6-26-86
Vol. 51 No. 123
Pages 23213-23402

federal register

Thursday
June 26, 1986

Briefings on How To Use the Federal Register—
For information on briefings in Washington, DC, Seattle, WA, and San Francisco, CA, see announcement on the inside cover of this issue.

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THE FEDERAL REGISTER
WHAT IT IS AND HOW TO USE IT

FOR: Any person who uses the Federal Register and Code of Federal Regulations.

WHO: The Office of the Federal Register.

WHAT: Free public briefings (approximately 2 1/2 hours) to present:

1. The regulatory process, with a focus on the Federal Register system and the public's role in the development of regulations.
2. The relationship between the Federal Register and Code of Federal Regulations.
3. The important elements of typical Federal Register documents.
4. An introduction to the finding aids of the FR/CFR system.

WHY: To provide the public with access to information necessary to research Federal agency regulations which directly affect them. There will be no discussion of specific agency regulations.

WASHINGTON, DC

WHEN: July 11; at 9 am.

WHERE: Office of the Federal Register, First Floor Conference Room, 1100 L Street NW., Washington, DC.

RESERVATIONS: Abram Primus 202-523-3419
Ina Masters 202-523-3419

SEATTLE, WA

WHEN: July 22; at 1:30 pm.

WHERE: North Auditorium, Fourth Floor, Federal Building, 915 2nd Avenue, Seattle, WA.

RESERVATIONS: Call the Portland Federal Information Center on the following local numbers:

Seattle	206-442-0570
Tacoma	206-383-5230
Portland	503-221-2222

SAN FRANCISCO, CA

WHEN: July 24; at 1:30 pm.

WHERE: Room 2007, Federal Building, 450 Golden Gate Avenue, San Francisco, CA.

RESERVATIONS: Call the San Francisco Federal Information Center, 415-556-6600

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Presidential Documents

Title 3—

The President

Presidential Determination No. 86–11 of June 10, 1986

Eligibility of Cape Verde, Mauritania, and Guinea-Bissau To Receive and Make Purchase of Defense Articles and Services Under the Foreign Assistance Act and the Arms Export Control Act

Memorandum for the Honorable George P. Shultz, the Secretary of State

Pursuant to the authority vested in me by Section 503 of the Foreign Assistance Act of 1961, as amended, and Section 3(a)(1) of the Arms Export Control Act, I hereby find that the furnishing, sale and/or lease of defense articles and services to the Governments of Cape Verde, Mauritania, and Guinea-Bissau will strengthen the security of the United States and promote world peace.

You are directed on my behalf to report this finding to the Congress.

This finding shall be published in the **Federal Register.**

Ronald Reagan

THE WHITE HOUSE,
Washington, June 10, 1986.

[FR Doc. 86–14623
Filed 6–25–86; 9:40 am]
Billing code 3195–01–M

Rules and Regulations

Federal Register
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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.
The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

8 CFR Part 238

Contracts With Transportation Lines; Addition of AeroTours Dominicano Airlines

AGENCY: Immigration and Naturalization Service, Justice.

ACTION: Final rule.

SUMMARY: This rule adds AeroTours Dominicano Airlines to the list of carriers which have entered into agreements with the Service to guarantee the passage through the United States in immediate and continuous transit of aliens destined to foreign countries.

EFFECTIVE DATE: June 12, 1986.

FOR FURTHER INFORMATION CONTACT: Loretta J. Shogren, Director, Policy Directives and Instructions, Immigration and Naturalization Service, 425 I Street, NW., Washington, DC 20536, Telephone: (202) 633-3048.

SUPPLEMENTARY INFORMATION: The Commissioner of Immigration and Naturalization entered into an agreement with AeroTours Dominicano on June 12, 1986 to guarantee passage through the United States in immediate and continuous transit of aliens destined to foreign countries.

The agreement provides for the waiver of certain documentary requirements and facilitates the air travel of passengers on international flights while passing through the United States.

Compliance with 5 U.S.C. 553 as to notice of proposed rulemaking and delayed effective date is unnecessary because the amendment merely makes an editorial change to the listing of transportation lines.

In accordance with 5 U.S.C. 605(b), the Commissioner of Immigration and Naturalization certifies that the rule will not have a significant impact on a substantial number of small entities.

This order constitutes a notice to the public under 5 U.S.C. 552 and is not a rule within the definition of section 1(a) of E.O. 12291.

List of Subjects in 8 CFR Part 238

Airlines, Aliens, Government contracts, Travel, Travel restriction.

Accordingly, Chapter I of Title 8 of the Code of Federal Regulations is amended as follows:

PART 238—CONTRACTS WITH TRANSPORTATION LINES

1. The authority citation for Part 238 continues to read as follows:

Authority: Secs. 103 and 238 of the Immigration and Nationality Act, as amended (8 U.S.C. 1103 and 1228).

§ 238.3 [Amended]

In § 238.3 *Aliens in immediate and continuous transit,* the listing of transportation lines in paragraph (b) *Signatory lines* is amended by adding in alphabetical sequence, "AeroTours Dominicano Airlines."

* * * * *

Dated: June 19, 1986.

Richard E. Norton,

Associate Commissioner, Examinations, Immigration and Naturalization Service.

[FR Doc. 86-14431 Filed 6-25-86; 8:45 am]

BILLING CODE 4410-10-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 85-NM-95-AD; Amdt. 39-5342]

Airworthiness Directives; Avions Marcel Dassault-Breguet (AMD) Aviation Mystere Falcon 50 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment adds a new airworthiness directive (AD) that requires inspection, replacement if necessary, and modification to the pressure fueling system on all AMD Mystere-Falcon 50 airplanes. This action is prompted by reports of fuel leaks, and is necessary to detect and prevent leaks in the system, thus removing a potential fire hazard.

EFFECTIVE DATE: August 4, 1986.

ADDRESSES: The service bulletin specified in this AD may be obtained upon request to the AMD-BA Representative, 40 FJC, Teterboro Airport, Teterboro, New Jersey 07608. This information may be examined at the FAA, Northwest Mountain Region, 17900 Pacific Highway South, Seattle, Washington, or the Seattle Aircraft Certification Office, 9010 East Marginal Way South, Seattle, Washington.

FOR FURTHER INFORMATION CONTACT: Ms. Judy Golder, Standardization Branch, ANM-113; telephone (206) 431-2909. Mailing address: FAA, Northwest Mountain Region, 17900 Pacific Highway South, C-68966, Seattle, Washington 98168.

SUPPLEMENTARY INFORMATION: A proposal to amend Part 39 of the Federal Aviation Regulations to include an airworthiness directive, which requires inspection, replacement, if necessary, and modification to the pressure fueling systems on all AMD Mystere Falcon 50 airplanes, was published in the **Federal Register** On October 21, 1985 (50 FR 42561). This action is considered necessary to detect and prevent fuel leaks in the system, thus removing a potential fire hazard.

Interested parties have been afforded an opportunity to participate in the making of this amendment. No comments were received.

After careful review of the available data, the FAA has determined that air safety and the public interest require the adoption of the rule as proposed.

It is estimated that 107 airplanes will be affected by this AD, that it will take approximately 3 manhours per airplane to accomplish the required actions, and that the average labor cost will be $40 per manhour. Repair parts are estimated to be $85 per airplane. Based on these figures, the total cost impact of this AD is estimated to be $21,935.

For the reasons discussed above, the FAA has determined that this regulation is not considered to be major under Executive Order 12291 or significant under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979) and it is further certified under the

criteria of the Regulatory Flexibility Act that this rule will not have a significant economic effect on a substantial number of small entities because the minimal cost of compliance per airplane ($205). A final evaluation has been prepared for this regulation and has been placed in the docket.

List of Subjects in 14 CFR Part 39

Aviation safety, Aircraft.

PART 39—[AMENDED]

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends § 39.13 of Part 39 of the Federal Aviation Regulations as follows:

1. The authority citation for Part 39 continues to read as follows:

Authority: 49 U.S.C. 1354(a), 1421 and 1423; 49 U.S.C. 106(g) (Revised Pub. L. 97-449, January 12, 1983); and 14 CFR 11.89.

