been producers under these orders during the base-forming period. Their bases would be calculated from their deliveries to that plant in the preceding September-December period.

It is expected that when such a plant acquires pool plant status it will add Class I sales to the market comparable to such sales in prior periods when it was not a pool plant. It is appropriate, therefore, that those dairy farmers who have been supplying the plant have bases computed for them according to their deliveries to the plant in the base-forming period. As proposed by the cooperative advocating the base plan, the months of September through December should be used as the base-forming period. It is during these months that milk production tends to be at its lowest level throughout the year. The need for encouraging more level production during this period is accentuated by the tendency for Class I sales to swing upward during this same period.

In addition to these four months, January is also now being used as one of the base-making months under the Central Arkansas, Fort Smith, and Memphis orders. Data for the 11 mar-
The period of March through July is when milk production tends to be at its highest level during the year and when the base plan should be encouraging a more seasonal production pattern. This is particularly so since within this period there is usually a seasonal decline in Class I sales.

Data for 1973 and 1975 which the cooperative relied on in support of its proposal does not support the use of February as one of the base-paying months. Producer receipts for such month on an daily basis were less than the daily average for each calendar year. There is no need to be discouraging the production of milk during this month.

Producers would establish new bases each year. The bases would be computed by the market administrator of the respective orders to be effective in the following March through July (the base-paying period). By February 10 of each year, the market administrator would notify each producer and the handler of his milk of the producer's base. The market administrator would notify a cooperative, if so requested by the cooperative, of the base established by its member producers.

The recommended decision provided that the market administrator would notify each producer of his new base by February 1. Upon further review, it appears questionable whether this deadline can be reasonably met due to the large number of producers involved and the extent of the intermarket shipments of milk by individual producers. Accordingly, the respective orders should provide that the producers must be notified of their new base no later than February 10.

Base milk would mean the producer milk of a producer in each month of March through July that is in excess of the amount equal to the producer's base multiplied by the number of days in the month. Excess milk would mean the producer milk of a producer in each month of March through July which is the producer's base milk for the month. Excess milk would also include all the producer milk in March through July of a producer who has no base.

Since the base a producer receives would be determined by the quantity of milk shipped in the base-forming months, he would have an incentive to maximize his shipments in September through December. In these months production for the market is normally shorted as milk value for his production in excess of his base milk for the month and thus would be encouraged to limit his production during such period.

The base-excess plan proposed herein provides that milk sold by a producer during March-July which is in excess of his base would be priced at the Class III price. The quantity of producer milk sold during the same months which does not exceed the producer's base would be priced at the base price. The base price for each marketwide pool order would be determined by subtracting the value of the excess milk delivered by producers under each order from the total value of all milk delivered by producers and dividing such amount by the pounds of base milk delivered by producers. The precise level of the base price would depend upon the classified use of milk in the market. The base price for producer milk received by individual handlers under the Memphis, Fort Smith, and Central Arkansas orders would be determined by subtracting the total value of all excess milk received at the plant of each handler from the handler's total obligation to producers and dividing such amount by the pounds of base milk. The base price for milk received by individual handlers would vary according to the classified use value of the handler's producer milk and the percentage of base milk received by the handler.

The base and excess prices adopted herein were proposed by proponent cooperative. A handler regulated under the Memphis order objected in his posthearing brief that the excess price should be a blend of the Class I, Class II, and Class III prices. Opponent noted that, if the excess price is the Class III price as proposed herein, the base price would exceed the Class I price. It was his position that such base price would be improper.

Under the base plan provisions adopted herein, the base price for the month would exceed the Class I price whenever the quantity of excess milk is greater than the amount of producer milk utilized for Class II and Class III uses. However, if the quantity of excess milk were less than the amount of producer milk utilized in Class II and Class III uses, the base price would be less than the Class I price but would exceed the weighted average price.

Those who opposed pricing excess milk at the Class III price level offered no basis for their conclusion that a base price below the Class I price level would be improper. Furthermore, pricing of excess milk at the Class III price will provide a greater incentive for a producer to even out his production than by pricing excess milk at the higher level suggested by opponents of the proposed pricing method. It is concluded, therefore, that excess milk should be priced at the Class III price level.

An opponent reiterated a contention made at the hearing and in his posthearing brief that the excess price should be a blend of the class I, Class II, and Class III prices according to the proportional use of the excess milk in such classes. He indicated that unless such a condition was met the change is made the base price could conceivably exceed the class I price. Opponent held that a base price higher than the class II price would be improper but failed to indicate a basis for such conclusion.

The arguments advanced in the exceptions provide no basis for revising the recommended decision in this regard.

Proponent requested that the location adjustment for producer milk apply only to the base milk delivered by a producer. The cooperative noted that the application of a location adjustment to the excess price would reduce such price (the Class III price) below the value of milk in manufacturing uses. Proponent contended that it would be inappropriate to pay producers less than the Class III price for milk.

Milk for manufacturing uses has practically the same value to milk processors wherever located. This is reflected under the order program through the use of a uniform surplus price in virtually all orders which is equal to the average price per hun-
dredweight for the month of manufacturing grade milk f.o.b. plants in Minnesota and Wisconsin. It a location adjustment were applied to the excess price, it would result in an excess price at various plant locations that is less than the value of manufacturing grade milk delivered to those same plant locations. Such pricing would not be consistent with the location value of milk for manufacturing uses. Consequently, the location adjustment for producer milk should apply only to the base milk delivered by a producer.

The Central Arkansas order presently provides for a 4-cent deduction in the computation of the excess price. The money accumulated from the 4-cent deduction is added to the producer-settlement fund reserve.

The producer-settlement fund is a necessary adjunct of the Central Arkansas order and all orders with marketwide pooling. It is maintained by the market administrator for the purpose of accumulating payments from pool handlers whose utilization of milk in Class I uses is in excess of the marketwide average. Disbursements from the fund are made to those pool handlers whose utilization of milk in Class I uses is less than the marketwide average. A portion of the funds accumulated (4 to 5 cents per hundredweight) is retained each month as a reserve. This reserve is maintained to provide funds for the market administrator to pay handlers in the event an audit adjustment, for example, results in money due a handler.

It is concluded that a reserve deduction of 4 to 5 cents should continue to apply to each hundredweight of base milk under the Central Arkansas order. The same deduction should apply to base milk under the other marketwide pool orders under consideration. There is no need, however, to apply a 4-cent deduction, as under the Central Arkansas order, to the excess price under such orders. In most instances excess milk will be classified as Class III milk. The 4-cent reduction could result in excess milk being priced to the producer, in effect, at less than the Class III price under the order. There is no justification on this record for pricing any milk at less than the Class III price.

Proponent proposed that the base transfer rules of the base-excess plan permit the transfer of all or any part of the base by a producer only in the event of death of the baseholder or upon termination of milk production and the complete dispersal of the herd. In the case of a jointly held base, it was proposed that, upon termination of the joint ownership, the base be apportioned among the joint holders. Limitations on base transfers are necessary, according to proponent, to prevent circumvention of the purpose of the base plan and to insure that the plan will provide producers with the incentive to increase their production of milk during the base-forming month. Proponent indicated that the proposed base transfer rules are not intended to prevent a producer who transfers his base upon the complete dispersal of his herd from immediately resuming production in the same or another area. Such producer would be free to reenter production and earn a base during the next base-forming period. Proponent noted that if the producer should reenter production during any period other than the base-forming period, then all milk that he markets would be priced as excess milk.

One handler and a cooperative association propose that handlers be permitted to transfer any portion of their base to other producers at any time.

Bases should be transferable in their entirety or in amounts of not less than 100 pounds. A transfer involves the remaining portion of such base. Such transfer, which could be made from one market to another, will facilitate the transfer of property when a baseholder dies or when the presuming production is the same or another area. Such producer would be permitted to reenter production and earn a base during the next base-forming period. In addition, the transfer of base will facilitate adjustments by those producers desiring to expand or contract their operations and will make it easier for new producers to enter the market during the base-paying period.

A 100-pound minimum on transfers of base is provided herein (unless the transfer involves the remaining portion of a producer's base) as a means of limiting the administrative work that could be connected with the frequent transfer of only a few pounds of base for a producer. The transfer of such minimum amounts would provide only minimal benefit for the producers involved and increase the cost of administering the program. The 100-pound minimum herein provided will aid in reducing the administrative expense involved in the transfer of bases without limiting to any insignificant extent the practical transferability of bases among producers.

As provided herein, a base may be transferred to be effective on the first day of the month following the date on which an application for such transfer is received by the market administrator. Such application would be required to be on a form approved by the market administrator and signed by a baseholder or his heirs and the person to whom the base is to be transferred. If a base is held jointly, it would be required that the application be signed by all joint holders or their heirs. These provisions will minimize the possibility of a misunderstanding between the parties involved concerning transfers.

The base established by a partnership may be divided between partners on any basis agreed on in writing or in writing, and transferred to them if written notification of the agreed upon division, signed by each partner, is received by the market administrator prior to the first day of the month in which the division is to be effective. This will facilitate the division of the assets of a partnership that is dissolved during the base-paying period. The division of the base will in no way affect the total quantity of base milk in the pool, irrespective of the manner in which the division of the base is made between the partners.

Bases assigned to producers who supplied a plant which was not a pool plant under one of the 11 markets in the base plan and which became a pool plant prior to or during the following base-paying period should not be transferable. Such restriction is necessary to deal with those instances in which a plant regularly associated with another market becomes regulated under one of the 11 orders for only a single or several months before shifting back to the originating market or to another market outside the 11-market area under consideration. This will facilitate the division in instances in which a plant becomes newly regulated and remains as a pool plant during all of the base-paying period, the producers delivering to that plant would want to retain their bases in order to receive a base price for such milk. If, however, the plant were to lose its pool plant status before the end of the base-paying period, producers delivering milk to such plant would lose the need for the bases and would offer such bases for sale. If it were not appropriate to permit the transfer of bases in such instance since Class I sales in the market would be reduced by the amount of the plant's Class I sales in the month the plant lost its pool plant status while the aggregate producer bases for the month would remain inflated by the bases that had been assigned to the producers associated with such plant. If producers were permitted to purchase such bases, they would benefit by receiving a greater share of the value associated with the Class I sales in these 11 markets at the expense of the handlers in these markets who did not choose to buy additional base.

AMPI excepted to the base rules adopted in the recommended decision. The cooperative argued that the unlimited transfer of base would frustrate the purpose and objective of the base plan by reducing the incentive for producers to increase production during the base-forming period and
would enable producers to circumvent the base plan and other order provisions. In particular, AMPI stated that "producers with wide seasonal production patterns who fail to increase production during the base-forming months will be able to cover market areas or pool plants with excess production by simply purchasing sufficient base from other producers."

It is possible that some producers will make little or no attempt to alter their seasonal AMPI order, a coop instead will purchase additional base to cover what otherwise would be "excess" production. It would be largely a matter of economics, of course, as to whether a producer is better off to build his own base or purchase the base from another. The more that producers choose not to build their bases but rely instead on purchased base, the more likely that the value of base will increase. This should dampen any substantial reliance on purchased base and, thus, give producers a greater incentive to build their own base rather than buy it.

AMPI also argues that the unlimited transfer of base will encourage producers to transfer their bases to other producers during March through July and market their milk to plants regulated under orders outside of the 11-market area where they would be able to receive the blend price for all their milk. Moreover, AMPI states, a cooperative could organize the transfer of base of its members to other members having excess milk. The cooperative could then market the milk of the members from whom base was transferred to plants regulated under orders outside of the 11-market area.

The purpose of the "dairy farmer for other markets" provision is to keep milk not regularly associated with the Texas market from being "dumped" there in the heavy production months when the milk is not needed elsewhere. The base transfer provisions adopted herein would not nullify this basic purpose. In most cases, dairy farmers who were not on the Texas market would continue to draw the milk of the producers during March through July, while at the same time increasing its members' total returns under the other orders where the cooperative represents less than 100 percent of the producers.

There is no doubt that AMPI could arrange for the transfer of base among its members on the 11 markets in the manner described so as to enhance its returns at the expense of other producers. However, if this were to occur, the purpose of the base plan in the affected markets would be seriously undermined. The continued use of the base plans in this case would need to be seriously questioned.

In his exceptions, a handler urged that an individual dairy farmer who shifts from outside the 11-market area to one of the 11 markets during any of the months of October through July be accorded a full base. This presumably would parallel the arrangement adopted herein whereby a producer who is associated with a plant that becomes newly pooled under one of the 11 orders during such month would be accorded a full base, as determined from prior marketings.

This situation is not comparable to one in which a dairy farmer becomes a new producer on one of the 11 markets as a result of a plant shifting from one market to another. In such instance, the plant that becomes newly regulated adds Class I sales to the market. It is appropriate that the producers supplying such plant should receive bases based upon their delivery of milk during the immediately prior base-making period.

This should not be the case with producers who may come onto the market on an individual basis. As provided herein, such a producer who enters one of the 11 markets during that period should be required to earn a base proportionate to the number of days that he delivers milk during the 3-month period. Instead of his total deliveries being divided by 90 days, a producer who enters the market during the period of January-July will not earn a base at all. In recognition of the fact that such producer would be entering the market during a period when additional milk is normally not needed to supply the fluid market.