2. By adding the following new airworthiness directive:

Avions Marcel Dassault-Breguet Aviation (AMD): Applies to all AMD Mystere Falcon 50 airplanes, certificated in any category. Compliance is required as indicated below. To detect and prevent leaks in the refueling system, accomplish the following:

A. Within the next 30 days after the effective date of this AD, unless accomplished within the last 30 days, and thereafter at intevals not to exceed 30 days, perform an inspection of the guide rod in the refueling connector for damage, in accordance with AMD Service Bulletin F50-28-11(137), dated December 30, 1982. Replace any damaged or leaking guide rod with a serviceable unit prior to further flight. NOTE: After each refueling under pressure, a visual leak check should be performed.

B. Within 6 months after the effective date of this AD, modify the refueling connector by installing a steel guide rod, in accordance with AMD Service Bulletin F50-28-11(137), unless previously accomplished. Accomplishment of this modification provides terminating action for the inspections required by paragraph A., above.

C. An alternative means of compliance or adjustment of the compliance time, which provides an acceptable level of safety, may be used when approved by the Manager, Standardization Branch, ANM-113, FAA, Northwest Mountain Region.

D. Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate airplanes to a base for the accomplishment of inspections and/or modifications required by this AD.

All persons affected by this directive, who have not already received the appropriate service document from the manufacturer, may obtain copies upon request to the AMD-BA Representative, 40 FJC, Teterboro Airport, Teterboro, New Jersey 07608. This document may be examined at the FAA, Northwest Mountain Region, 17900 Pacific Highway South, Seattle, Washington, or the Seattle Aircraft Certification Office, 9010 East Marginal Way South, Seattle, Washington.

This amendment becomes effective August 4, 1986.

Issued in Seattle, Washington, on June 19, 1986.

David E. Jones,

Acting Director, Northwest Mountain Region.

[FR Doc. 86-14394 Filed 6-25-86; 8:45 am]

BILLING CODE 4910-13-M

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14 CFR Part 39

[Docket No. 85-NM-92-AD; Amdt. 39-5343]

Airworthiness Directives; Fokker B.V. Model F28 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment adds a new airworthiness directive (AD) that requires modification of the horizontal stabilizer flight control unit on certain Fokker Model F28 airplanes. Tests have shown that it is necessary to replace a closed plug with a filter plug to prevent buildup of hydraulic fluid in the clutch. This action is necessary to prevent uncontrolled movement of the horizontal stabilizer.

EFFECTIVE DATE: August 4, 1986.

ADDRESSES: The service bulletin specified in this AD may be obtained upon request to the Manager of Maintenance and Engineering, Fokker B.V., Product Support, P.O. Box 7600, 11172J Schiphol Oost, The Netherlands. This information may be examined at the FAA, Northwest Mountain Region, 17900 Pacific Highway South, Seattle, Washington, or the Seattle Aircraft Certification Office, 9010 East Marginal Way South, Seattle, Washington.

FOR FURTHER INFORMATION CONTACT: Ms. Judy Golder, Standardization Branch, ANM-113; telephone (206) 431-2909. Mailing address: FAA, Northwest Mountain Region, 17900 Pacific Highway South, C-68966, Seattle, Washington 98168.

SUPPLEMENTARY INFORMATION: A proposal to amend Part 39 of the Federal Aviation Regulations to include an airworthiness directive, which requires a modification of the horizontal stabilizer flight control unit on certain Fokker Model F28 airplanes to prevent uncontrolled movement of the stabilizer, was published in the **Federal Register** on October 21, 1985 (50 FR 42566).

Interested parties have been afforded an opportunity to participate in the making of this amendment. No comments were received.

After careful review of the available data, the FAA has determined that air safety and the public interest require the adoption of the rule as proposed.

It is estimated that 30 airplanes of U.S. registry will be affected by this AD, that it will take approximately 2 manhours per airplane to accomplish the required actions, and that the average labor cost will be $40 per manhour. Parts are estimated to be $138 per airplane. Based on these figures, the total cost impact of this AD to U.S. operators is estimated to be $6,540.

For the reasons discussed above, the FAA has determined that this regulation is not considered to be major under Executive Order 12291 or significant under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979) and it is further certified under the criteria of the Regulatory Flexibility Act that this rule will not have a significant economic effect on a substantial number of small entities because of the minimal cost of compliance per airplane ($218). A final evaluation has been prepared for this regulation and has been placed in the docket.

List of Subjects in 14 CFR Part 39

Aviation safety, Aircraft.

PART 39—[AMENDED]

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends § 39.13 of Part 39 of the Federal Aviation Regulations as follows:

1. The authority citation for Part 39 continues to read as follows:

Authority: 49 U.S.C. 1354(a), 1421 and 1423; 49 U.S.C. 106(g) (Revised Pub. L. 97-449, January 12, 1983); and 14 CFR 11.89.

2. By adding the following new airworthiness directive:

FOKKER B.V.: Applies to Model F28 series airplanes as listed in Fokker Service Bulletin F28/27-161, dated May 6, 1985, certificated in any category. Compliance is required within 6 months after the effective date of this AD. To prevent uncontrolled movement of the horizontal stabilizer, accomplish the following, unless previously accomplished:

A. Modify the horizontal stabilizer control unit in accordance with Fokker Service Bulletin F28/27-161, dated May 6, 1985.

B. An alternate means of compliance or adjustment of the compliance time which provides an acceptable level of safety, may be used when approved by the Manager,

Stabilization Branch, ANM-113, FAA, Northwest Mountain Region.

C. Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate airplanes to a base for the accomplishment of inspections and/or modifications required by this AD.

All persons affected by this directive, who have not already received the appropriate service document from the manufacturer, may obtain copies upon request to the Manager of Maintenance and Engineering, Fokker B.V., Product Support, P.O. Box 7600, 1117ZJ Schipol Oost, The Netherlands. This document may be examined at the FAA, Northwest Mountain Region, 17900 Pacific Highway South, Seattle, Washington, or the Seattle Aircraft Certification Office, 9010 East Marginal Way South, Seattle, Washington.

This amendement becomes effective August 4, 1986.

Issued in Seattle, Washington, on June 19, 1986.

David E. Jones,

Acting Director, Northwest Mountain Region.

[FR Doc. 86-14393 Filed 6-25-86; 8:45 am]

BILLING CODE 4910-13-M

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14 CFR Part 39

[Docket No. 85-NM-107-AD; Amdt. 39-5341]

Airworthiness Directives; Israel Aircraft Industries (IAI) Models 1121, 1121A, 1121B, 1123, 1124, and 1124A Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment adds a new airworthiness directive (AD) that requires repetitive inspections to detect cracks and replacement, as necessary, of the horizontal stabilizer aft spar splice fitting on all IAI Models 1121, 1121A, 1121B, 1123, 1124, and 1124A series airplanes. Cracks have been reported in the splice fitting lugs on several airplanes. This condition, if not corrected, could lead to failure of the fitting, which would compromise the structural integrity of the horizontal stabilizer assembly.

EFFECTIVE DATE: August 4, 1986.

ADDRESSES: The service bulletins specified in this AD may be obtained upon request to Israel Aircraft Industries, Delaware Office, P.O. Box 10086, Wilmington, Delaware 19850. These documents may be examined at the FAA, Northwest Mountain Region, 17900 Pacific Highway South, Seattle, Washington, or the Seattle Aircraft Certification Office, 9010 East Marginal Way South, Seattle, Washington.

FOR FURTHER INFORMATION CONTACT: Ms. Judy Golder, Standardization Branch, ANM-113; telephone (206) 431-2909. Mailing address: FAA, Northwest Mountain Region, 17900 Pacific Highway South, C-68966, Seattle, Washington 98168.

SUPPLEMENTARY INFORMATION: A proposal to amend Part 39 of the Federal Aviation Regulations to include an airworthiness directive, which requires repetitive inspections and replacement, as necessary, of the horizontal stabilizer aft spar splice fitting on all Israel Aircraft Industries Models 1121, 1121A, 1121B, 1123, 1124, and 1124A series airplanes was published in the **Federal Register** on December 19, 1985 (50 FR 51707).

Interested parties have been afforded an opportunity to participate in the making of this amendment. Three comments were received.

The first commenter supported the AD, but suggested that the service bulletin titles be included with the service bulletin numbers to prevent confusion. The FAA agrees this comment and has included the titles in the final rule.

The second and third commenters both stated that the AD, as written, does not address a wear problem which they have both experienced with their airplanes. They also suggested more stringent repetitive inspection requirements. The FAA has notified the Israel Civil Aviation Authority (CAA) about these comments and has requested an investigation. Further rulemaking action may be initiated as a result of the findings of the investigation.

After careful review of the available data, the FAA has determined that air safety and the public interest require the adoption of the rule as proposed with the changes noted above.

It is estimated that 350 airplanes of U.S. registry will be affected by this AD, that it will take approximately 2 manhours per airplane to accomplish the required actions, and that the average labor cost will be $40 per manhour. Based on these figures, the total cost impact of this AD to U.S. operators is estimated to be $28,000 per inspection cycle.

For the reasons discussed above, the FAA has determined that this regulation is not considered to be major under Executive Order 12291 or significant under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979) and it is further certified under the criteria of the Regulatory Flexibility Act that this rule will not have a significant economic effect on a substantial number of small entities because of the minimal cost of compliance per airplane ($80). A final evaluation has been prepared for this regulation and has been placed in the docket.

List of Subjects in 14 CFR Part 39

Aviation safety, Aircraft.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends § 39.13 of Part 39 of the Federal Aviation Regulations as follows:

1. The authority citation for Part 39 continues to read as follows:

Authority: 49 U.S.C. 1354(a), 1421 and 1423; 49 U.S.C. 106(g) (Revised Pub. L. 97-449, January 12, 1983); and 14 CFR 11.89.

2. By adding the following new airworthiness directive:

Israel Aircraft Industries (IAI): Applies to all Models 1121, 1121A, 1121B, 1123, 1124, and 1124A airplanes, certificated in any category. Compliance is required as indicated below. To detect cracks in the hinge lugs of the horizontal stabilizer aft spar splice fitting (hinge assembly), accomplish the following, unless previously accomplished:

A. Within the next 75 flight hours time-in-service, unless previously inspected within the last 525 flight hours time-in-service, inspect the horizontal stabilizer aft spar splice fitting (hinge assembly), part number 453005-501, in accordance with the following IAI service bulletins titled, "Horizontal Stabilizer Aft Spar Splice Fitting PN 453005-501 (Hinge Assembly) Inspection."

Model	Service bulletin
1121, 1121A, 1121B	1121-55-003, dated April 2, 1985.
1123	1123-55-006, dated April 2, 1985.
1124, 1124A	1124-55-020, dated April 2, 1985.

B. If no cracks are found, repeat the inspection required by paragraph A., above, at intervals not to exceed 600 hours time-in-service.

C. If cracks are found, replace the splice fitting prior to further flight, in accordance with the following IAI service bulletins titled, "Horizontal Stabilizer Assembly—Inspection, Repair, and Improvement (AFC 2037)."

Model	Service bulletin
1121, 1121A, 1121B	1121-55-004, dated August 5, 1985.
1123	1123-55-007, dated August 5, 1985.
1124, 1124A	1124-55-021, dated August 5, 1985.

If the installation improvement modifications described in paragraph D(2) of each service bulletin is performed, repeat the inspection of paragraph A. of this AD at intervals not to exceed 2,400 hours time-in-service for subsequent inspections. If the

installation improvement modification is not accomplished, the inspections must be repeated in accordance with paragraph B. of this AD.

D. An alternate means of compliance or adjustment of the compliance time, which provides an acceptable level of safety, may be used when approved by the Manager, Standardization Branch, ANM-113, FAA, Northwest Mountain Region.

E. Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate airplanes to a base for the accomplishment of inspections and/or modifications required by this AD.

All persons affected by this directive who have not already received the appropriate service bulletins from the manufacturer may obtain copies upon request to Israel Aircraft Industries, Delaware Office, P.O. Box 10086, Wilmington, Delaware 19850. These documents may be examined at the FAA, Northwest Mountain Region, 17900 Pacific Highway South, Seattle, Washington, or the Seattle Aircraft Certification Office, 9010 East Marginal Way South, Seattle, Washington.

This amendment becomes effective August 4, 1986.

Issued in Seattle, Washington, on June 19, 1986.

David E. Jones,

Acting Director, Northwest Mountain Region.

[FR Doc. 86-14396 Filed 6-25-86; 8:45 am]

BILLING CODE 4910-13-M

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14 CFR Part 39

[Docket No. 85-NM-77-AD; Amdt. 39-5344]

Airworthiness Directives; Short Brothers, Ltd., Model SD3-60 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment adds a new airworthiness directive (AD) that requires replacement of certain ⅛-inch diameter standard blind rivets in the horizontal stabilizer lower skin to rear spar attachment joint with larger Cherrymax rivets and bolts on certain Short Brothers Model SD3-60 airplanes. This action is prompted by reports of loose fasteners and is necessary to prevent the stabilizer skin from detaching from the spar chord. These failures, if not corrected, could compromise the structural capability of the stabilizer.

EFFECTIVE DATE: August 4, 1986.

ADDRESSES: The service bulletin specified in this AD may be obtained upon request to Shorts Aircraft, 1725 Jefferson Davis Highway, Suite 510, Arlington, Virginia 22202. This document may be examined at the FAA, Northwest Mountain Region, 17900 Pacific Highway South, Seattle, Washington, or the Seattle Aircraft Certification Office, 9010 East Marginal Way South, Seattle, Washington.

FOR FURTHER INFORMATION CONTACT: Ms. Judy Golder, Standardization Branch, ANM-113; telephone (206) 431-2909. Mailing address: FAA, Northwest Mountain Region, 17900 Pacific Highway South, C-68966, Seattle, Washington 98168.

SUPPLEMENTARY INFORMATION: A proposal to amend Part 39 of the Federal Aviation Regulations to include an airworthiness directive, which requires the replacement of certain blind rivets in the horizontal stabilizer on Short Brothers Model SD3-60 airplanes, was published in the **Federal Register** on August 26, 1985 (50 FR 34496).

Interested parties have been afforded an opportunity to participate in the making of this amendment. Two comments were received. The first commenter supported the rule. The second commenter also supported the rule, but believed the loose fasteners might be the result of high vibration levels experienced during takeoff and landing. The commenter recommended that the vibration levels be reevaluated, and that the AD be expanded to include the Shorts Model SD3-30 airplane. The FAA has notified the United Kingdom Civil Aviation Authority about these comments. Additional rulemaking may be initiated as a result of the findings.

After careful review of the available data, the FAA has determined that air safety and the public interest require the adoption of the rule as proposed.

It is estimated that 33 airplanes of U.S. registry will be affected by this AD, that it will take approximately 48 manhours per airplane to accomplish the required actions, and that the average labor cost will be $40 per manhour. The cost of modification parts is estimated to be $50 per airplane. Based on these figures, the total cost impact of this AD to U.S. operators is estimated to be $65,010.

For the reasons discussed above, the FAA has determined that this regulation is not considered to be major under Executive Order 12291 or significant under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979) and it is further certified under the criteria of the Regulatory Flexibility Act that this rule will not have a significant economic effect on a substantial number of small entities because of the minimal cost of compliance per airplane ($1,970). A final evaluation has been prepared for this regulation and has been placed in the docket.

List of Subjects in 14 CFR Part 39

Aviation safety, Aircraft.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends § 39.13 of Part 39 of the Federal Aviation Regulations as follows:

1. The authority citation for Part 39 continues to read as follows:

Authority: 49 U.S.C. 1354(a), 1421 and 1423; 49 U.S.C. 106(g) (Revised Pub. L. 97-449, January 12, 1983); and 14 CFR 11.89.

2. By adding the following new airworthiness directive:

Short Brothers, Ltd.: Applies to Model SD3-60 airplanes, serial numbers SH3601 through SH3676 inclusive, certificated in any category. Compliance is required within 90 days after the effective date of this AD. To maintain the structural integrity of the horizontal stabilizer, accomplish the following, unless previously accomplished:

1. Modify the horizontal stabilizer lower skin to spar attachment in accordance with Short Brothers, Ltd., Service Bulletin SD36-55-06, Revision 1, dated May 1985.

2. An alternate means of compliance or adjustment of the compliance time, which provides an acceptable level of safety, may be used when approved by the Manager, Standardization Branch, ANM-113, FAA, Northwest Mountain Region.

3. Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate airplanes to a base for the accomplishment of inspections and/or modifications required by this AD.