It is necessary that the reporting sections of the orders be revised to require handlers under the 11 orders to submit reports to the market administrator of the amounts of producer milk and base milk received from each producer at each plant location. Cooperative associations in their role as producers, on the Texas market. The cooperative would then market the milk of the producers during March through July, while at the same time depressing the blend price levels under the other orders.

It is recognized that the potential for these situations exists. From a practical standpoint, however, it is questionable whether much milk would shift to markets outside the 11-market area during the March-July period. This is the time in most markets when handlers are seeking ways to dispose of milk that is surplus to their fluid needs rather than seeking additional supplies. Presumably, there would be little opportunity for cooperatives or individual producers in the 11-market area to find continuing outlets for milk in outside markets.

Another possible problem cited by AMPI is that the unlimited transfer of bases could nullify the "dairy farmer for other markets" provision of the Texas order. In short, the order provides that if a dairy farmer is not a "producer" under the order through-out the months of September through November he cannot qualify as a "producer" under the order during the following months of February through July. It is claimed by AMPI, however, that a producer who cannot qualify as a producer under the Texas order in this situation nevertheless could have a base under the Texas order in the fall months which he could sell to producers on the Texas market. The cooperative contends that the sale of base in this case would undermine the purpose of the "dairy farmer for other markets" provision.

The purpose of the "dairy farmer for other markets" provision is to keep milk not regularly associated with the Texas market from being "dumped" there in the heavy production months when the milk is not needed elsewhere. The base transfer provisions adopted herein would not nullify this basic purpose. In most cases, dairy farmers who were not on the Texas market during the entire September-November period still would not be able to have their milk pooled under the Texas order during the February-July period.

A final argument made by AMPI is that a cooperative, such as itself, whose members supplied 100 percent of the producer milk under one of the 11 base-excess plan orders could circumvent the provisions by arranging for the transfer of base from those producers to members with excess production on one or more of the other 10 orders. In that event, it was claimed, the cooperative representing 100 percent of the producer milk under the order would continue to draw the same total dollar value on member milk marketed under that order during March through July, while at the same time increasing its members' total returns under the other orders where the cooperative represents less than 100 percent of the producers.

There is no doubt that AMPI could arrange for the transfer of base among its members on the 11 markets in the manner described so as to enhance its returns at the expense of other producers. However, if this were to occur, the purpose of the base plan in the affected markets would be seriously undermined. The continued use of the base plans in this case would need to be seriously questioned.

In his exceptions, a handler urged that an individual dairy farmer who shifts from outside the 11-market area to one of the 11 markets during any of the months of October through July be accorded a full base. This presumably would parallel the arrangement adopted herein whereby a producer who is associated with a plant that becomes newly pooled under one of the 11 orders during such month would be accorded a full base, as determined from prior marketings.

This situation is not comparable to one in which a dairy farmer becomes a new producer on one of the 11 markets as a result of a plant shifting from one market to another. In such instance, the plant that becomes newly regulated adds Class I sales to the market. It is appropriate that the producers supplying such plant should receive bases based upon their delivery of milk during the immediately prior base-making period.

This should not be the case with producers who may come onto the market on an individual basis. As provided herein, such a producer who enters one of the 11 markets during the period of January-July will not earn a base at all. In recognition of the fact that such producer would be entering the market during a period when additional milk is normally not needed to supply the fluid market.

It is necessary that the reporting sections of the orders be revised to require handlers under the 11 orders to submit reports to the market administrator of the amounts of producer milk and base milk received from each producer at each plant location. Cooperative associations in their role as handlers should report the quantities of producer milk and base milk delivered to pool plant and non-pool plant under the respective order as well as the producer milk deliveries of each member under the other 10 orders. The reporting by cooperatives under each of the orders will facilitate the computation under the individual orders of the base milk of members delivering milk under more than one order.

Because of the time required to complete the remaining procedures in this proceeding, the proposed amended orders adopted herein, if approved by producers, could not be made effective until October 1, 1978. Therefore, it is necessary to provide a shorter base-making period for 1978 than would otherwise be the case. As provided herein, a base for each producer would be established by adding the pounds of producer milk delivered by him under the orders during October through December 1977 and dividing such amount by the number of days' production represented by such producer milk or by 60, whichever is greater. The base established for each producer during the October-December 1978 period would then be used in
determining the payments to producers during the base-paying months of March through July 1979.

RULINGS ON PROPOSED FINDINGS AND CONCLUSIONS

Briefs and proposed findings and conclusions were filed on behalf of certain interested parties. These briefs, proposed findings and conclusions and the evidence in the record were considered in making the findings and conclusions set forth above. To the extent that the suggested findings and conclusions filed by interested parties are inconsistent with the findings and conclusions set forth herein, the requests to make such findings or reach such conclusions are denied for the reasons previously stated in this decision.

GENERAL FINDINGS

The following findings and determinations are made for each of the orders in this decision. They supplement those that were made when the orders were first issued and when they were amended. The previous findings and determinations are hereby ratified and confirmed, except where they may conflict with those set forth below.

(a) The tentative marketing agreement and the order, as hereby proposed to be amended, and all of the terms and conditions thereof, will tend to effectuate the declared policy of the act; and
(b) The parity prices of milk as determined pursuant to section 2 of the act are not reasonable in view of the price of feeds, available supplies of feeds, and other economic conditions which affect market supply and demand for milk in the marketing area, and the minimum prices specified in the tentative marketing agreement and the order; as hereby proposed to be amended, are such prices as will reflect the aforesaid factors, insure a sufficient quantity of pure and wholesome milk, and be in the public interest; and
(c) The tentative marketing agreement and the order, as hereby proposed to be amended, will regulate the handling of milk in the same manner as, and will be applicable only to persons in the respective classes of industrial or commercial activity specified in, a marketing agreement upon which a hearing has been held.

RULINGS ON EXCEPTIONS

In arriving at the findings and conclusions, and the regulatory provisions of this decision, each of the exceptions received was carefully and fully considered in conjunction with the record evidence. To the extent that the findings and conclusions, and the regulatory provisions of this decision are at variance with any of the exceptions, such exceptions are hereby overruled for the reasons previously stated in this decision.

PROPOSED RULES

MARKETING AGREEMENT AND ORDER

Annexed hereto and made a part hereof are two documents, a Marketing Agreement regulating the handling of milk, and an Order amending the orders regulating the handling of milk in, the aforesaid marketing area. The hearing was held upon, certain proposed amendments to the tentative marketing agreement and order amending the handling of milk in the aforesaid marketing area. The hearing was held pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 900 et seq.), and the applicable rules of practice and procedure (7 CFR Part 900).

It is hereby ordered, That this entire decision, except the attached marketing agreement, be published in the FEDERAL REGISTER. The regulatory provisions of the marketing agreement are identical with those contained in the orders as hereby proposed to be amended by the attached order which is published with this decision.

REFERENDUM ORDER TO DETERMINE PRODUCER APPROVAL; DETERMINATION OF REPRESENTATIVE TO DESIGNATION OF REFERENDUM AGENTS

It is hereby directed that referenda be conducted and completed on or before the 30th day from the date this decision is issued, in accordance with the procedure for the conduct of referenda (7 CFR 900.300 et seq.), to determine whether the issuance of each of the attached orders as amended and as hereby proposed to be amended, regulating the handling of milk in each of the aforesaid marketing areas, is approved or favored by producers, as defined under the terms of each of the orders (as amended and as hereby proposed to be amended), who during the representative period were engaged in the production of milk for sale within the aforesaid marketing area. The representative period for the conduct of such referenda is hereby determined to be January 1, 1977 to June 30, 1977.

The agents of the Secretary to conduct such referenda are hereby designated to be Richard E. Arnold for Parts 1071, 1073, 1104, 1106, 1120, 1122, 1138, and 1139, and Charles S. McDonald for Parts 1079, 1102, and 1108.

An Impact Analysis relative to this decision is available from the Deputy Administrator for Marketing Program Operations, Agricultural Marketing Service.

Dated: July 23, 1978

P. R. "Bobby" Smith
Assistant Secretary for Marketing Services.

Order amending the orders, regulating the handling of milk in the Neosho Valley, Wichita, Kans.; Memphis, Tenn.; Fort Smith, Ark.; Red River Valley, Oklahoma Metropolitan, Central Arkansas, Lubbock-Plainview, Tex.; Rio Grande Valley, Texas Panhandle, and Texas marketing areas.

FINDINGS AND DETERMINATIONS

The findings and determinations hereinafter set forth are supplementary and in addition to the findings and determinations previously made in connection with the issuance of each of the aforesaid orders and of the previously issued amendments thereto; and all of said previous findings and determinations are hereby ratified and affirmed, except insofar as such findings and determinations may be in conflict with the findings and determinations set forth herein.

(a) Findings. A public hearing was held upon certain proposed amendments to the orders regulating the handling of milk in the aforesaid marketing areas. The hearing was held pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 900 et seq.), and the applicable rules of practice and procedure (7 CFR Part 900).

It is hereby ordered, That this entire decision, except the attached marketing agreement, be published in the FEDERAL REGISTER. The regulatory provisions of the marketing agreement are identical with those contained in the orders as hereby proposed to be amended by the attached order which is published with this decision.

ORDER

A public hearing was held upon certain proposed amendments to the orders regulating the handling of milk in the aforesaid marketing areas. The hearing was held pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 900 et seq.), and the applicable rules of practice and procedure (7 CFR Part 900).

It is hereby ordered, That this entire decision, except the attached marketing agreement, be published in the FEDERAL REGISTER. The regulatory provisions of the marketing agreement are identical with those contained in the orders as hereby proposed to be amended by the attached order which is published with this decision.
PART 1071—MILK IN THE NEOSHO VALLEY MARKETING AREA

1. In §1071.31, paragraph (a)(2) and (4) is revised as follows:

§1071.31 Payroll reports.

(a) * * *

(2) The total pounds of milk received from such producer and during the months of March through July the pounds of base milk:

(4) The price per hundredweight (during the months of March through July the price per hundredweight for base milk and for excess milk), the gross amount due, the amount and nature of any deductions, and the net amount paid.

2. In §1071.32, paragraph (b) is revised and a new paragraph (c) is added to read as follows:

§1071.32 Other reports.

(b) In addition to the reports required pursuant to paragraphs (a) and (c) of this section and §§1071.30 and 1071.31, each handler shall report such other information as the market administrator deems necessary to verify or establish such handler's obligation under the order.

(c) Each handler who receives milk from producers shall report to the market administrator on or before the 7th day after the end of each of the months of March through July the following information:

(1) The name and address or other appropriate identification of each producer;

(2) The total pounds of milk and the pounds of base milk of such producer delivered to each pool plant (and diverted to each plant that is not a pool plant) under any of the orders specified in §1071.92.

3. Section 1071.61 is revised as follows:

§1071.61 Computation of uniform price (including weighted average price and uniform prices for base and excess milk).

(a) The market administrator shall compute the weighted average price for each month and the uniform price for each of the months of August through February per hundredweight for milk of 3.5 percent butterfat content as follows:

(1) Combine into one total the values computed pursuant to §1071.60 for all handlers who filed the reports prescribed by §1071.30 for the month and who made the payments pursuant to §§1071.71 and 1071.75 for the preceding month;

(2) Add an amount equal to the total value of the location adjustments computed pursuant to §1071.75;

(3) Add an amount equal to not less than one-half of the unobligated balance in the producer-settlement fund;

(4) Subtract an amount computed by multiplying the total hundredweight of producer milk included pursuant to paragraph (a)(1) of this section by 5 cents;

(5) Divide the resulting amount by the sum of the following for all handlers included in these computations:

(i) The total hundredweight of producer milk; and

(ii) The total hundredweight for which a value is computed pursuant to §1071.60(c); and

(6) Subtract not less than 4 cents nor more than 5 cents per hundredweight.

(b) For each of the months of March through July, the market administrator shall compute the uniform prices per hundredweight for base milk and for excess milk, each of 3.5 percent butterfat content, as follows:

(1) Compute the uniform price for base milk by deducting 5 cents from the Class III price for the month.

(2) Compute the uniform price for base milk as follows:

(i) From the amount resulting from the computations pursuant to paragraphs (a)(1) through (4) of this section, subtract an amount computed by multiplying the hundredweight of milk specified in paragraph (a)(5)(ii) of this section by the weighted average price;

(ii) Subtract an amount computed by multiplying the uniform price for excess milk for the month times the hundredweight of excess milk;

(iii) Divide the resulting amount by the total hundredweight of base milk included in these computations; and

(iv) Subtract not less than 4 cents nor more than 5 cents per hundredweight.

4. Section 1071.62 is revised as follows:

§1071.62 Announcement of uniform prices and butterfat differential.

The market administrator shall announce publicly on or before:

(a) The 5th day after the end of each month the butterfat differential for such month; and

(b) The 12th day after the end of each month the applicable uniform prices for such month.

§1071.71 [Amended]

5. Section 1071.71(a)(2)(i) is amended by changing the word “price” to “prices.”

6. Section 1071.71(a)(2)(ii) is amended by changing the words “uniform price” to “weighted average price.”

7. In §1071.73, the introductory text of paragraph (b) is revised as follows:

§1071.73 Payments to producers and to cooperative associations.

(b) On or before the 17th day after the end of each delivery period, for all milk (or base milk and excess milk) received during such delivery period from such producer at not less than the applicable uniform price(s) for such delivery period subject to the following adjustments:

§1071.74 [Amended]

8. Section 1071.74 is amended by changing the words “uniform price” to “uniform prices.”

9. Section 1071.75 is revised as follows:

§1071.75 Plant location adjustments for producers and on nonpool milk.

(a) For producer milk received at a pool plant the uniform price and the uniform price for base milk shall be adjusted according to the location of the pool plant at the rates set forth in §1071.52.

(b) The weighted average price applicable to other source milk shall be adjusted at the rates set forth in §1071.52, except that the adjusted weighted average price plus 5 cents not be less than the Class III price.

§1071.76 [Amended]

10. Section 1071.76(a)(4) is amended by changing the words “uniform price” wherever they appear to “weighted average price.”

11. A new center head “Base-Excess Plan” and five new sections (§§1071.90 through 1071.94) are added immediately following §1071.86 as follows:

FEDERAL REGISTER, VOL. 43, NO. 146—FRIDAY, JULY 28, 1978
§ 1071.90 Base milk.

“Base milk” means the producer milk of a producer under all of the orders specified in § 1071.92 in each of the months of March through July that is in excess of the producer's base milk multiplied by the number of days in the month. If milk is received as producer milk (as defined under any order specified in § 1071.92) from the same producer during the month by a handler regulated under this order and by a handler fully regulated under any other order specified in § 1071.92, the amount of such producer's base milk received by the handler under this order at each plant location shall be determined by multiplying the producer's total base milk by the percentage of his total deliveries of producer milk under all of the orders specified in § 1071.93 that is delivered under this order at each respective plant location.

§ 1071.91 Excess milk.

“Excess milk” means the producer milk of a producer in each of the months of March through July that is in excess of the producer's base milk under this order for the month, and shall include all the producer milk of a producer for whom no base can be computed pursuant to § 1071.92.

§ 1071.92 Computation of base for each producer.

(a) The base of each producer shall be determined by the market administrator by dividing the total pounds of producer milk (as defined under the respective orders) received from the producer by all handlers fully regulated under the terms of the respective orders regulating the handling of milk in the Neosho Valley; Wichita, Kans.; Red River Valley; Oklahoma Metropolis; Memphis, Tenn.; Fort-Smith, Ark.; Central Arkansas; Texas; Lubbock-Plainview, Tex.; Texas Panhandle; and Rio Grande Valley marketing areas (Parts 1071, 1073, 1104, 1106, 1097, 1102, 1106, 1126, 1120, 1132, and 1138, respectively, of this chapter) during the immediately preceding period of September through December by the number of days’ production represented by such producer milk or by 90, whichever is greater: Provided, That any base that is based on milk deliveries during 1978 shall be determined by dividing the total pounds of producer milk received from the producer, in the manner previously described in this paragraph, during the period of October through December by the number of days’ production represented by such producer milk or by 60, whichever is greater.

(b) The base for a producer whose milk is delivered to a plant that did not become a pool plant under any of the orders specified in paragraph (a) of this section until after the beginning of the base-forming period shall be calculated as if the plant were a pool plant under such orders for the entire base-forming period. A base thus assigned shall not be transferable.

§ 1071.93 Base rules.

(a) A base may be transferred in its entirety, or in amounts of not less than 100 pounds (unless the transfer involves the remaining portion of such base), effective on the first day of the month following the date on which an application for such transfer is received by the market administrator. Such application shall be on a form approved by the market administrator and signed by the baseholder or his heirs and the person to whom the base is to be transferred. If a base is held jointly, the application shall be signed by all joint holders or their heirs.

(b) If a base is held jointly and such joint holding is terminated, the base may be apportioned among the joint holders on any basis agreed to in writing by them. Written notification of the agreed upon division of base signed by each of the joint holders must be received by the market administrator prior to the first day of the month on which such division is to be effective.

§ 1071.94 Announcement of established bases.

On or before February 10 of each year the market administrator shall notify each producer, the handler receiving milk from him and, if requested, a cooperative association in behalf of each of its producer members of the base established by such producer.

1071.121 [Amended]

12. Section 1071.121(b) is amended by changing all references to “§ 1071.61(b)” to read “§ 1071.61(a)(4).”

PART 1073—MILK IN THE WICHITA, KANS., MARKETING AREA

1. In § 1073.31, paragraph (a) (2) and (4) is revised as follows:

§ 1073.31 Payroll reports.

(a) • • •

(2) The total pounds of milk received from such producer during the months of March through July the pounds of base milk;

• • •

(4) The price per hundredweight (during the months of March through July the price per hundredweight for base milk and for excess milk), the gross amount due, the amount and nature of any deductions, and the net amount paid.

2. Section 1073.32 is revised as follows:

§ 1073.32 Other reports.

(a) Each handler who receives milk from producers shall report to the market administrator on or before the 8th day after the end of each of the months of March through July the following information:

(1) The name and address or other appropriate identification of each producer; and

(2) The total pounds of milk and the pounds of base milk of such producer delivered to each pool plant (and diverted to each plant that is not a pool plant) under any of the orders specified in § 1073.92.

(b) In addition to the reports required pursuant to paragraph (a) of this section and §§ 1073.30 and 1073.31, each handler shall report such other information as the market administrator deems necessary to verify or establish such handler’s obligation under the order.

3. Section 1073.61 is revised as follows:

§ 1073.61 Computation of uniform price (including weighted average price and uniform prices for base and excess milk).

(a) The market administrator shall compute the weighted average price for each month and the uniform price for each of the months of August through February per hundredweight of milk of 3.5 percent butterfat content as follows:

(1) Combine into one total the values computed pursuant to § 1073.60 for all handlers who filed the reports prescribed by § 1073.30 for the month and who made the payments pursuant to § 1073.71 for the preceding month;

(2) Deduct the amount of the plus adjustments and add the amount of the minus adjustments, which are applicable pursuant to § 1073.76;

(3) Add an amount equal to not less than one-half of the unobligated balance in the producer-settlement fund;

(4) Subtract an amount computed by multiplying the total hundredweight of producer milk included pursuant to § 1073.31 paragraph (a)(1) of this section by 5 cents;

(5) Divide the resulting amount by the sum of the following for all handlers included in these computations:

(a) The total hundredweight of producer milk; and

(b) The total hundredweight for which a value is computed pursuant to § 1073.60(1); and
(6) Subtract not less than 4 cents nor more than 5 cents.

(7) For each of the months of March through July, the market administrator shall compute the uniform prices per hundredweight for base milk and for excess milk, each of 3.5 percent butterfat content, as follows:

(i) Compute the uniform price for excess milk by deducting 5 cents from the price of the Class III price for the month.

(ii) Compute the uniform price for base milk as follows:

(a) From the amount resulting from the computations pursuant to paragraph (a)(1) through (4) of this section, subtract an amount computed by multiplying the hundredweight of milk specified in paragraph (a)(5)(ii) of this section by the weighted average price.

(b) Subtract an amount computed by multiplying the uniform price for excess milk for the month times the number of days from the 12th day after the end of the month the butterfat differential included in these computations; and

(c) Subtract not less than 4 cents nor more than 5 cents.

4. Section 1073.92 is revised as follows:

§ 1073.92 Payment to producers and to cooperative associations.

(a) On or before the second working day following the 12th day after the end of the month during which the milk was received, each producer for whom payment is not made pursuant to paragraph (c) of this section, at not less than the uniform price(s) computed for such producer’s deliveries of milk (or base milk and excess milk) adjusted by the butterfat differential and location adjustments computed pursuant to §§ 1073.74 and 1073.75, and less the amount of the payment made pursuant to paragraph (b) of this section. If by such date such handler has not received full payment pursuant to § 1073.72, he may reduce his total payments uniformly to all producers by not more than the amount of the reduction in payment by the market administrator. He shall, however, complete such payments pursuant to this paragraph not later than the date for making such payments next following receipt of the balance from the market administrator.

(d) * * * *

(2) In making final settlement, the value of such milk at the appropriate uniform prices adjusted pursuant to §§ 1073.74 and 1073.75, less payment made pursuant to paragraph (d)(1) of this section.

§ 1073.74 [Amended]

8. Section 1073.74 is amended by changing the words “uniform price” to “uniform prices.”

9. Section 1073.75 is revised as follows:

§ 1073.75 Plant location adjustments for producers and on nonpool milk.

(a) For producer milk received at plants located outside Zone 1 the uniform price and the uniform price for base milk shall be increased or decreased by an adjustment for each such plant at the rates specified in § 1073.52(a).

(b) For purposes of computations pursuant to §§ 1073.71(a)(2)(ii) and 1073.72, the weighted average price shall be adjusted at the rates set forth in § 1073.52, applicable at the location of the nonpool plant(s) from which the milk was received, except that the adjusted weighted average price plus 5 cents shall not be less than the Class III price.

§ 1073.76 [Amended]

10. Section 1073.76(a)(4) is amended by changing the words “uniform price” wherever they appear to “weighted average price.”

11. A new center head “Base-Excess Plan” and five new sections (§§ 1073.90 through 1073.94) are added immediately following § 1073.86 as follows:

Base-Excess Plan

§ 1073.90 Base milk.

“Base milk” means the producer milk of a producer under all of the orders specified in § 1073.92 in each of the months of March through July that is not in excess of the producer’s base milk multiplied by the number of days in the month. If milk is received as producer milk (as defined under any other order specified in § 1073.92) from the same producer during the month by a handler regulated under this order and by a handler fully regulated under any other order specified in § 1073.92, that milk shall be included in the base milk received by the handler under this order at each plant location shall be determined by multiplying the producer’s total base milk by the percentage of his total deliveries of producer milk (as defined under any other order specified in § 1073.92) that is delivered under this order at each respective plant location.

§ 1073.91 Excess milk.

“Excess milk” means the producer milk of a producer in each of the months of March through July that is in excess of the producer’s base milk under this order for the month, and shall include all the producer milk of a producer for whom no base can be computed pursuant to § 1073.92.

§ 1073.92 Computation of base for each producer.

(a) The base of each producer shall be determined by the market administrator by dividing the total pounds of producer milk (as defined under the respective orders) received from the producer by all handlers fully regulated under the terms of the respective orders regulating the handling of milk in the producer’s base milk by any other order specified in this paragraph. That any base that is based on any other order specified in this paragraph shall not be less than the Class III price.

(b) The base for a producer whose milk is delivered to a plant that did not become a pool plant under any of the orders specified in paragraph (a) of this section until after the beginning of the base-forming period shall be calculated as if the plant were a pool plant under such orders for the entire base-forming period. A base thus assigned shall not be transferable.

§ 1073.93 Base rules.

(a) A base may be transferred in its entirety, or in amounts of not less than 100 pounds (unless the transfer involves the remaining portion of such
§1073.94 Announcement of established bases.

On or before February 10 of each year the market administrator shall notify each producer, the handler receiving milk from him and, if requested, a cooperative association in behalf of each of its producer members of the base established by such producer.

§1073.121 [Amended]

12. Section 1073.121(b) is amended by changing all references to "§1073.61(d)" to read "§1073.61(a)(4)."

PART 1079—MILK IN THE MEMPHIS, TENN., MARKETING AREA

1. In §1097.31, paragraph (a)(3) is revised as follows:

§1097.31 Payroll reports.

(a) (3) The total pounds of milk received from such producer and for the months of March through July the total pounds of milk and the pounds of base milk of such producer delivered to each fluid milk (pool) plant (and diverted to each plant that is not a fluid milk (pool) plant) under any of the orders specified in §1097.32;

2. Section 1097.61, paragraph (b) is revised as follows:

§1097.61 Computation of uniform price for each handler (including uniform prices for base milk and excess milk).

(b) For each month of March through July, the market administrator shall compute for each handler with respect to producer milk, a uniform price for base milk and for excess milk, each of 3.5 percent butterfat content, as follows:

1. Compute the uniform price for excess milk by deducting 5 cents from the Class III price for the month.

2. Compute the uniform price for base milk as follows:

(i) From the amount resulting from the computations pursuant to paragraph (a)(1) through (4) of this section subtract, for each handler, an amount computed by multiplying the uniform price for excess milk for the month times the hundredweight of excess milk received by such handler as producer milk and bulk milk received from a handler described in §1097.9(c); and

(ii) Divide the resulting amount by the total hundredweight of such handler's base milk and deduct any fraction of a cent.

3. Section §1097.75 is revised as follows:

§1097.75 Plant location adjustments for producers.

In making payment pursuant to §1097.73, for milk received the uniform price and the uniform price for base milk shall be adjusted according to the location of the fluid milk plant where such milk was received at the rate provided pursuant to §1097.52.

4. Section 1097.90 is revised as follows:

§1097.90 Base milk.

"Base milk" means the producer milk of a producer under all of the orders specified in §1097.92 in each of the months of March through July that is in excess of the producer's base multiplied by the number of days in the month. If milk is received as producer milk (as defined under any order specified in §1097.92) from the same producer during the month by a handler regulated under this order and by a handler fully regulated under any other order specified in §1097.92, the amount of such producer's base milk received by the handler under this order at each plant location shall be determined by multiplying the producer's total base milk by the percentage of his total deliveries of producer milk under all of the orders specified in §1097.92 that is delivered under this order at each respective plant location.

5. Section 1097.91 is revised as follows:

§1097.91 Excess milk.