All persons affected by this directive who have not already received the appropriate service document from the manufacturer may obtain copies upon request to Shorts Aircraft, 1725 Jefferson Davis Highway, Suite 510, Arlington, Virginia 22202. This document may be examined at the FAA, Northwest Mountain Region, 17900 Pacific Highway South, Seattle, Washington, or the Seattle Aircraft Certification Office, 9010 East Marginal Way South, Seattle, Washington.

This amendment becomes effective August 4, 1986.

Issued in Seattle, Washington, on June 19, 1986.

David E. Jones,

Acting Director, Northwest Mountain Region.

[FR Doc. 86-14392 Filed 6-25-86; 8:45 am]

BILLING CODE 4910-13-M

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14 CFR Part 39

[Docket No. 86-NM-137-AD; Amdt. 39-5340]

Airworthiness Directives; Sperry Corporation, Aerospace & Marine Group, AHZ-600 Attitude and Heading Reference System (AHRS)

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD) that requires modification of the Sperry Corporation, Aerospace and Marine Group, AHZ-600 Attitude and Heading Reference System (AHRS). This AD is prompted by reports of an unusually high number of in-flight system failures, resulting in loss of attitude/heading presentations. This condition, if not corrected, could result in loss of essential attitude information.

DATES: Effective July 14, 1986.

Compliance is required within 30 days after the effective date of this AD, unless already accomplished.

ADDRESSES: The applicable service information may be obtained from Sperry Corporation, Aerospace & Marine Group, P.O. Box 29000, Phoenix, Arizona 85038-9000. This information may be examined at the FAA, Northwest Mountain Region, 17900 Pacific Highway South, C-68966, Seattle, Washington 98168, or at the Western Aircraft Certification Office, 15000 Aviation Boulevard, Hawthorne, California 90261.

FOR FURTHER INFORMATION CONTACT: Mr. Elvin Wheeler, Aerospace Engineer, Systems & Equipment Section, ANM-173W, FAA, Northwest Mountain Region, Western Aircraft Certification Office, 15000 Aviation Boulevard, Hawthorne, California 90261; telephone (213) 297-1132.

SUPPLEMENTARY INFORMATION: The FAA has received numerous reports of in-flight failures of the Sperry AHZ-600 AHRS. The AHZ-600 is intended to provide the primary source of attitude information for use in flight. There have been two reported cases of dual failures, i.e., loss of both the first pilot's AHRS and the second pilot's AHRS at the same time. Failures such as this can result in the loss of essential attitude information, which is critical to the safety of flight.

It has been determined that the AH-600 Strapdown Attitude and Heading Reference Unit (AHRU), which is a component of the Sperry AHZ-600 AHRS, is the cause of the reported problems. Sperry Corporation, Aerospace and Marine Group has developed a series of modifications to improve the reliability of the AH-600 Strapdown AHRU. To ensure a minimum level of safety and continued safe flight, the FAA has determined that all modifications through Modification AB to the AH-600 Strapdown AHRU must be incorporated.

Sperry Corporation has issued the following Service Bulletins:

21-1985-175, dated April 7, 1986 (Modification T);
21-1985-186, dated April 7, 1986 (Modifications S and V);
21-1985-187, dated April 7, 1986 (Modification U);
21-1986-19, dated April 22, 1986 (Modification Z);
21-1986-20, dated April 22, 1986 (Modification AA); and
21-1986-29, dated April 22, 1986 (Modification AB).

Sperry has advised the FAA that the AHZ-600 AHRS is known to have been installed in DeHavilland Model DHC-8, British Aerospace Model BAe 125-800, Cessna Model 650, and Aerospatiale Model ATR-42 series airplanes.

Since this situation is likely to exist or develop on other equipment of the same type design, this AD requires incorporation of all the modifications through modification AB to the Sperry AH-600 Strapdown AHRU, in accordance with the Sperry service bulletins referenced above.

Since a situation exists that requires immediate adoption of this regulation, it is found that notice and public procedure hereon are impracticable, and good cause exists for making this amendment effective in less than 30 days.

The Federal Aviation Administration has determined that this regulation is an emergency regulation that is not considered to be major under Executive Order 12291. It is impracticable for the agency to follow the procedures of Order 12291 with respect to this rule since the rule must be issued immediately to correct an unsafe condition in aircraft. It has been further determined that this document involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979). If this action is subsequently determined to involve a significant/major regulation, a final regulatory evaluation or analysis, as appropriate, will be prepared and placed in the regulatory docket (otherwise, an evaluation or analysis is not required).

List of Subjects in 14 CFR Part 39

Aviation safety, Aircraft.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends § 39.13 of Part 39 of the Federal Aviation Regulations as follows:

1. The authority citation for Part 39 continues to read as follows:

Authority: 49 U.S.C. 1354(a), 1421 and 1423; 49 U.S.C. 106(g) (Revised Pub. L. 97-449, January 12, 1983); and 14 CFR 11.89.

2. By adding the following new airworthiness directive:

Sperry Corporation, Aerospace and Marine Group: Applies to Sperry Corporation AHZ-600 Attitude Heading Reference System (AHRS), known to be installed in, but not limited to, DeHavilland Model DHC-8, British Aerospace Model BAe 125-800, Cessna Model 650, and Aerospatiale Model ATR-42 series airplanes, certificated in any category. Compliance is required within 30 days after the effective date of this AD, unless previously accomplished.

To prevent loss of attitude/heading reference information, accomplish the following:

A. Modify the Sperry Corporation AH-600 Strapdown Attitude and Heading Reference Unit (AHRU) by incorporating modifications in accordance with the following Sperry Service Bulletins or later revisions approved by the Manager, Western Aircraft Certification Office, FAA, Northwest Mountain Region:

21-1985-175, dated April 7, 1986 (Modification T);
21-1985-186, dated April 7, 1986 (Modifications S & V);
21-1985-187, dated April 7, 1986 (Modification U);
21-1986-19, dated April 22, 1986 (Modification Z);
21-1986-20, dated April 22, 1986 (Modification AA); and
21-1986-29, dated April 22, 1986 (Modification AB).

B. Alternate means of compliance which provide an acceptable level of safety may be used when approved by the Manager, Western Aircraft Certification Office, FAA, Northwest Mountain Region.

C. Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate airplanes to a base in order to comply with the requirements of this AD.

All persons affected by this directive who have not already received the appropriate service documents from the manufacturer may obtain copies upon request to Sperry Corporation, Aerospace & Marine Group, P.O. Box 29000, Phoenix, Arizona 85038-9000. These documents may be examined at the FAA, Northwest Mountain Region, 17900 Pacific Highway South, Seattle, Washington, or the Western Aircraft Certification Office, 15000 Aviation Boulevard, Hawthorne, California.

This amendment becomes effective July 14, 1986.

Issued in Seattle, Washington, on June 19, 1986.

David E. Jones,

Acting Director, Northwest Mountain Region.

[FR Doc. 86-14395 Filed 6-25-86; 8:45 am]

BILLING CODE 4910-13-M

14 CFR Part 71

[Airspace Docket No. 86-ASO-22]

Alteration of Control Zone, Atlanta, GA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment updates the geographical coordinates, runway numbers and navigational aids upon which the Atlanta, Georgia, control zone is predicated. No significant change in airspace designation will result from this action.

DATES: Effective date: 0901 UTC, October 23, 1986. Comments must be received on or before August 28, 1986.

ADDRESSES: Send comments on the rule in triplicate to:

Federal Aviation Administration, ASO-530, Manager, Airspace and Procedures Branch, Docket No. 86-ASO-22, Air Traffic Division, P.O. Box 20636, Atlanta, Georgia 30320.

The official docket may be examined in the Office of the Regional Counsel, Room 652, 3400 Norman Berry Drive, East Point, Georgia 30344, telephone: (404) 763-7646.

FOR FURTHER INFORMATION CONTACT: Donald Ross, Supervisor, Airspace Section, Airspace and Procedures Branch, Air Traffic Division, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone: (404) 763-7646.

SUPPLEMENTARY INFORMATION:

Request for Comments on the Rule

Although this action is in the form of a final rule, which involves editorial corrections to the Atlanta, Georgia, control zone, and was not preceded by notice and public procedure, comments are invited on the rule. When the comment period ends, the FAA will use the comments submitted, together with other available information, to review the regulation. After the review, if the FAA finds that changes are appropriate, it will initiate rulemaking proceedings to amend the regulation. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in evaluating the effects of the rule and determining whether additional rulemaking is needed. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy aspects of the rule that might suggest the need to modify the rule.