"Excess milk" means the producer milk of a producer in each of the months of March through July that is in excess of the producer's base milk under this order for the month, and shall include all the producer milk of a producer for whom no base can be computed pursuant to §1097.92.

6. Section 1097.92 is revised as follows:

§1097.92 Computation of base for each producer.

(a) The base of each producer shall be determined by the market administrator by dividing the total pounds of producer milk (as defined under the respective orders) received from the producer by all handlers fully regulated under the terms of the respective orders regulating the handling of milk in the Neosho Valley; Wichita, Kans.; Red River Valley; Oklahoma Metropolitan; Memphis, Tenn.; Fort Smith, Ark.; Central Arkansas; Texas Lubbock-Friona, Tex.; Texas Panhandle; and Rio Grande Valley marketing areas (Parts 1071, 1073, 1104, 1105, 1097, 1102, 1108, 1120, 1132, and 1138, respectively, of this chapter) during the immediately preceding period of September through December by the number of days' production represented by such producer milk or by 90, whichever is greater. Provided, That any base that is based on milk deliveries during 1978 shall be determined by dividing the total pounds of producer milk received from the producer, in the manner previously described in this paragraph, during the period of October through December by the number of days' production represented by such producer milk or by 90, whichever is greater.

(b) The base for a producer whose milk is delivered to a plant that did not become a pool plant under any of the orders specified in paragraph (a) of this section until after the beginning of the base-forming period shall be calculated as if the plant were a pool plant under such orders for the entire base-forming period. A base thus assigned shall not be transferable.

7. Section 1097.93 is revised as follows:

§1097.93 Base rules.

(a) A base may be transferred in its entirety, or in amounts of not less than 100 pounds (unless the transfer involves the remaining portion of such base), effective on the first day of the month following the date on which an application for such transfer is received by the market administrator. Such application shall be on a form approved by the market administrator and signed by the baseholder or his heirs and the person to whom the base is to be transferred. If a base is held jointly, the application shall be signed by all joint holders or their heirs.

(b) If a base is held jointly and such joint holding is terminated, the base may be apportioned among the joint holders on any basis agreed to in writing by them. Written notification of the agreed upon division of base
signed by each of the joint holders must be received by the market administrator prior to the first day of the month on which such division is to be effective.

8. Section 1097.94 is revised as follows:

§ 1097.94 Announcement of established bases.

On or before February 10 of each year the market administrator shall notify each producer, the handler receiving milk from him and, if requested, a cooperative association in behalf of each of its producer members of the base established by such producer.

§ 1097.95 (Revoked)

9. Section 1097.95 is revoked.

PART 1102—MILK IN THE FORT SMITH, ARK., MARKETING AREA

1. In § 1102.31, paragraphs (b) and (d) are revised as follows:

§ 1102.32 Payroll reports.

.. . . . . .

(b) The total pounds of milk received from such producer and during the months of March through July the pounds of base milk:

.. . . . . .

(d) The price per hundredweight (during the months of March through July the price per hundredweight for base milk and for excess milk), the gross amount due, the amount and nature of any deductions, and the net amount paid.

2. In § 1102.32, paragraph (a)(2) is revised as follows:

§ 1102.32 Other reports.

(a) .. . . . .

(2) The total pounds of milk and butterfat and the pounds of base milk of such producer delivered to each approved (pool) plant (and diverted to each plant that is not an approved (pool) plant) under any of the orders specified in § 1102.92.

.. . . . . .

3. In § 1102.61, paragraph (b) is revised as follows:

§ 1102.61 Computation of uniform price for each handler (including uniform prices for base milk and excess milk).

.. . . . . .

(b) For each month of March through July, the market administrator shall compute for each handler with respect to milk received from producers, a uniform price for base milk and for excess milk, each of 3.5 percent butterfat content, as follows:

(1) Compute the uniform price for excess milk by deducting 5 cents from the Class III order (for the month) for each hundredweight delivered.

(2) Compute the uniform price for base milk as follows:

(i) From the amount resulting from the computations pursuant to paragraphs (a) (1) through (3) of this section, subtract, for each and every handler, an amount computed by multiplying the uniform price for excess milk for the month times the hundredweight of such handler's excess milk; and

(ii) Divide the resulting amount by the total hundredweight of such handler's base milk, and deduct any fraction of a cent.

4. Section 1102.75 is revised as follows:

§ 1102.75 Plant location adjustments for producers.

For producer milk received at an approved plant the uniform price and the uniform price for base milk shall be reduced according to the location of the approved plant at the rates set forth in § 1102.52.

5. Section 1102.90 is revised as follows:

§ 1102.90 Base milk.

"Base milk" means the producer milk of a producer under all of the orders specified in § 1102.92 in each of the months of March through July that is not in excess of the producer's base multiplied by the number of days in the month. If milk is received as producer milk as defined under any order specified in § 1102.92 from the same producer during the month by a handler regulated under this order and by a handler fully regulated under any other order specified in § 1102.92, the amount of such producer's base milk received by the handler under this order at each plant location shall be determined by multiplying the producer's total base milk by the percentage of his total deliveries of producer milk under all of the orders specified in § 1102.92 that is delivered under this order at each respective plant location.

6. Section 1102.91 is revised as follows:

§ 1102.91 Excess milk.

"Excess milk" means the producer milk of a producer in each of the months of March through July that is in excess of the producer's base milk under this order for the month, and shall include all the producer milk of a producer for whom no base can be computed pursuant to § 1102.92.

7. Section 1102.92 is revised as follows:

§ 1102.92 Computation of base for each producer.

(a) The base of each producer shall be determined by the market administrator by dividing the total pounds of producer milk (as defined under the respective orders) received from the producer by all handlers fully regulated under the terms of the respective orders regulating the handling of milk in the respective marketing areas (see § 1102.92) by 60, whichever is greater.

(b) The base for a producer whose milk is delivered to a plant that did not become a pool plant under any of the orders specified in paragraph (a) of this section until after the beginning of the base-forming period shall be calculated as if the plant were a pool plant under such orders for the entire base-forming period. A base thus assigned shall not be transferable.

8. Section 1102.93 is revised as follows:

§ 1102.93 Base rules.

(a) A base may be transferred in its entirety, or in amounts of not less than 100 pounds (unless the transfer involves the remaining portion of such base), effective on the first day of the month following the date on which an application for such transfer is received by the market administrator. Such application shall be on a form approved by the market administrator and signed by the baseholder or his heirs and the person to whom the base is to be transferred. If a base is held jointly, the application shall be signed by all joint holders or their heirs.

(b) If a base is held jointly and such joint holding is terminated, the base may be apportioned among the joint holders on any basis agreed to in writing by them. Written notification of the agreed upon division of base signed by each of the joint holders must be received by the market ad-
ammonator prior to the first day of
the month on which such division is to
be effective.

9. Section 1102.94 is revised as follows:

§ 1102.94 Announcement of established
bases.
On or before February 10 of each year the market administrator shall
notify each producer, the handler re-
cieving milk from him and, if request-
ed a cooperative association in behalf
of each of its producer members of the
base established by such producer.

§ 1102.95 [Revoked]
10. Section 1102.95 is revoked.

PART 1104—MILK IN THE RED RIVER
VALLEY MARKETING AREA

1. In §1104.31, paragraph (a) (2) and
(4) is revised as follows:

§ 1104.31 Payroll reports.
   (a) • • • •
   (2) The total pounds of milk received
from such producer and during the
months of March through July the
pounds of base milk;

   • • • • •
   (4) The price per hundredweight
(during the months of March through
July the price per hundredweight for
base milk and for excess milk), the
gross amount due, the amount and
nature of any deductions, and the net
amount paid.

   • • • •
2. In §1104.32 paragraph (b) is re-
vised and a new paragraph (c) is added
to read as follows:

§ 1104.32 Other reports.
   • • • • •
   (b) In addition to the reports re-
quired pursuant to §§1104.30 and
1104.31 and paragraphs (a) and (c) of
this section, each handler shall report
such other information as the market
administrator deems necessary to
verify or establish such handler's obli-
gation under the order.
   (c) Each handler who receives milk
from producers shall report to the
market administrator on or before the
7th day after the end of each of the
months of March through July the
following information:
   (1) The name and address or other
appropriate identification of each pro-
ducer; and
   (2) The total pounds of milk and the
pounds of base milk of each producer
delivered to each pool plant (and di-
verted to each plant that is not a pool
plant) under any of the orders speci-
fied in §1104.82.

3. Section 1104.61 is revised as follows:

§ 1104.61 Computation of uniform price
(including weighted average price and
uniform prices for base and excess
milk).
   (a) The market administrator shall
compute the weighted average price
for each month and the uniform price
for each of the months of August
through February per hundredweight
of milk of 3.5 percent butterfat con-
tent as follows:
   (1) Combine into one total the
values computed pursuant to §1104.60
for all handlers who filed the reports
prescribed by §1104.30 for the month
and who made the payments pursuant
to §§1104.71 and 1104.75 for the pre-
ceeding month;
   (2) Add an amount equal to the
total value of the location adjustments
computed pursuant to §1104.75;
   (3) Add an amount equal to not less
than one-half of the unobligated bal-
bance in the producer-settlement fund;
   (4) Subtract an amount computed by
multiplying the total hundredweight
of producer milk included pursuant to
paragraph (a)(1) of this section by 5
cents;
   (5) Divide the resulting amount by
the sum of the following for all han-
dlers included in these computations:
   (i) The total hundredweight of pro-
ducer milk; and
   (ii) The total hundredweight for
which a value is computed pursuant to
§1104.60(f); and
   (6) Subtract not less than 4 cents
nor more than 5 cents.

4. Section 1104.62 is revised as follows:

§ 1104.62 Announcement of uniform
prices and butterfat differential.
   The market administrator shall an-
nounce publicly on or before:
   (a) The 5th day after the end of
each month the butterfat differential
for such month; and
   (b) The 12th day after the end of
each month the applicable uniform
prices for such month.

§ 1104.71 [Amended]
5. Section 1104.71(a)(2)(i) is amended
by changing the word “price” to
“prices.”

§ 1104.73 Payments to producers and to
cooperative associations.
   (a) • • • •
   (2) On or before the 15th day of the
following month, an amount equal to
not less than the applicable uniform
price(s), as adjusted pursuant to
§§1104.74 and 1104.75, multiplied by
the hundredweight of milk (or base
milk and excess milk) received from
such producer during the month, sub-
ject to the following adjustments:

   • • • • •
   (b) • • • •
       (1) • • • •
           (i) Submit to the cooperative asso-
ciation on or before the 10th day of
each month written information
which shows for each member-produc-
er (a) the total pounds of milk re-
divered during the preceding month,
and for the months of March
through July the pounds of base
milk), (b) the total pounds of butterfat
 contained in such milk, (c) the num-
ber of days of production included in
such receipts, and (d) the amounts with-
held by the handler in payment for
supplies sold; and

   • • • •
       (2) In making final settlement, the
value of such milk at the appropriate
price(s), as adjusted pursuant to
§§1104.74 and 1104.75, less the
amount of partial payment made for
such milk.

§ 1104.74 [Amended]
8. Section 1104.74 is amended by
changing the words “uniform price” to
“uniform prices.”
9. Section 1104.75 is revised as follows:

§ 1104.75  Plant location adjustments for producers and on nonpool milk.

(a) In making payments to producers pursuant to §1104.73 for producer milk received at a location, the uniform price and the uniform price for base milk shall be reduced according to the location of the pool plant at the rate set forth in §1104.52(a); and

(b) For the purpose of computations pursuant to §§1104.71 and 1104.72, the weighted average price plus 5 cents shall be adjusted at the rate set forth in §1104.52(a) applicable at the location of the nonpool plant from which the milk was received (but not to be less than the Class III price); and

(c) In making payments to producers pursuant to §1104.73 for producer milk diverted from a pool plant to a nonpool plant, the uniform price and the uniform price for base milk shall be reduced according to the location of the nonpool plant at which the milk is received at the rate set forth in §1104.52(a).

§ 1104.76  [Amended]

10. Section 1104.76(a)(4) is amended by changing the words "uniform price" wherever they appear to "weighted average price."*1

11. A new center head "Base-Excess Plan" and five new sections (§§ 1104.90 through §1104.94) are added immediately following §1104.86 as follows:

BASE-EXCESS PLAN

§ 1104.90  Base milk.

"Base milk" means the producer milk of a producer under all of the orders specified in §1104.92 in each of the months of March through July that is not in excess of the producer's base multiplied by the number of days in the month. If milk is received as producer milk (as defined under any order specified in §1104.92) from the same producer during the month by a handler fully regulated under any other order specified in §1104.92, the amount of such producer's base milk received by the handler under this order at each plant location shall be determined by multiplying the producer's total base milk by the percentage of his total deliveries of producer milk under all of the orders specified in §1104.92 that is delivered under this order at each respective plant location.

§ 1104.91  Excess milk.

"Excess milk" means the producer milk of a producer in each of the months of March through July that is in excess of the producer's base milk under this order for the month, and shall include all the producer milk of a producer for whom no base can be computed pursuant to §1104.82.

§ 1104.92  Computation of base for each producer.