The Rule

The purpose of this amendment to § 71.171 of Part 71 of the Federal Aviation Regulations (14 CFR Part 71) is to correctly list the geographical coordinates, runway numbers and type of navigational aids upon which the Atlanta, Georgia, control zone is predicated. Section 71.171 of Part 71 of the Federal Aviation Regulations was republished in FAA Order 7400.6B dated January 2, 1986.

Under the circumstances presented, the FAA concludes that there is a need to alter the description of the Atlanta, Georgia, control zone to properly reflect the data upon which airspace is designated. The changes are so minor and nonsubstantive, I find that notice or public procedure under 5 U.S.C. 553(b) is unnecessary.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore, (1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Aviation safety, Control zone.

PART 71—[AMENDED]

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, Part 71 of the Federal Aviation Regulations (14 CFR Part 71) is amended, as follows:

1. The authority citation for Part 71 continues to read as follows:

Authority: 49 U.S.C. 1348(a), 1354(a), 1510; Executive Order 10854; 49 U.S.C. 106(g) (Revised Public Law 97-449, January 12, 1983); 14 CFR 11.69.

2. Section 71.171 is amended as follows:

Atlanta, GA—[Revised]

Within a 5-mile radius of the William B. Hartsfield Atlanta International Airport (lat. 33°38'25" N, long. 84°25'37" W.); within 2 miles each side of Atlanta ILS Runway 26R localizer east course, extending from the 5-mile radius zone to the LOM; within 2 miles each side of Atlanta ILS Runway 27L localizer east course, extending from the 5-mile radius zone to the OM; within 2 miles each side of Atlanta ILS Runway 9R localizer west course, extending from the 5-mile radius zone to the OM; within 2 miles each side of Atlanta ILS Runway 8L localizer west course, extending from the 5-mile radius zone to the LOM.

Issued in East Point, Georgia, on June 17, 1986.

James L. Wright,

Acting Manager, Air Traffic Division, Southern Region.

[FR Doc. 86-14398 Filed 6-25-86; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF DEFENSE

Department of the Air Force

32 CFR Part 901

Appointment to the United States Air Force Academy

AGENCY: Department of the Air Force, Department of Defense.

ACTION: Final rule.

SUMMARY: The Department of the Air Force is revising Part 901 of Chapter VII, Title 32, of the Code of Federal Regulations. This part tells civilian and enlisted personnel (including Air Force Reserve and National Guard) the methods of applying and the requirements and procedures for appointing young men and women to the United States Air Force Academy.

EFFECTIVE DATE: July 28, 1986.

FOR FURTHER INFORMATION CONTACT: Ms. Norma Nottingham, telephone (202) 697-7116.

SUPPLEMENTARY INFORMATION: This revision changes nominating authority of Panama Canal Commission to Administrator; redefines alcohol and drug abuse; changes physical aptitude examination to Candidate Fitness Test Requirement; revises foreign cadet program; defines appointment vacancy selection, qualified alternate selection, and charging of appointees; and changes military obligation of a cadet to not more than 8 years.

Portions of this Part 901 implement DOD Directive 5160.20, "Appointment of Foreigners to the Academies," and are exempt from inviting public comment under rulemaking procedures in 5 U.S.C. 553.

List of Subjects in 32 CFR Part 901

Military academies.

The regulation on Appointment to the United States Air Force Academy, Part 901, is revised to read as follows:

PART 901—APPOINTMENT TO THE UNITED STATES AIR FORCE ACADEMY

Sec.
901.0 Purpose.

Subpart A—Appointment Policies and Requirements

901.1 General policy.
901.2 Appointments and nominations.
901.3 Categories of nominations for appointment.
901.4 Basic eligibility requirements.
901.5 Academic examination requirements.
901.6 Candidate fitness test requirement.

Subpart B—Nomination Procedures and Requirements

901.7 Precandidate evaluation.
901.8 Congressional and U.S. Possessions categories.
901.9 Vice-Presidential category.
901.10 Presidential category.
901.11 Children of deceased or disabled veterans and children of military or civilian personnel in a missing status category.
901.12 Honor military and honor Naval schools—AFROTC and AFJROTC category.
901.13 Children of Medal of Honor recipients category.
901.14 Regular airmen category.
901.15 Reserve airmen category.
901.16 Superintendent category.
901.17 Foreign students category.
901.18 Appointment vacancy selection.
901.19 Qualified alternate selection.
901.20 Notice of nomination.
901.21 Notification of selection or nonselection.
901.22 Notification of change of address or station assignment.
901.23 Filling Presidential and airmen nominating categories.
901.24 Supply of forms.
901.25 Obligation of cadet appointment.
901.26 Cadet's oath of allegiance.
901.27 Charging of appointees.
901.28 OMB approval of information collection requirements.

Authority: 10 U.S.C., Chapter 903, and 10 U.S.C. 8012, except as otherwise noted.

Note.—This part is derived from Air Force Regulation 53-10, October 22, 1985.

Part 806 of this chapter states the basic policies and instructions governing the disclosure of records and tells members of the public what they must do to inspect or obtain copies of the material referenced herein.

§ 901.0 Purpose.

This part tells civilian and enlisted personnel (including Air Force Reserve and National Guard) the methods of applying and the requirements and procedures for appointing young men and women to the United States Air Force Academy.

Note.—This part is affected by the Privacy Act of 1974. The systems of records prescribed in this part are authorized by 10 U.S.C., Chapter 903; and 10 U.S.C. 8012. Each form that is subject to the provisions of Part 806b.5 of this chapter, and is required by this Part, contains a Privacy Act Statement either incorporated in the body of the document or in a separate statement accompanying each such document.

Subpart A—Appointment Policies and Requirements

§ 901.1 General policy.

Appointments as U.S. Air Force Academy cadets are offered to those candidates having the strongest potential to become successful career officers. Offers of appointment are made according to the law and guidance provided by HQ USAF to most effectively accomplish the Academy's mission. All candidates are appointed as cadets under the authority of the President; however, an appointment is conditional until the candidate is admitted.

§ 901.2 Appointments and nominations.

Appointments and nominations are based on statutory authority contained in 10 U.S.C., Chapter 903. Specific authorities may nominate eligible applicants for appointment vacancies at the Academy. Each applicant must obtain a nomination to receive an appointment. Applicants may apply for a nomination in each category in which they are eligible.

§ 901.3 Categories of nominations for appointment.

All appointees must have a nomination in at least one of the following categories:

(a) Congressional and U.S. Possessions categories include the following nominating authorities:

(1) U.S. Senators and Representatives.

(2) Delegates in Congress from the District of Columbia, Guam, Virgin Islands, and American Samoa.

(3) Resident Commissioner of Puerto Rico.

(4) Governor of Puerto Rico.

(5) Administrator of the Panama Canal Commission.

(b) Vice-Presidential category.

(c) Presidential competitive category.

(d) Children of deceased or disabled veterans and children of military or civilian personnel in missing status competitive category.

(e) Honor military and honor Naval schools, Air Force Reserve Officers' Training Corps (AFROTC), and Air Force Junior Reserve Officers' Training Corps (AFJROTC) competitive category.

(f) Children of Medal of Honor recipients category.

(g) Air Force enlisted regular competitive category.

(h) Air Force enlisted reserve competitive category.

(i) Superintendent competitive category.

(j) Foreign students competitive category (40 foreign persons designated to receive instruction under 10 U.S.C 9344).

§ 901.4 Basic eligibility requirements.

Each applicant must meet the following eligibility requirements:

(a) *Age.* Applicants must be at least 17, and not have passed their 22nd birthday on July 1 of the year of entry into the Academy.

(b) *Citizenship.* Except for students sponsored by foreign governments under 10 U.S.C. 9344, applicants must be citizens or nationals of the United States. All incoming cadets must verify citizenship status before admission:

(1) For American-born citizens, certified birth certificate presented to the Director of Admissions (USAFA/RRS), U.S. Air Force Academy, Colorado Springs CO 80840-5651 before administration of oath of appointment.

(2) Foreign cadets must present certified copies of certificates of arrival and nationalization or citizenship to USAFA/RRS before administration of oath of appointment.

Note.—Facsimiles, copies, photographs or otherwise of birth certificate or certificate of citizenship will not be accepted unless properly certified by the raised seal of the issuing authority.

(c) *Domicile.* If nominated by an authority designated in the Congressional and U.S. Possessions categories, the applicant must be domiciled within the constituency of such authority.

(d) *Exemplary standards.* Applicants must be of highest moral character, personal conduct, and integrity. The Academy requires applicants to explain or clarify any of the circumstances below. For any military applicant or nominee whose official records indicate questionable background, commanders furnish the applicable information to USAFA/RRS.

(1) Applicant is or has been a conscientious objector. In this case, an affidavit is required stating that such beliefs and principles have been abandoned so far as they pertain to willingness to bear arms and give full

and unqualified military service to the United States.

(2) Any facts that indicate the applicant's appointment may not be consistent with the interests of national security.

(3) Conviction by court-martial of other than a "minor offense" (MCM, 1984, Part V, paragraph 1e, page V-1) or conviction of a felony in a civilian court.

(4) Elimination from any officer training program or any preparatory school of the Army, Navy, or Air Force Academies for military inaptitude, indifference, or undesirable traits of character. This includes any person who resigned in lieu of impending charges or who was eliminated by official action.

(5) Habitual alcohol misuse or drug abuse which exceeds the standards of AFR 30-2 is disqualifying.

(6) Any behavior, activity, or association showing the applicant's conduct is incompatible with exemplary standards of personal conduct, moral character, and integrity.

(e) *Marital status.* Applicant must be unmarried. (Any cadet who marries is disenrolled from the Academy.)

(f) *Dependents.* Applicant must not have a legal obligation to support a child, children, or any other person.

Note.—For the purpose of this regulation, children are defined as the natural children of a parent and adopted children whose adoption proceedings were initiated before their 15th birthday.

(g) *Medical requirements for admission.* Before being admitted to the academy, candidates must take a medical examination and meet the medical standards outlined in AFRs 160-13 and 160-43. All candidates must meet the medical standards specified by the Secretary of the Air Force. Waivers may be granted by the Air Force Academy Command Surgeon. As specified by HQ USAF, most of the candidates admitted to the Academy must meet the eligibility standards for flying training.

§ 901.5 Academic examination requirements.

Before being offered an appointment, candidates must take either the College Board Admission Testing Program (ATP) or the American College Testing Program (ACT) test.

(a) *ATP.* A candidate who elects to use the ATP tests must take the Scholastic Aptitude Tests (SAT). The candidate is encouraged but not required to take achievement tests of English Composition and Level 1 (Standard) Mathematics or Level II (Intensive) Mathematics. (Level 1 recommended for candidates without advanced high school mathematics.)

(b) *ACT.* Candidates who elect to use the ACT tests must take the complete battery of tests: English, mathematics, social studies, and natural sciences.

§ 901.6 Candidate fitness test requirement.

Before being offered an appointment, candidates must take a Candidate Fitness Test (CFT) which consists of exercises designed to measure muscular strength, coordination, and aerobic power. Waivers to the CFT requirement may be granted by the Air Force Academy Director of Athletics if a candidate's participation in high school athletics conflicts with test administration dates and the candidate clearly demonstrates an acceptable level of physical fitness.

Subpart B—Nomination Procedures and Requirements

§ 901.7 Precandidate evaluation.

The Air Force Academy conducts a precandidate evaluation program as an initial step in the admissions process and as an aid to Members of Congress in screening their applicants for nomination.

(a) Applicants normally are sent a precandidate packet, including USAFA Form 149, Precandidate Questionnaire, with a request for the applicant to provide academic, athletic, leadership, and medical information.

(b) The Academy evaluates the precandidate information and provides an analysis to appropriate congressional offices. Such information gives the nominating authorities an indication of the applicant's potential to qualify for admission and the applicant's self-reported medical status; it does not, however, reflect the applicant's final admission status. It is intended only to aid in selecting the best-qualified applicants for nomination.

(c) Applicants whose evaluation indicates they are fully qualified will be notified and advised to seek a nomination. Individuals whose evaluations reflect areas needing improvement are informed and encouraged to submit additional test scores or information in an effort to meet the qualifying levels.

§ 901.8 Congressional and U.S. Possessions categories.

Individuals who meet the basic eligibility requirements of § 901.4 may apply for a nomination according to their domicile (permanent legal residence).

(a) U.S. Senators, U.S. Representatives, the District of Columbia Delegate to the House of Representatives, and the Resident Commissioner of Puerto Rico are each authorized a quota of five cadets attending the Academy at any one time. If a vacancy occurs in their quota, each may nominate ten candidates to fill each vacancy.

(b) Delegates in Congress from Guam and from the Virgin Islands are each authorized a quota of two cadets attending the Academy at any one time. If a vacancy occurs in their quota, each may make ten nominations. Eligible residents may apply for a nomination directly to their Delegate.

(c) The Governor of Puerto Rico, the Delegate from American Samoa, and the Panama Canal Commission Administrator may each have one cadet attending the Academy and each may nominate ten candidates to fill their vacancy.

(1) Applicants domiciled in and natives of Puerto Rico may apply to the Governor of Puero Rico in addition to the Resident Commissioner.

(2) Applicants domiciled in American Samoa may apply to their Delegate.

(3) Children of civilian personnel of the U.S. Government residing in the Republic of Panama who are citizens of the United States may apply to the Panama Canal Commission Administrator.

(d) Nominating authorities in these categories normally submit their nominations by January 31 for the class entering the following summer.

(1) These nominating authorities may nominate only if a vacancy occurs from their authorized quota of cadets attending the Academy. Vacancies normally occur from graduation or separation of cadets from the Academy. Failure of a member of a graduating class to complete the Academy program with his class does not delay the admission of his or her successor. HQ USAF/DPPA maintains the master records of cadets nominated and appointed, determines vacancies in each nominating authority's quota, and validates nominations submitted by each nominating authority.

(2) These nominating authorities forward their nominations on DD Form 1870, Nomination for Appointment to the U.S. Military Academy, Naval Academy, or Air Force Academy, for each Air Force Academy nominee through HQ USAF/DPPA, Washington, DC 20330-5060, to USAFA/RRS, USAF Academy, Colorado Springs, CO 80840-5651.

§ 901.9 Vice-Presidential category.

The Vice President of the United States nominates from the United States at large, and is authorized a quota of five cadets attending the Academy at

any one time. For each vacancy occurring in the quota, ten individuals may be nominated to fill the vacancy. Requests for a nomination are submitted directly to the Vice President no later than October 31. Any individual who meets the basic eligibility requirements of § 901.4 may apply to the Vice President for a nomination. The Vice President forwards nominations on DD Form 1870 for each Air Force Academy nominee through HQ USAF/DPPA, Washington, DC 20330-5060, to USAFA/RRS, USAF Academy, Colorado Springs, CO 80840-5651.

§ 901.10 Presidential category.

Appointments to fill vacancies from this category are made from candidates in order of merit. One hundred appointments are authorized each year.

(a) The child of a Regular or Reserve member of the Armed Forces of the United States is eligible for nomination if:

(1) The parent is on active duty and has completed 8 years of continuous active duty service (other than for training) by July 1 of the year that the candidate would enter the U.S. Air Force Academy; or

(2) The parent was retired with pay or was granted retired or retainer pay (children of reservists retired and receiving pay pursuant to 10 U.S.C., Chapter 67, are ineligible); or

(3) The parent died after retiring with pay or died after being granted retired or retainer pay (children of such reservists who were retired and receiving pay pursuant to 10 U.S.C., Chapter 67, are ineligible); and

(4) The applicant does not meet the eligibility requirements for the Children of Deceased or Disabled Veterans (CODDV) nomination category. (By law, a person eligible for appointment consideration under the DOCCV category is not a candidate in the Presidential category.)

(b) An eligible individual applies to USAFA/RRS, U.S. Air Force Academy, Colorado Springs, CO 80840-5651. A suggested letter format is included in the precandidate packet. The nominating period opens on May 1 and closes January 31. Applicants do not write directly to the President of the United States, since the applications are processed by the Air Force Academy.