(a) The base of each producer shall be determined by the market administrator using the pounds of producer milk (as defined under the respective orders) received from the producer by all handlers fully regulated under the terms of the respective orders regulating the handling of milk in the Neosho Valley; Wichita, Kansas; Red River Valley; Oklahoma Metropolitan; Memphis, Tenn.; Fort Smith, Ark.; Central Arkansas; Texas; Lubbock-Plainview, Tex.; Texas Panhandle; and Rio Grande Valley marketing areas (Parts 1071, 1073, 1074, 1102, 1104, 1105, 1106, 1120, 1126, 1132, and 1138, respectively, of this chapter) during the immediately preceding period of September through December by the number of days' production represented by such producer milk or, by 90, whichever is greater: Provided, That any base that is based on milk deliveries during 1978 shall be determined by dividing the total pounds of producer milk delivered during the period of October through December by the number of days' production represented by such producer milk or, by 90, whichever is greater: Provided, That any base that is based on milk deliveries during 1978 shall be determined by dividing the total pounds of producer milk delivered during the period of October through December by the number of days' production represented by such producer milk or, by 90, whichever is greater:

(b) The base for a producer whose milk is delivered to a plant that did not become a pool plant under any of the orders specified in paragraph (a) of this section until after the beginning of the baseforming period shall be calculated as if the plant were a pool plant under such orders for the entire baseforming period. A base thus assigned shall not be transferable.

§ 1104.93  Base rules.

(a) A base may be transferred in its entirety, or in amounts of not less than 100 pounds (unless the transfer involves the remaining portion of such base), effective on the first day of the month following the date on which an application for such transfer is received by the market administrator. Such application shall be on a form approved by the market administrator and signed by the baseholder or his heirs and the person to whom the base is to be transferred. If a base is held jointly, the application shall be signed by all joint holders or their heirs.

(b) If a base is held jointly and such joint holding is terminated, the base may be apportioned among the joint holders on any basis agreed to in writing by them. Written notification of the agreed upon division of base signed by each of the joint holders in base received by the market administrator prior to the first day of the month on which such division is to be effective.

§ 1104.94  Announcement of established bases.

On or before February 10 of each year the market administrator shall notify each producer, the handler receiving milk from him, and, if requested, a cooperative association in behalf of each of its producer members of the base established by such producer.

§ 1104.121  [Amended]

12. Section 1104.121(b) is amended by changing all references to §1104.61(d) to read "§1104.61(a)(4)."

PART 1106—MILK IN THE OKLAHOMA METROPOLITAN MARKETING AREA

1. In §1106.31, paragraph (a)(2) and (4) is revised as follows:

§ 1106.31  Payroll reports.

(4) The price per hundredweight (during the months of March through July the price per hundredweight for base milk and for excess milk), the gross amount due, the amount and nature of any deductions, and the net amount paid.

2. In §1106.32, paragraph (b) is revised and a new paragraph (c) is added to read as follows:

§ 1106.32  Other reports.

(b) In addition to the reports required pursuant to §§1106.30 and 1106.31 and paragraphs (a) and (c) of this section, each handler shall report such other information as the market administrator deems necessary to verify or establish such handler's obligation under the order.

(c) Each handler who receives milk from producers shall report to the market administrator on or before the 7th day after the end of each of the months of March through July the following information:

(1) The name and address or other appropriate identification of each producer;

(2) The total pounds of milk and the pounds of base milk of such producer delivered to each pool plant (and diverted to each plant that is not a pool plant) under any of the orders specified in §1106.92.
3. Section 1106.61 is revised as follows:

§ 1106.61 Computation of uniform price (including weighted average price and uniform prices for base and excess milk).

(a) The market administrator shall compute the weighted average price for each month and the uniform price for each of the months of August through February per hundredweight for milk of 3.5 percent butterfat content as follows:
(1) Combine into one total the values computed pursuant to §1106.50 for all handlers who made the reports prescribed in §1106.30 and who made the payments pursuant to §§1106.71 and 1106.73 for the preceding month.
(2) Add the aggregate of the values of all allowable location adjustments to producers pursuant to §1106.75.
(3) Add not less than one-half of the cash balance on hand in the producer-settlement fund less the total amount of the contingent obligations to handlers pursuant to §1106.72.
(4) Subtract an amount computed by multiplying the total hundredweight of producer milk included pursuant to paragraph (a)(1) of this section by 5 cents.
(5) Divide the resulting amount by the sum of the following for all handlers included in these computations:
   (i) The total hundredweight of producer milk; and
   (ii) The total hundredweight for which a value is computed pursuant to §1106.50.
(6) Subtract not less than 4 cents nor more than 5 cents.
(b) For each of the months of March through July, the market administrator shall compute the uniform prices per hundredweight for base milk and for excess milk, each of 3.5 percent butterfat content, as follows:
(1) Compute the uniform price for excess milk by deducting 5 cents from the Class III price for the month.
(2) Compute the uniform price for base milk as follows:
   (i) From the amount resulting from the computations pursuant to paragraphs (a) (1) through (4) of this section, subtract an amount computed by multiplying the hundredweight of milk specified in paragraph (a)(5) of this section by the weighted average price;
   (ii) Subtract an amount computed by multiplying the uniform price for excess milk for the month times the hundredweight of excess milk;
   (iii) Divide the resulting amount by the total hundredweight of base milk included in these computations; and
   (iv) Subtract not less than 4 cents nor more than 5 cents.

4. Section 1106.62 is revised as follows:

§ 1106.62 Announcement of uniform prices and butterfat differential.
The market administrator shall announce publicly on or before:
(a) The 5th day after the end of each month the butterfat differential for such month; and
(b) The 12th day after the end of each month the applicable uniform prices for such month.

§ 1106.71 [Amended]
5. Section 1106.71(a)(2)(i) is amended by changing the word “price” to “prices.”
6. Section 1106.71(a)(2)(ii) is amended by changing the words “uniform price” to “weighted average price.”
7. In §1106.73, paragraphs (a) and (d)(1)(i)(A) are revised as follows:

§ 1106.73 Payments to producers and to cooperative associations.

(a) On or before the 15th day after the end of the month during which the milk (or base milk and excess milk) was received, to each producer to whom payment is not made pursuant to paragraph (d) of this section, at not less than the applicable uniform price(s) for such month, as adjusted pursuant to §§1106.74 and 1106.75, and less the amount of the payment made pursuant to paragraphs (b) of this section; provided, that if by such date such handler has not received full payment pursuant to §1106.72, he may reduce his total payments to all producers uniformly by not more than the amount of reduction in payment from the market administrator; he shall, however, complete such payments pursuant to this paragraph not later than the date for making such payments next following receipt of the balance from the market administrator:

§ 1106.74 [Amended]
8. Section 1106.74 is amended by changing the words “uniform price” to “uniform prices.”
9. Section 1106.75 is revised as follows:

§ 1106.75 Plant location adjustments for producers and on nonpool milk.
(a) In making payments to producers pursuant to §1106.73 for producer milk received at a pool plant, the uniform price and the uniform price for base milk shall be reduced according to the location of the pool plant at the rates set forth in §1106.82.
(b) For the purpose of computations pursuant to §§1106.71 and 1106.72, the weighted average price plus 5 cents shall be adjusted at the rates set forth in §1106.82 applicable at the location of the nonpool plant from which the milk was received (but not to be less than the Class III price); and
(c) In making payments to producers pursuant to §1106.73 for producer milk diverted from a pool plant to a nonpool plant, the uniform price and the uniform price for base milk shall be reduced according to the location of the nonpool plant at which the milk is received at the rates set forth in §1106.52.

§ 1106.76 [Amended]
10. Section 1106.76(a)(4) is amended by changing the words “uniform price” wherever they appear to “weighted average price.”

11. A new center head “Base-Excess Plan” and five new sections (§§1106.90 through 1106.94) are added immediately following §1106.86 as follows:

BASE-EXCESS PLAN

§ 1106.90 Base milk.
“Base milk” means the producer milk of a producer under all of the orders specified in §1106.92 in each of the months of March through July that is not in excess of the producer’s base multiplied by the number of days in the month. If milk is received as producer milk (as defined under any order specified in §1106.92) from the same producer during the month by a handler regulated under this order and by a handler fully regulated under any other order specified in §1106.92, the amount of such producer’s base milk received by the handler under this order at each plant location shall be determined by multiplying the producer’s total base milk by the percentage of his total deliveries of producer milk under all of the orders specified in §1106.92 that is delivered under this order at each respective plant location.

§ 1106.91 Excess milk.
“Excess milk” means the producer milk of a producer in each of the months of March through July that is in excess of the producer’s base milk under this order for the month, and shall include all the producer milk of a producer for whom no base can be computed pursuant to §1106.92.

§ 1106.92 Computation of base for each producer.
(a) The base of each producer shall be determined by the market adminis-
Announcement of established bases.

On or before February 10, of each year the market administrator shall notify each producer, the handler receiving milk from him and, if requested, a cooperative association in behalf of each of its producer members of the base established by such producer.

PART 1108—MILK IN THE CENTRAL ARKANSAS MARKETING AREA

1. In § 1108.31, paragraph (a)(2) and (4) is revised as follows:

§ 1108.31 Payroll reports.

(a) * * *

(2) The total pounds of milk received from such producer and during the months of March through July the pounds of base milk; * * *

(4) The price per hundredweight (during the months of March through July the price per hundredweight for base milk and for excess milk), the gross amount due, the amount and nature of any deductions, and the net volume paid.

2. Section 1108.32(a)(1) is revised as follows:

§ 1108.32 Other reports.

(a) * * *

(1) On or before the seventh day of each month of April through August, for each producer for the preceding month:

(i) The name and address or other appropriate identification of each producer; and

(ii) The total pounds of milk and the pounds of base milk of such producer delivered to each pool plant (and divided to each plant that is not a pool plant) under any of the orders specified in § 1108.92;

3. In § 1108.61, the introductory text of paragraph (a) (immediately preceding subparagraph (1)), and paragraph (a)(5) and (b) are revised as follows:

§ 1108.61 Computation of uniform price

(a) The market administrator shall compute the weighted average price for each month and the uniform price for each of the months of August through February per hundredweight for milk containing 3.5 percent butter-fat content as follows:

(1) Computed the uniform price for excess milk by deducting 5 cents from the Class III price for the month.

(b) Compute the uniform price for base milk as follows:

(i) From the amount resulting from the computations pursuant to paragraphs (a) (1) through (4) of this section, subtract an amount computed by multiplying the hundredweight of milk specified in paragraph (a)(5) of this section by the weighted average price;

(ii) Subtract an amount computed by multiplying the uniform price for excess milk for the month times the hundredweight of excess milk;

(iii) Divide the resulting amount by the total hundredweight of base milk included in these computations;

(iv) Subtract not less than 4 cents nor more than 5 cents.

4. Section 1108.75(a) is revised as follows:

§ 1108.75 Plant location adjustments for producers and on nonpool milk.

(a) The uniform price and the uniform price for base milk to be paid for producer milk received at a pool plant located 60 miles or more from the County Courthouse in Arkadelphia, Ark., the County Courthouse in Forrest City, Ark., or the State Capital in Little Rock, Ark., whichever is nearer by the shortest highway distance, as determined by the market administrator, shall be reduced according to the distance of the plant from the respective buildings designated above at the rate of 1.5 cents for each 10 miles or residual fraction thereof.

5. Section 1108.90 is revised as follows:

§ 1108.90 Base milk.

"Base milk" means the producer milk of a producer under all of the orders specified in § 1108.92 in each of the months of March through July that is not in excess of the producer's base multiplied by the number of days in the month. If milk is received as producer milk (as defined under any order specified in § 1108.92) from the same producer during the month by a handler regulated under this order and by a handler fully regulated under
any other order specified in §1108.92, the amount of such producer's base milk received by the handler under this order at each plant location shall be determined by multiplying the producer's total base milk by the percentage of his total deliveries of producer milk under all of the orders specified in §1108.92 that is delivered under this order at each respective plant location.

6. Section 1108.981 is revised as follows:

§1108.91 Excess milk. “Excess milk” means the producer milk of a producer in each of the months of March through July that is in excess of the producer's base milk under this order for the month, and shall include all the producer milk of a producer for whom no base can be computed pursuant to §1108.92.

7. Section 1108.92 is revised as follows:

§1108.92 Computation of base for each producer. (a) The base of each producer shall be determined by the market administrator by dividing the total pounds of producer milk (as defined under the respective orders) received from the producer by all handlers fully regulated under the terms of the respective orders regulating the handling of milk in the Neosho Valley; Wichita, Kans.; Red River Valley; Oklahoma Metropolitan; Memphis, Tenn.; Fort Smith, Ark.; Central Arkansas; Texas Lubbock-Plainview, Tex.; Texas Panhandle; and Rio Grande Valley marketing areas (Parts 1071, 1073, 1104, 1105, 1097, 1102, 1108, 1126, 1120, 1132, and 1136, respectively, of this chapter) during the immediately preceding period of September through December by the number of days' production represented by such producer milk or by 90, whichever is greater.

That any base that is based on milk deliveries during 1978 shall be determined by dividing the total pounds of producer milk received from the producer, in the manner previously described in this paragraph, during the period of October through December by the number of days' production represented by such producer milk or by 90, whichever is greater.

(b) The base for a producer whose milk is delivered to a plant that did not become a pool plant under any of the orders specified in paragraph (a) of this section until after the beginning of the base-forming period shall be calculated as if the plant were a pool plant under such orders for the entire base-forming period. A base thus assigned shall not be transferable.

8. Section 1108.93 is revised as follows:

§1108.93 Base rules. (a) A base may be transferred in its entirety, or in amounts of not less than 100 pounds (unless the transfer involves the remaining portion of such base), effective on the first day of the month following the date on which an application for such transfer is received by the market administrator. Such application shall be on a form approved by the market administrator and signed by the base-holder or his heirs and the person to whom the base is to be transferred. If a base is held jointly, the application shall be signed by all joint holders or their heirs.

(b) If a base is held jointly and such joint holding is terminated, the base may be apportioned among the joint holders on any basis agreed to in writing by them. Written notification of the agreed upon division of base signed by each of the joint holders must be received by the market administrator prior to the first day of the month in which such division is to be effective.

9. Section 1108.94 is revised as follows:

§1108.94 Announcement of established bases. On or before February 10 of each year the market administrator shall notify each producer, the handler receiving milk from him, and, if requested, a cooperative association in behalf of each of its producer members of the base established by such producer.

§1108.95 and 1108.96. [Revoked].

10. Sections 1108.95 and 1108.96 are revoked.

PART 1120—MILK IN THE LUBBOCK-PLAINVIEW, TEX., MARKETING AREA

1. In §1120.31, paragraph (a) (2) and (4) is revised as follows:

§1120.31 Payroll reports. (a) • • • • • • • (2) The total pounds of milk received from such producer and during the months of March through July the pounds of base milk;

• • • • • • • (4) The price per hundredweight (during the months of March through July the price per hundredweight for base milk and for excess milk), the gross amount due, the amount and nature of any deductions, and the net amount paid.

2. In §1120.32, paragraph (b) is revised and a new paragraph (c) is added to read as follows:

§1120.32 Other reports. • • • • • • • (b) In addition to the reports required pursuant to §1120.30 and §1120.31 and paragraphs (a) and (c) of this section, each handler shall report such other information as the market administrator deems necessary to verify or establish such handler's obligation under the order.

(c) Each handler who receives milk from producers shall report to the market administrator on or before the 5th day after the end of each of the months of March through July the following information:

(1) The name and address or other appropriate identification of each producer; and

(2) The total pounds of milk and the pounds of base milk of such producer delivered to each pool plant (and diverted to each plant that is not a pool plant) under any of the orders specified in §1120.92.

3. Section 1120.61 is revised as follows:

§1120.61 Computation of uniform price (including weighted average price and uniform prices for base and excess milk). (a) The market administrator shall compute the weighted average price for each month and the uniform price for each of the months of August through September, per hundredweight for milk of 3.5 percent butterfat content as follows:

(1) Combine into one total the values computed pursuant to §1120.60 for all pool handlers who made the reports prescribed in §1120.30 for the month and who have made the payments required pursuant to §1120.71 for the preceding month;

(2) Add an amount equal to the sum of the deductions to be made for location adjustments pursuant to §1120.76;

(3) Add an amount equal to not less than one-half the unobligated balance on hand in the producer-settlement fund;

(4) Subtract an amount computed by multiplying the total hundredweight of producer milk included in such paragraph (a)(1) of this section by 5 cents;

(5) Divide the resulting amount by the sum of the following for all handlers included in such computations:

(d) The total hundredweight of producer milk; and

(d) The total hundredweight for which a value is computed pursuant to §1120.60(c); and

(6) Subtract not less than 4 cents nor more than 5 cents.

(b) For each of the months of March through July, the market adminis-
tor shall compute the uniform prices per hundredweight for base milk and for excess milk, each of 3.5 percent butterfat content, as follows:

1. Compute the uniform price for excess milk by deducting 5 cents from the Class III price for the month.

2. Compute the uniform price for base milk as follows:

   (i) From the amount resulting from the computations pursuant to paragraph (a)(1) through (4) of this section, subtract an amount computed by multiplying the hundredweight of milk specified in paragraph (a)(5)(i)(A) of this section by the weighted average price;

   (ii) Subtract an amount computed by multiplying the uniform price for excess milk for the month times the hundredweight of excess milk;

   (iii) Divide the resulting amount by the total hundredweight of base milk included in these computations; and

   (iv) Subtract not less than 4 cents nor more than 5 cents.

3. Section 1120.62 is revised as follows:

   § 1120.62 Announcement of uniform prices and butterfat differential.

   The market administrator shall announce publicly on or before:

   (a) The 5th day after the end of each month the butterfat differential for such month; and

   (b) The 10th day after the end of each month the applicable uniform prices for such month.

§ 1120.71 [Amended]

5. Section 1120.71(a)(2)(i) is amended by changing the word "price" to "weighted average price."

6. Section 1120.71(a)(2)(ii) is amended by changing the words "uniform price" to "weighted average price."

7. In § 1120.73, the introductory text of paragraph (a)(2)(iii) (immediately preceding subdivision (ii)), and paragraph (d)(3) are revised as follows:

   § 1120.73 Payments to producers and to cooperative associations.

   (a) * * *

   (2) On or before the 15th day after the end of each month for milk (or base milk and excess milk) received during such month, an amount computed at not less than the uniform price(s) per hundredweight pursuant to § 1120.61 as adjusted pursuant to § 1120.74; and less

   * * * * *

   (d) * * *

   (3) The daily and total pounds and the average butterfat content of milk received from such producer during the months of March through July the pounds of base milk; * * * * *
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jointly, the application shall be signed by all joint holders or their heirs.

(b) If a base is held jointly and such joint holding is terminated, the base may be apportioned among the joint holders on any basis agreed to in writing by them. Written notification of the agreed upon division of base signed by each of the joint holders must be received by the market administrator prior to the first day of the month on which such division is to be effective.

§ 1120.94 Announcement of established bases.

On or before February 10 each year the market administrator shall notify each producer, the handler receiving milk of him and, if requested, a cooperative association in behalf of each of its producer members of the base established by such producer.

§ 1120.121 [Amended]

12. Section 1120.121(b) is amended by changing all references to "§ 1120.61(d)" to read "§ 1120.61(a)(4)"

PART 1126—MILK IN THE TEXAS MARKETING AREA

1. In § 1126.32 paragraph (b)(2) is revised as follows:

§ 1126.32 Other reports.

(2) The total pounds of producer milk received from such producer, its average butterfat content and for the months of March through July the total pounds of milk and the pounds of base milk of such producer delivered to each pool plant (and diverted to each plant that is not a pool plant) under any of the orders specified in § 1126.92;

2. Section 1126.61 is revised as follows:

§ 1126.61 Computation of uniform price (including weighted average price and uniform prices for base and excess milk).

(a) The market administrator shall compute the weighted average price for each month and the uniform price for each of the months of August through February per hundredweight for milk of 3.5 percent butterfat content at pool plants at which no location adjustment applies as follows:

(1) Combine into one total the values computed pursuant to § 1126.60 for all handlers who filed the report prescribed in § 1126.30 for the month and who made the payments pursuant to § 1126.71 for the preceding month;

(2) Add not less than one-fourth of the unobligated balance in the producer-settlement fund;

(3) Add the aggregate of all minus location adjustments and subtract the aggregate of all plus location adjustments pursuant to § 1126.75;

(4) Subtract an amount computed by multiplying the total hundredweight of producer milk included pursuant to paragraph (a)(1) of this section by 5 cents;

(5) Divide the resulting amount by the sum of the following for all handlers included in these computations:

(i) The total hundredweight of producer milk; and

(ii) The total hundredweight for which a value is computed pursuant to § 1126.60(f);

(6) Subtract not less than 4 cents nor more than 5 cents.

(b) For each of the months of March through July, the market administrator shall compute the uniform price per hundredweight for base milk and for excess milk, each of 3.5 percent butterfat content, as follows:

(1) Compute the uniform price for 5 cents by deducting 5 cents from the Class III price for the month.

(2) Compute the uniform price for base milk as follows:

(i) From the amount resulting from the computations pursuant to paragraph (a) (1) through (4) of this section, subtract an amount computed by multiplying the hundredweight of milk specified in paragraph (a)(5)(ii) of this section by the weighted average price;

(ii) Subtract an amount computed by multiplying the uniform price for excess milk for the month times the hundredweight of excess milk;

(iii) Divide the resulting amount by the total hundredweight of base milk included in these computations; and

(iv) Subtract not less than 4 cents nor more than 5 cents.

3. Section 1126.62 is revised as follows:

§ 1126.62 Announcement of uniform prices and butterfat differential.

The market administrator shall announce publicly on or before:

(a) The 5th day after the end of each month the butterfat differential for such month; and

(b) The 15th day after the end of each month the applicable uniform prices for such month.

§ 1126.71 [Amended]

4. Section 1126.71(b)(4) is amended by changing the words "uniform price" to "weighted average price.

5. In § 1126.75 the introductory text of paragraph (b) (immediately preceding subparagraph (1)), and paragraph (d)(2) are revised as follows:

§ 1126.73 Payments to producers and to cooperative associations.

(b) Subject to paragraphs (e) through (f) of this section, the market administrator shall pay each producer on or before the 18th day after the end of each month for milk (or base milk and excess milk) for which payment pursuant to § 1126.71(b) has been received by the market administrator or offset pursuant to § 1126.71(d).

Such payment shall be at the applicable uniform price(s) for the month, subject to the following adjustments:

• • • •

§ 1126.74 [Amended]

6. Section 1126.74 is amended by changing the words "uniform price" to "uniform prices.

7. Section 1126.75 is revised as follows:

§ 1126.75 Plant location adjustments for producers and on nonpool milk.

(a) In making the payments required pursuant to § 1126.73, the uniform price and the uniform price for base milk for the month shall be adjusted by the amounts set forth in § 1126.52 according to the location of the plant in which the milk being paid was received.

(b) For purposes of computing the value of other source milk pursuant to § 1126.71, the weighted average price shall be adjusted by the amount set forth in § 1126.52 that is applicable at the location of the nonpool plant from which the milk was received, except that the adjusted weighted average price plus 5 cents shall not be less than the Class III price.

§ 1126.76 [Amended]

8. Section 1126.76(a)(4) is amended by changing the words "uniform price" wherever they appear to "weighted average price.

9. A new center head "Base-Excess Plan" and five new sections (§§ 1126.80 through 1126.84) are added immediately following § 1126.86 as follows:

BASE-EXCESS PLAN

§ 1126.99 Base milk.

"Base milk" means the producer milk of a producer under all of the orders specified in § 1126.92 in each of
the months of March through July that is not in excess of the producer’s base multiplied by the number of days in the month. If milk is received as producer milk of a producer under any order specified in §1126.92 from the same producer during the month by a handler regulated under this order and by a handler fully regulated under any other order specified in §1126.92, the amount of such producer’s base milk received by the handler under this order at each plant location shall be determined by multiplying the producer’s total base milk by the percentage of his total deliveries of producer milk under all of the orders specified in §1126.92 that is delivered under this order at each respective plant location.

§1126.91 Excess milk.

"Excess milk" means the producer milk of a producer in each of the months of March through July that is in excess of the producer’s base milk under this order for the month, and shall include all the producer milk of a producer for whom no base can be computed pursuant to §1126.92.

§1126.92 Computation of base for each producer.

(a) The base of each producer shall be determined by the market administrator by dividing the total pounds of producer milk (as defined under the respective orders) received from the producer by all handlers fully regulated under the terms of the respective orders regulating the handling of milk in the Neosho Valley; Wichita, Kans.; Red River Valley; Oklahoma metropolitan; Memphis, Tenn.; Fort Smith, Ark.; central Arkansas; Texas; Lubbock-Plainview, Tex.; Texas Panhandle; and Rio Grande Valley marketing areas (par. 1071, 1073, 1097, 1102, 1104, 1106, 1108, 1120, 1126, 1132, and 1138, respectively, of this chapter) during the immediately preceding period of September through December by the number of days’ production represented by such producer’s milk, or by 90, whichever is greater: Provided, That any base that is based on milk deliveries during 1978 shall be determined by dividing the total pounds of producer milk received from the producer, in the manner previously described in this paragraph, during the period of October through December by the number of days’ production represented by such producer milk or by 90, whichever is greater.

(b) The base for a producer whose milk is delivered to a plant that did not become a pool plant under any of the orders specified in paragraph (a) of this section until after the beginning of the base-forming period shall be calculated as if the plant were a pool plant under such orders for the entire base-forming period. A base thus assigned shall not be transferable.

§1126.93 Base rules.

(a) A base may be transferred in its entirety, or in amounts of not less than 100 pounds (unless the transfer involves the remaining portion of such base), effective on the first day of the month following the date on which an application for such transfer is received by the market administrator. Such application shall be on a form approved by the market administrator and signed by the baseholder or his heirs and the person to whom the base is to be transferred. If a base is held jointly, the application shall be signed by all joint holders or their heirs.

(b) If a base is held jointly and such joint holding is terminated, the base may be apportioned among the joint holders on any basis agreed to in writing by them. Written notification of the agreed upon division of base signed by each of the joint holders must be received by the market administrator prior to the first day of the month on which such division is to be effective.

§1126.94 Announcement of established bases.

On or before February 10 of each year the market administrator shall notify each producer, the handler receiving milk from him and, if requested, a cooperative association in behalf of each of its producer members of the base established by such producer.