Note.—For the purpose of this category, children are defined as the natural children of a parent and adopted children whose adoption proceedings were initiated before their 15th birthday.

§ 901.11 Children of deceased or disabled veterans and children of military or civilian personnel in a missing status category.

Appointments to fill vacancies from this competitive category are made from candidates in order of merit. Appointments authorized in this category are limited to 65 cadets at the Academy at any one time.

(a) The child of a deceased or disabled member of the Armed Forces of the United States is eligible for nomination if:

(1) The parent was killed in action or died of wounds or injuries received or diseases contracted while in active service or of preexisting injury or disease aggravated by active service; or

(2) The parent has a permanent service-connected disability rated at not less than 100 percent resulting from wounds or injuries received or diseases contracted while in active service, or of preexisting injury or disease aggravated by active service.

(b) The child of a parent who is in "missing status" is eligible if the parent is a member of the Armed Services or a civilian employee in active government service who is officially carried or determined to be absent in a status of missing; missing in action; interned in a foreign country; captured, beleaguered, or beseiged by a hostile force; or detained in a foreign country against the person's will.

(c) To request a nomination in this category, an individual submits an application to USAFA/RRS between May 1 and January 31. A suggested letter format is included in the precandidate packet.

Note.—For the purpose of this category, children are defined as the natural children of a parent and adopted children whose adoption proceedings were initiated before the 15th birthday.

§ 901.12 Honor military and honor Naval schools—AFROTC and AFJROTC category.

Appointments to fill vacancies from this competitive category are made from candidates in order of merit. Twenty appointments are authorized each year.

(a) Honor military and honor Naval schools:

(1) Five honor graduates, or prospective honor graduates, from each designated honor military and honor naval school may be nominated to fill the vacancies allocated to this category. School authorities must certify that each nominee is a prospective honor graduate or an honor graduate, and meets the basic eligibility requirements.

(2) School authorities submit nominees directly to the Academy (USAFA/RRS) using specific nomination forms. Such nominations are submitted no later than January 31 of the entry year. Nominations are not limited to honor graduates of the current year. An individual eligible for nomination in this category applies to the administrative authority of the school involved.

(b) AFROTC and AFJROTC:

(1) Five students from each college or university AFROTC detachment may be nominated to compete for the vacancies allocated in this category.

(i) Students must apply for nomination to the Professor of Aerospace Studies (PAS) who must certify that the applicants meet the basic eligibility requirements and have or will have satisfactorily completed at least 1 year of scholastic work at the time the class for which they are applying enters the Academy.

(ii) The PAS uses the forms provided by the Academy to recommend for nomination the five best-qualified applicants to the president of the educational institution in which the AFROTC detachment is established.

(iii) Nominations from the president of the institution are submitted directly to the Academy (USAFA/RRS) by January 31 of the entry year.

(2) Five students from each high school AFJROTC detachment may be nominated to compete for the vacancies allocated to this category.

(i) Students must apply for nomination to the Aerospace Science Instructor, who must certify that the applicants meet the basic eligibility requirements and have or will have successfully completed the prescribed AFJROTC program by the end of the school year.

(ii) The Aerospace Science Instructor uses the nomination forms provided by the Academy to recommend for nomination the five best-qualified applicants to the principal of the high school in which the AFJROTC detachment is established.

(iii) Nominations from the principal of the high school are submitted directly to the Academy by January 31 of the entry year.

§ 901.13 Children of Medal of Honor recipients category.

(a) The child of any Medal of Honor recipient who served in any branch of the Armed Forces may apply for nomination. If applicants meet the eligibility criteria and qualify on the entrance examinations, they are admitted to the Academy. Appointments from this category are not limited.

(b) The applicant applies directly to the Academy requesting a nomination in this category. The nominating period opens on May 1 and closes January 31.

A suggested letter format is included in the precandidate packet.

Note.—For the purpose of this category, children are defined as the natural children of a parent and adopted children whose adoption proceedings were initiated before their 15th birthday.

§ 901.14 Regular airmen category.

Appointments to fill vacancies from this competitive category are made from candidates in order of merit. A total of 85 appointments are authorized from this category each year. Applications must be submitted no later than January 31 of the entry year.

(a) Any enlisted member of the Regular component of the Air Force may apply for nomination. Selectees must be in active duty enlisted status when appointed as cadets.

(b) Regular category applicants must arrange to have their high school transcripts submitted to USAFA/RRS. They must also complete AF Form 1786, "Application for Appointment to the United States Air Force Academy Under Quota Allotted to Enlisted Members of the Regular and Reserve Components of the Air Force," and submit it to their organization commander who:

(1) Determines if the applicant meets the basic eligibility requirements shown in § 901.4 of this part. If disqualified, the application is returned and the applicant is informed of the reason.

(2) Advises the Consolidated Base Personnel Office (CBPO) to hold any reassignment action of the airman pending selection for an appointment. The CBPO places the airman in assignment availability code (AAC) 05 and coordinates on AF Form 1786. Applicants not selected are reassigned on Academy notification to the CBPO. Applicants to technical school follow-on training (if there is any) or PCS to their end assignment also are reassigned. The initial application package from the technical training center CBPO to USAFA/RRS includes the following information on all pipe-line students: name, SSN, AFSC, course graduation date, follow-on training, and end assignment.

(3) Completes an indorsement and forwards AF Form 1786 through the CBPO to USAFA/RRS, USAF Academy, Colorado Springs CO 80840–5651. The commander's indorsement must include a comprehensive statement of the applicant's character, ability, and motivation to become a career officer. Statements in the application regarding component, length of service, and date of birth must be verified from official records.

§ 901.15 Reserve airmen category.

Appointments to fill vacancies from this competitive category are made from candidates in order of merit. A total of 85 appointments are authorized from this category each year. Applications must be submitted no later than January 31 of the entry year.

(a) Any enlisted member of the Air Force Reserve or the Air National Guard of the United States (ANGUS) may apply for nomination.

(b) A Reserve commissioned officer who satisfactorily completes 1 year of service in an active Reserve assignment by July 1 of the year in which admission is sought may apply for vacancies in this category. (Reserve commissioned officer on extended active duty (EAD) may apply for vacancies in the Regular competitive category.) If selected, such candidates must have commissioned officer status terminated and be in the enlisted Air Force Reserve before appointment as Air Force Academy cadets. Cadets in this category who are separated from the Air Force Academy without prejudice and under honorable conditions may apply for reappointment as Reserve commissioned officers.

(c) Reserve category applicants must arrange to have their high school transcripts submitted to USAFA/RRS, complete AF Form 1786, and submit it to their organization commander. The organization commander processes the application as outlined in § 901.14(b). A Reserve applicant is not placed on active duty to be processed for nomination or appointment to the Air Force Academy.

(d) Reserve airmen on EAD as a result of an honor suspension from the Air Force Academy Cadet Wing must reapply for admission under the procedures specified in § 901.14(b). Additionally, the AF Form 1786 which they submit must be endorsed by their wing commander, as well as their squadron commander, and must make specific recommendations about their potential to conform to Cadet Honor Code standards.

§ 901.16 Superintendent category.

Fifty eligible applicants who have not secured a nomination to the Academy from any other nominating authority may be nominated by the Superintendent. Highly qualified applicants are selected for nomination from the nationwide precandidate program by the Academy. Appointments from this category are made in order of merit from the nationwide pool of qualified alternates to fill the class.

§ 901.17 Foreign students category.

(a) The Academy is authorized to provide instruction to as many as 40 foreign persons at any one time. Foreign citizens must apply to the government of their own country. Coordination with the U.S. Embassy is necessary to ensure all admission and appointment requirements are met. HQ USAF/DPPA effects necessary consultation before nomination invitations are forwarded to each country.

(b) The application must contain complete particulars about the applicant's background and must be submitted as early as possible. Nominations from this category must be received by the Academy by December 31 before their desired summer admission. Applicants in these categories must meet the eligibility and admissions requirements established for all Academy candidates, except the requirement to be a U.S. citizen, and they must be able to read, write, and speak English proficiently.

§ 901.18 Appointment vacancy selection.

To fill a vacancy in the Vice-Presidential quota or in the quota of a nominating authority in the congressional and U.S. Possessions categories, selections for appointment offers are made according to the following nomination methods.

(a) *The principal numbered-alternate method.* The nominating authority indicates his or her personal preference by designating a principal nominee and listing nine numbered alternate nominees in order of preference, and the appointment is offered to the first fully qualified nominee.