§1126.121 [Amended]

10. Section 1126.121(b) is amended by changing all references to "§1126.81(d)") to read "§1126.81(a)(4)"

PART 1132—MILK IN THE TEXAS PANHANDLE MARKETING AREA

1. In §1132.31, paragraph (a)(2) and (4) is revised as follows:

§1132.31 Payroll reports.

(a) * * *

(2) The total pounds of milk and the pounds of base milk of such producer for each month and the uniform price for milk of 3.5 percent butterfat content: I.o.b. pool plants located within 100 miles of the city hall of Amarillo, Tex., as follows:

(b) Add an amount equal to one-half of the unobligated cash balance in the producer-settlement fund

(c) Subtract an amount computed by multiplying the total unobligated cash balance in the producer-settlement fund

(d) Subtract an amount equal to one-half of the unobligated cash balance in the producer-settlement fund

(e) Subtract an amount equal to one-half of the unobligated cash balance in the producer-settlement fund

(f) Subtract an amount equal to one-half of the unobligated cash balance in the producer-settlement fund

(g) Subtract an amount equal to one-half of the unobligated cash balance in the producer-settlement fund

(h) Subtract an amount equal to one-half of the unobligated cash balance in the producer-settlement fund

(i) Subtract an amount equal to one-half of the unobligated cash balance in the producer-settlement fund

(j) Subtract an amount equal to one-half of the unobligated cash balance in the producer-settlement fund

(k) Subtract an amount equal to one-half of the unobligated cash balance in the producer-settlement fund

(l) Subtract an amount equal to one-half of the unobligated cash balance in the producer-settlement fund

(m) Subtract an amount equal to one-half of the unobligated cash balance in the producer-settlement fund

(n) Subtract an amount equal to one-half of the unobligated cash balance in the producer-settlement fund

(o) Subtract an amount equal to one-half of the unobligated cash balance in the producer-settlement fund

(p) Subtract an amount equal to one-half of the unobligated cash balance in the producer-settlement fund

(q) Subtract an amount equal to one-half of the unobligated cash balance in the producer-settlement fund

(r) Subtract an amount equal to one-half of the unobligated cash balance in the producer-settlement fund

(s) Subtract an amount equal to one-half of the unobligated cash balance in the producer-settlement fund

(t) Subtract an amount equal to one-half of the unobligated cash balance in the producer-settlement fund

(u) Subtract an amount equal to one-half of the unobligated cash balance in the producer-settlement fund

(v) Subtract an amount equal to one-half of the unobligated cash balance in the producer-settlement fund

(w) Subtract an amount equal to one-half of the unobligated cash balance in the producer-settlement fund

(x) Subtract an amount equal to one-half of the unobligated cash balance in the producer-settlement fund

(y) Subtract an amount equal to one-half of the unobligated cash balance in the producer-settlement fund

(z) Subtract an amount equal to one-half of the unobligated cash balance in the producer-settlement fund

1. In §1132.32, paragraph (b) is revised as follows:

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tor shall compute the uniform prices per hundredweight for base milk and for excess milk, each of 3.5 percent butterfat content as follows:

(1) Compute the uniform price for excess milk by deducting 5 cents from the class III price for the month.

(2) Compute the uniform price for base milk as follows:

(i) From the amount resulting from the computations pursuant to paragraph (a)(1) through (4) of this section, subtract an amount computed by multiplying the hundredweight of milk specified in paragraph (a)(5)(ii) of this section by the weighted average price:

(ii) On or before the 13th day of the following month, in final settlement, the value of such milk received during the month, at the applicable uniform price(s) as adjusted pursuant to § 1132.74 and 1132.75, less the amount of payment made pursuant to paragraph (c)(4)(i) of this section.

(4) * * *

(ii) On or before the 13th day of the following month, in final settlement, the value of such milk received during the month, at the applicable uniform price(s) as adjusted pursuant to § 1132.74 and 1132.75, less the amount of payment made pursuant to paragraph (c)(4)(i) of this section.

(d) * * *

(2) The daily and total pounds of milk and the average butterfat content of milk received from such producer, and for each of the months of March through July, the pounds of base milk;

§ 1132.74 [Amended]

8. Section 1132.74 is amended by changing the words "uniform price" to "uniform prices."

9. Section 1132.75 is revised as follows:

§ 1132.75 Plant location adjustments for producers and on nonpool milk.

(a) In making payment pursuant to § 1132.73 the uniform price and the uniform price for base milk to be paid for milk which is received from producers at a pool plant located 100 miles or more from the city hall, Amarillo, Tex., by the shortest hard-surfaced highway distance as determined by the market administrator shall be reduced at the rate set forth in the following schedule according to the location of the pool plant where such milk is received from producers:

<table>
<thead>
<tr>
<th>Distance from the Amarillo City Hall (miles):</th>
<th>Rate per hundredweight (cents)</th>
</tr>
</thead>
<tbody>
<tr>
<td>100 but less than 110</td>
<td>15.0</td>
</tr>
<tr>
<td>For each additional 10 ml or fraction thereof</td>
<td>1.5</td>
</tr>
</tbody>
</table>

(b) For purposes of computations pursuant to §§ 1132.71 and 1132.72, the weighted average price plus 5 cents shall be adjusted at the rates set forth in § 1132.52 applicable at the location of the nonpool plant from which the milk was received (but the resulting price shall not be less than the class III price.)

§ 1132.76 [Amended]

10. Section 1132.76(a)(4) is amended by changing the words "uniform price" where they appear to "weighted average price."

11. A new center head "Base-Excess Plan" and five new sections (§§ 1132.90 through 1132.94) are added immediately following § 1132.88 as follows:

BASE-EXCESS PLAN

§ 1132.90 Base milk.

"Base milk" means the producer milk of a producer under all of the orders specified in § 1132.92 in each of the months of March through July that is not in excess of the producer's base milk multiplied by the number of days in the month. If milk is received as producer milk (as defined under any order specified in § 1139.92) from the same producer during the month by a handler regulated under that order and by a handler fully regulated under any other order specified in § 1132.92, the amount of such producer's base milk received by the handler under this order at each plant location shall be determined by multiplying the producer's total base milk by the percentage of his total deliveries of producer milk under all of the orders specified in § 1132.92 that is delivered under this order at each respective plant location.

§ 1132.91 Excess milk.

"Excess milk" means the producer milk of a producer in each of the months of March through July that is in excess of the producer's base milk under this order for the month, and shall include all the producer milk of a producer for whom no base can be computed pursuant to § 1132.92.

§ 1132.92 Computation of base for each producer.

(a) The base of each producer shall be determined by the market administrator by dividing the total pounds of producer milk (as defined under the respective orders) received from the producer by all handlers fully regulated under the terms of the respective orders regulating the handling of milk in the Neosho Valley; Wichita, Kansas; Red River Valley; Oklahoma Metropolitan; Memphis, Tennessee; Fort Smith, Arkansas; Central Arkansas; Texas, Lubbock-Plainview Texas Panhandle; and Rio Grande Valley marketing areas (Parts 1071, 1073, 1104, 1106, 1097, 1102, 1108, 1126, 1120, 1132, and 1138, respectively; of this chapter) during the immediately preceding period of September through December by the number of days' production represented by such producer milk or by 90, whichever is
§ 1138.31 The total pounds of milk received from such producer and during the months of March through July the pounds of base milk:

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§ 1138.76 [Amended]
10. Section 1138.76(a)(4) is amended by changing the words “uniform price” wherever they appear to “weighted average price.”

11. A new center head “Base-Excess Plan” and five new sections (§§1138.90 through 1138.94) are added immediately following §1138.86 as follows:

### BASE-EXCESS PLAN

§ 1138.90 Base milk.

“Base milk” means the producer milk of a producer under all of the orders specified in §1138.92 during the months of March through July that is not in excess of the producer’s base multiplied by the number of days in the month. If milk is received as base milk from any other order specified in §1138.92 from the same producer during the month by a handler regulated under this order and by a handler fully regulated under another order specified in §1138.92, the amount of such producer’s base milk received by the handler under this order at each plant location shall be determined by multiplying the producer’s total base milk by the percentage of his total deliveries of producer milk under all of the orders specified in §1138.92 that is delivered under this order at each respective plant location.

§ 1138.91 Excess milk.

“Excess milk” means the producer milk of a producer in each of the months of March through July that is in excess of the producer’s base milk under this order for the month, and shall include all the producer milk of a producer for which no base can be computed pursuant to §1138.92.

§ 1138.92 Computation of base for each producer.

(a) The base of each producer shall be determined by the market administrator by dividing the total pounds of producer milk (as defined under the respective orders) received from the producer by all handlers fully regulated under the terms of the respective orders regulating the handling of milk in the Neosho Valley; Wichita, Kans.; Red River Valley; Oklahoma Metropolitan; Memphis, Tenn.; Fort Smith, Ark.; Texas; Lubbock-Plainview, Tex.; Texas Panhandle; and Rio Grande Valley marketing areas (Parts 1071, 1073, 1104, 1097, 1102, 1108, 1126, 1120, 1132, and 1138, respectively, of this chapter) during the immediately preceding period of July through December by the number of days’ production represented by such producer milk or by 90, whichever is greater; Provided, That any base that is based on milk deliveries during 1978 shall be determined by dividing the total pounds of producer milk received from the producer, in the manner previously described in this paragraph, during the period of October through December by the number of days’ production represented by such producer milk or by 90 whichever is greater.

(b) The base for a producer whose milk is delivered to a plant that did not become a pool plant under any of the orders specified in paragraph (a) of this section until after the beginning of the base-forming period shall be calculated as if the plant were a pool plant under such orders for the entire base-forming period. A base thus assigned shall not be transferable.

§ 1138.93 Base rules.

(a) A base may be transferred in its entirety, or in amounts of not less than 100 pounds (unless the transfer involves the remaining portion of such base), effective on the first day of the month following the date on which the application for such transfer is received by the market administrator. Such application shall be on a form approved by the market administrator and signed by the baseholder or his heirs. If a base is held jointly, the application shall be signed by all joint holders or their heirs.

(b) If a base is held jointly and such joint holding is terminated, the base may be apportioned among the joint holders on any basis agreed to in writing by them. Written notification of the agreed upon division of base signed by each of the joint holders must be received by the market administrator prior to the first day of the month on which such division is to be effective.

§ 1138.94 Announcement of established bases.

On or before February 10 of each year the market administrator shall notify each producer, the handler receiving milk from him and, if requested, a cooperative association in behalf of each of its producer members of the base established by such producer.

§ 1138.12112 [Amended]
12. Section 113.1211(b) is amended by changing all references to “§1138.61(dy)” to read “§1138.61(a)(4)”
STANDARD FOR BENEFIT PAYMENT PROMPTNESS—UNEMPLOYMENT COMPENSATION

Revised Regulation
[4510-30]  
Title 20—Employees' Benefits  
CHAPTER V—EMPLOYMENT AND TRAINING ADMINISTRATION, DEPARTMENT OF LABOR  
PART 640—STANDARD FOR BENEFIT PAYMENT PROMPTNESS—UNEMPLOYMENT COMPENSATION  
Revised Regulation  
AGENCY: Employment and Training Administration, Labor.  
ACTION: Final rule.  
SUMMARY: The Secretary of Labor's Standard for Benefit Payment Promptness requires that State unemployment compensation laws provide for the payment of unemployment benefits within the greatest promptness that is administratively feasible, and sets forth criteria for first payments of unemployment benefits. Changes are made also to provide for appropriate corrective action when a State's performance falls below the criteria for promptness.  
SUMMARY OF PROPOSED CHANGES  
In the document published on November 22, 1977, the Department of Labor proposed to make the following changes in part 640:  
1. Change the standard as it applies to States which do not require a waiting period.  
2. Change the measurement period from the 12-month period ending June 30 to the 12-month period ending March 31.  
3. Change the standard by introducing higher and graduated criteria to be achieved over a 3-year period.  
COMMENTS RECEIVED  
Comments were invited on the proposed revision to part 640 with a closing date of December 22, 1977. Responses were received within the time limit from 33 State agencies, two Department of Labor regional offices, five legal aid and legal services organizations in four States, and the National Governors' Association. One response was received after the time limit. While the last response cannot be considered, it did not contain comments substantially different from those received within the time limit.  
All of the responses received within the time limit have been considered. Many of the comments received were similar to comments submitted when part 640 was first proposed and published on March 5, 1976. The most significant comments related to (a) the effective dates of the more stringent performance criteria, (b) the proposed higher criteria levels of performance, and (c) establishment of separate criteria applicable to agent State performance.  
The comments received and changes made in the proposal are discussed below.  
1. NONWAITING WEEK STATES  
All parties responding to this proposal except one favored allowing nonwaiting week States 21 days instead of 14 days after the end of the first compensable week to make first payments under the intrastate and interstate criteria. The single respondent not favoring the extension from 14 to 21 days proposed that a nonwaiting week State that is meeting the current criteria, but that may be required to continue to do so. The Department does not consider it feasible nor equitable to develop separate rules for a few States.  
No change is made in this proposal, except that the first measurement period for the higher criteria will, as explained below, be the period beginning with the month following the effective date of this final regulation and ending on March 31, 1979, instead of March 31, 1978.  
For the measurement period ending March 31, 1978, the present criteria will apply with only a change from 14 days to 21 days in the time limits for nonwaiting week States to make first payments. Thus, although the present criteria are retained through March 31, 1978, the change with respect to nonwaiting week States is incorporated to accomplish this improvement at the earliest feasible time.  
2. CHANGE OF MEASUREMENT PERIOD  
Several States objected to the retroactive application of the amendment to the Standard, which set more stringent criteria for achievement beginning with the 12-month period ending March 31, 1978. The States would not have reasonable time to plan their operations or to take appropriate action to meet the goal. Accordingly, to afford States enough lead time to gear up to meet the performance criteria, the measurement period for applying the present criteria of 80 percent for intrastate first payments and 60 percent for interstate first payments is retained for the 12-month period ending March 31, 1978. The measurement period for the new criteria of 85 percent and 65 percent, respectively, is changed from the 12-month period ending on March 31, 1978, to the 12-month period ending on March 31, 1979, but in order to avoid retroactive effect the first measurement period for the period ending March 31, 1970, will begin with the month following the effective date of this final regulation instead of April 1, 1978. In addition, the measurement period for the second step in the higher criteria (87 percent and 70 percent) is changed from the 12-month period ending on March 31, 1978, to the 12-month period ending on March 31, 1980.  
3. HIGHER AND GRADUATED CRITERIA  
State responses generally reflected concern with the prospect of their meeting the proposed higher criteria. Reports of accomplishment through February 1978, show that 43 States are exceeding the current intrastate criterion of performance and 31 States are exceeding the current interstate criterion calculated with allowance of 21 days for making first payments in nonwaiting week States. These results reflect the substantial effort States are making to improve their performance. This demonstrated effort, combined with continued improvements in automated systems, strongly indicates that the proposed higher criteria are attainable goals, as is more fully explained in the proposal.  
In addition, the advances in the effective dates of the higher criteria make these goals more readily attainable. Further, the increased criteria of 80 percent and 75 percent proposed for the 12-month period ending March 31, 1980, have been deleted. This deletion was made because the effective date of the increased criteria would have been advanced to March 31, 1981, and analysis of available information indicates that a valid projection so far into the future cannot be made at this time.  
Studies conducted in 17 States have been completed in the remaining States. Results of the later studies were consistent with the results of the
RULES AND REGULATIONS

earlier studies: Factors identified as uncontrollable and their adverse effect on benefit payment promptness were very similar in both series of studies. Accordingly, no change is made in the higher criteria except as explained above.

4. ENFORCEMENT PROVISIONS

The enforcement provisions have been amended to allow the Department of Labor flexibility in applying the appropriate remedial steps to specific situations rather than applying all remedial steps to all situations of noncompliance.

The fact that a State does not meet the applicable intrastate or interstate criterion within a prescribed measurement period does not necessarily mean to meet the Secretary’s standard.

The standard requires substantial compliance with a requirement for the greatest promptness that is administratively feasible. A State that has met the specified percentage of first payment promptness from 1% to 100% is changed from the 12-month period ending March 31, 1979, and the second increase in the period will be the 12-month period ending March 31, 1980. The proposed third increase to have been effective for the 12-month period ending March 31, 1980, is deleted.

2. Nonwaiving states are allowed 21 days to meet the criteria, effective for the period ending March 31, 1979.

3. The period over which the benefit payment promptness is to be measured is changed from the 12-month period ending June 30 to the 12-month period ending March 31.

4. Enforcement provisions are modified to allow the Department of Labor to determine the capability of the State to achieve and maintain substantial improvement in intrastate benefit payment promptness.

5. Sections 640.1 and 640.3 relating to purpose and interpretation of Federal law requirements, are clarified by added provisions.

6. Other minor clarifying and technical changes are made.

Note—The Department of Labor has determined that this document does not contain a major proposal requiring the preparation of an economic impact statement under Executive Order 11949 and applicable authority.

This document was prepared under the direction and control of Lawrence Ey, Assistant Administrator, Unemployment Insurance Service, Employment and Training Administration, U.S. Department of Labor, 601 D Street NW., Washington, D.C. 20213, telephone 202-376-7032.

Accordingly, part 640 of chapter V of title 20, Code of Federal Regulations, is revised as set forth below.


Ernest G. Green, Assistant Secretary for Employment and Training.

Sec.

640.1 Purpose and scope.

640.2 Federal law requirements.

640.3 Interpretation of Federal law requirements.

640.4 Standard for conformity.

640.5 Criteria for compliance.

640.6 Review of State compliance.

640.7 Benefit payment performance plans.

640.8 Enforcement of the standard.

640.9 Information, reports and studies.

Authority: Sec. 1102, Social Security Act (42 U.S.C. 1327; Secretary’s order No. 4-75, dated April 16, 1975 (40 FR 15515) (5 U.S.C. § 352), Interpret and apply secs. 303(c)(1) and 303(c)(2) of the Social Security Act (42 U.S.C. 503(a)(1), 503(b)(2)).

§ 640.1 Purpose and scope.

(a) Purpose. (1) Section 303(a)(1) of the Social Security Act requires, for the purposes of title III of that act, that a State unemployment compensation law include provision for methods of administering Federal law that are reasonably calculated to insure the full payment of unemployment compensation when determined under the State law to be due to claimants. The standard in this part is issued to implement section 303(a)(1) in regard to promptness in the payment of unemployment benefits to eligible claimants.

(2) Although the standard applies to the promptness of all benefit payments and the criteria apply directly to the promptness of first benefit payments, it is recognized that adequate performance is contingent upon the prompt determination of eligibility by the State as a condition for the payment or denial of benefits. Accordingly, implicit in prompt performance with respect to benefit payments is the corresponding need for promptness by the State in making determinations of eligibility. However, applicable Federal laws provide no authority for the Secretary of Labor to determine the eligibility of individuals under a State law.

(b) Scope. (1) The standard in this part applies to all State laws approved by the Secretary of Labor under the Federal Unemployment Tax Act (section 3304 of the Internal Revenue Code of 1954, 26 U.S.C. 3304), and to the administration of the State laws.

(2) The standard specified in § 640.4 applies to all claims for unemployment compensation. The criteria for State compliance in § 640.5 apply to first payments of unemployment compensation under the State law to eligi-
able claimants following the filing of initial claims and first compensable claims.

§ 640.2 Federal law requirements.

(a) Conformity. Section 303(a)(1) of the Social Security Act, 42 U.S.C. 603(a)(1), requires that a State law include provision for:

Such methods of administration * * * as are found by the Secretary of Labor to be reasonably calculated to insure full payment of unemployment compensation when due.

(b) Compliance. Section 303(b)(2) of the Social Security Act, 42 U.S.C. 603(b)(2), provides in part that:

Whenever the Secretary of Labor, after reasonable notice and opportunity for hearing to the State agency charged with the administration of the State law, finds that in the administration of the law there is:

(1) * * *
(2) a failure to comply substantially with any provision specified in subsection (a) of this section;

the Secretary of Labor shall notify such State agency that further payments will not be made to the State until the Secretary of Labor is satisfied that there is no longer any such * * * failure to comply.

Until he is so satisfied, he shall make no further certification to the Secretary of the Treasury with respect to such State * * *. 

§ 640.3 Interpretation of Federal law requirements.

(a) Section 303(c)(1). The Secretary interprets section 303(a)(1) of the Social Security Act to require that a State law include provision for such methods of administration as will reasonably assure the full payment of unemployment benefits to eligible claimants with the greatest promptness that is administratively feasible.

(b) Section 303(b)(2). (1) The Secretary interprets section 303(b)(2) of the Social Security Act to require that, in the administration of a State law, there shall be substantial compliance with the provision required by section 303(a)(1) in the issuance of benefit payments to eligible claimants for the first compensable weeks of unemployment in their benefit years:

| Percentage of first payments issued—days following end of first compensable week |
|---------------------------------|-----|-----|-----|
| 14 days                         | 80  | 80  | 80  |
| 21 days                         | 83  | 83  | 83  |
| 28 days                         | 87  | 87  | 87  |

Intrastate claims

Performance to be achieved for the 12-mo. period ending:

Mar. 31, 1978: 80 80 80
Mar. 31, 1979: 83 83 83
Mar. 31, 1980, and thereafter: 87 87 87

Interstate claims

Performance to be achieved for the 12-mo. period ending:

Mar. 31, 1978: 60 60 60
Mar. 31, 1979: 65 65 65
Mar. 31, 1980, and thereafter: 70 70 70

1A nonwaiving week State is any State whose law does not require that a non-compensable period of unemployment be served before the payment of benefits commences.

2Beginning with the month following the effective date of this revised regulation.

§ 640.4 Standard for conformity.

A State law will satisfy the requirement of section 303(a)(1), if it contains a provision requiring, or which is construed to require, such methods of administration as will reasonably assure the full payment of unemployment benefits to eligible claimants for the first compensable weeks of unemployment in their benefit years.

§ 640.5 Criteria for compliance.

The criteria in the schedule below shall apply in determining whether, in the administration of a State law, there has been substantial compliance with the provision required by section 303(a)(1) in the issuance of benefit payments to eligible claimants for the first compensable weeks of unemployment in their benefit years:

| Performance to be achieved—days following end of first compensable week |
|-------------------------------|-----|-----|-----|
| 14 days                       | 80  | 80  | 80  |
| 21 days                       | 83  | 83  | 83  |
| 28 days                       | 87  | 87  | 87  |

Intrastate claims

Performance to be achieved for the 12-mo. period ending:

Mar. 31, 1978: 80 80 80
Mar. 31, 1979: 83 83 83
Mar. 31, 1980, and thereafter: 87 87 87

Interstate claims

Performance to be achieved for the 12-mo. period ending:

Mar. 31, 1978: 60 60 60
Mar. 31, 1979: 65 65 65
Mar. 31, 1980, and thereafter: 70 70 70

§ 640.6 Review of State compliance.

(a) Annual reviews. The administration of each State law shall be reviewed annually for compliance, as set out in §§ 640.2(b) and 640.3(b). Annual reviews shall be for the 12-month period ending on March 31 of each year. An annual review with respect to any State shall be based upon the monthly reports of performance submitted by the Secretary of Labor to the Department by the State agency, any special reports of performance submitted to the Department by the State agency, any benefit payment performance plan applicable to the period being reviewed, any study or analyses of performance relevant to the period being reviewed, and any other audit, study, or analyses as directed by the Department of Labor.

(b) Periodic review. The administration of any State law may be reviewed at any other time, when there is reason to believe that there may be failure of compliance as set out in §§ 640.2(b) and 640.3(b). Such a review shall be based upon the same elements as may be required for an annual review.

§ 640.7 Benefit payment performance plans.

(a) Annual plan. An annual benefit payment performance plan shall be submitted by a State agency to the Department of Labor when average performance over a 12-month period ending on March 31 of any year does not meet the criteria specified in § 640.5. An annual benefit payment plan shall be submitted by July 31 following the applicable March 31, and shall be a plan for the fiscal year that begins on the succeeding October 1. An annual plan shall cover all benefit payment appraisal during the period it is in effect, and shall be subject to modification from time to time as may be directed by the Department of Labor after consultation with the State agency.

(b) Periodic plan. A periodic benefit payment performance plan shall be submitted by a State agency to the Department of Labor when average performance over a 12-month period ending on March 31 of any year does not meet the criteria specified in § 640.5. An annual plan shall be subject to modification from time to time as may be required by the Department of Labor after consultation with the State agency.

§ 640.8 Enforcement of the standard.

(a) Action by the Department of Labor. When a State agency fails, for an extended period, to meet the standards set forth in § 640.4 or the criteria specified in § 640.5, or fails to show the administration of the law there is:

§§ 640.2(b) and 640.3(b). Annual reviews shall be for the 12-month period ending on March 31 of each year. An annual review with respect to any State shall be based upon the monthly reports of performance submitted by the Secretary of Labor to the Department by the State agency, any special reports of performance submitted to the Department by the State agency, any benefit payment performance plan applicable to the period being reviewed, any study or analyses of performance relevant to the period being reviewed, and any other audit, study, or analyses as directed by the Department of Labor.

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satisfactory improvement after having submitted a benefit payment performance plan of action, the Department of Labor shall pursue any of the following remedial steps that it deems necessary before considering application of the provisions of § 640.2:

(1) Initiate informal discussion with State agency officials pursuant to § 601.5(b) of this chapter.

(2) Conduct an evaluation of the State's benefit payment processes and analyze the reasons for the State's failure to meet the standard.

(3) Recommend specific actions for the State to take to improve its benefit payment performance.

(4) Request the State to submit a plan for complying with the standard by a prescribed date.

(5) Initiate special reporting requirements for a specified period of time.

(6) Consult with the Governor of the State regarding the consequences of the State's noncompliance with the standard.

(7) Propose to the Governor of the State and on an agreed upon basis arrange for the use of expert Federal staff to furnish technical assistance to the State agency with respect to its payment operations.

(b) Action by the Assistant Secretary. If, after all remedial steps have been exhausted, a State fails to take appropriate action, or otherwise fails to meet the standard specified in § 640.4, the Assistant Secretary for Employment and Training shall, after taking all factors into consideration, recommend to the Secretary of Labor that appropriate notice be sent to the State agency and that an opportunity for a hearing be extended in accordance with section 303(b) of the Social Security Act.

§ 640.9 Information, reports and studies.

A State shall furnish to the Secretary of Labor such information and reports and make such studies as the Secretary decides are necessary or appropriate to carry out this part.

(Final Rule Doc. 78-21654 Filed 7-27-78; 8:45 am)