(b) *The principal competitive-alternate method.* The nominating authority designates his or her principal nominee and names up to nine other nominees who are evaluated by the Academy and ranked behind the principal nominee in order of merit. If the principal nominee is fully qualified, that individual is offered the appointment; otherwise, the fully qualified nominee ranked the highest by the Academy is offered the appointment.

(c) *The competitive method.* At the request of the nominating authority, the Academy evaluates the records of all the nominees and ranks them in order of merit. The fully qualified nominee ranked the highest by the Academy is offered the appointment.

§ 901.19 Qualified alternate selection.

Fully qualified candidates not offered appointments in their nominating category are placed in a nationwide pool of qualified alternates. To bring the

Cadet Wing up to full strength, additional appointments are selected from this pool in order of merit. The first 150 additional appointments are of individuals having nominations from Members of Congress. Thereafter, three of every four additional appointments are of individuals having nominations from the Vice President, Members of Congress, Delegates to Congress (from the District of Columbia, Virgin Islands, and Guam), Governor of Puerto Rico, Resident Commissioner of Puerto Rico, or Administrator of Panama Canal Commission.

§ 901.20 Notice of nomination.

The Director of Admissions (USAFA/RRS) acknowledges receipt of all applicants' nominations. If not previously received, USAFA/RRS forwards a precandidate questionnaire for completion. If the precandidate questionnaire indicates the potential to qualify for admission to the Academy or the Preparatory School, USAFA/RRS sends the individual a candidate kit which includes: USAFA Form 146, AFA Candidate Personal Data Record; USAFA Form 147, AFA Candidate Activities Record; and USAFA Form 148, AFA Request for Secondary School Transcript; AF Form 2030, Drug Abuse Certificate; and complete processing instructions.

§ 901.21 Notification of selection or nonselection.

(a) Notification of candidates selected for appointment are furnished by USAFA/RRS to HQ USAF/DPPA. HQ USAF/DPPA notifies Members of Congress and the Vice President of offers of appointment. After HQ USAF/DPPA notifies the nominating sources and advises USAFA/RRS that notification has been completed, USAFA/RRS notifies each appointee (civilian, Regular or Reserve service member) by letter, enclosing an acceptance or declination statement form. On receipt of an acceptance statement for each unconditional offer of appointment, USAFA/RRS forwards the completed candidate file to Cadet Examinations and Records (USAFA/RR). Conditional offers of appointment that have been accepted are held by USAFA/RRS until the conditional factor is resolved—medical status cleared, satisfactory preparatory school or college transcript received, proof of citizenship provided, etc. HQ USAF/DPPA is notified of removal of conditional status from offer of appointment in order to notify nominating sources as stated above. USAFA/RR completes admissions in-processing by:

(1) Forwarding an appointment kit which includes detailed reporting instructions to each appointee.

(2) Issuing invitation to travel orders.

(3) Notifying the Directorate of Cadet Personnel (USAFA/DPYC) of Regular airmen appointees. Regular airmen in technical school completes all phases of training, if time permits, before reporting to the Academy. On graduation, the airmen remain at the technical school in casual status (unless otherwise directed by HQ AFMPC/MPCRAC1) until earliest reporting date for the Academy.

(b) The Department of Defense Medical Examination Review Board (DODMERB) notifies applicants of their medical status. USAFA/RRS informs HQ USAF/DPPA of changes in medical status of candidates offered conditional appointments.

(c) USAFA/RRS notifies each unsuccessful candidate by May 1. For active duty Air Force personnel, the servicing CBPO also is notified and cancels the airman's Assignment Availability Code 05.

§ 901.22 Notification of change of address or station assignment.

The applicant or nominee is personally responsible for notifying USAFA/RRS, USAF Academy, Colorado Springs, CO 80840-5651, of every change of address or station assignment. Notifications from military personnel must include complete name, grade, SSN, and new organization or unit to which assigned.

§ 901.23 Filling Presidential and airmen nominating categories.

If any of the annual quotas of cadets authorized in the Regular airman, Reserve airman, or Presidential nomination categories are not filled, then candidates from the other two categories may fill the vacancies on a best-qualified basis.

§ 901.24 Supply of forms.

USAFA Forms 146, 147, 148 and 149 are stocked and issued by USAFA/RRS, USAF Academy, Colorado Springs, CO 80840-5651. DD Form 1870 is stocked and issued by the Air Force Academy Activities Group, HQ USAF/DPPA, Washington, DC 20330-5060.

§ 901.25 Obligation of cadet appointment.

(a) A cadet who enters the Air Force Academy directly from civilian status and takes an oath of allegiance as a cadet normally assumes a military service obligation of not less than 6 years nor more than 8 years under 10 U.S.C. 651.

(b) A cadet who enters the Air Force Academy from the Regular or Reserve component of the Air Force and fails to complete the Academy course of instruction reverts to enlisted status to complete any prior service obligation under 10 U.S.C. 516.

(c) If they are minors, cadets are required to sign an agreement with the parent's or guardian's consent that they will fulfill the following obligations:

(1) Complete the Academy course of instruction unless disenrolled from the Academy by competent authority.

(2) Accept an appointment and on graduation serve as a commissioned officer in a Regular component of one of the armed services for 5 years.

(3) Serve as a commissioned officer in the Reserve component until the 8th anniversary if authorized to resign from the Regular component before the 8th anniversary of their graduation.

(4) Be subject to the separation policies in AFR 53-3 and, perhaps, be required to serve on active duty in enlisted status if disenrolled from the Academy before graduation.

(5) Reimburse the U.S. Air Force under regulations prescribed by the Secretary of the Air Force for the costs of Academy education if the recipient, voluntarily or because of misconduct, fails to complete the period of active duty incurred.

§ 901.26 Cadet's oath of allegiance.

On admission, each appointee (except foreign cadets) will be required to take the following oath of allegiance:

"I (name), having been appointed an Air Force cadet in the United States Air Force, do solemnly swear (or affirm) that I will support and defend the Constitution of the United States against all enemies, foreign and domestic; that I will bear true faith and allegiance to the same; that I take this obligation freely, without any mental reservation or purpose of evasion; and that I will well and faithfully discharge the duties of the office of which I am about to enter. So Help Me God."

If an appointee refuses to take and subscribe to the oath, the appointment is terminated.

§ 901.27 Charging of appointees.

Appointment of candidates is according to § 901.18. Selecting of the charged cadets from the nominees for each vacancy is accomplished as follows:

(a) *Principal nominee, numbered-alternate method.* Principal, if meeting the admission criteria, is appointed and charged. Otherwise the 1st alternate, if meeting the admission criteria, is appointed and charged or the next succeeding numbered alternate who

meets the admission criteria is appointed and charged. In instances where a candidate received two principal nominations from two Congressional sources, the principal normally is charged to the Member of Congress submitting the principal nomination first.

(b) *Principal nominee, competitive-alternate method.* Principal, if meeting the admission criteria, is appointed and charged. All alternates are ranked according to merit. If the principal does not meet admission criteria, the highest ranking alternate is appointed and charged.

(c) *Competitive nominee method.* The group of competitive nominees are evaluated, ranked according to merit, and the highest-ranked nominee, if meeting the admission criteria, is appointed and charged.

(d) *Multiple Congressional nominations.* For candidates receiving numerous nominations, normally the candidate is charged to the congressional source. If the candidate is nominated by several congressional sources, the candidate normally is charged to the slate of the congressional member where the candidate ranks the highest, unless the candidate is the principal nominee or a numbered alternate.

(e) *Other sources of nomination.* All other candidates not nominated by congressional, Vice-Presidential, or U.S. Possessions who are appointed are charged to that nominating source (Presidential, AFJROTC, AFROTC, CODDV, Medal of Honor, etc.).

(f) *Qualified alternates.* To bring the Cadet Wing up to strength, the qualified alternate appointed according to § 901.19 is charged to the Secretary of the Air Force as a qualified alternate. Those candidates having congressional, Vice-Presidential, or U.S. Possessions nominations appear as a qualified alternate for that nominating source.

(g) *Multiple congressional and other sources of nominations.* For appointees who have multiple nominations, USAFA/RRS determines the appointment category to which they are assigned. Normally a cadet with both congressional and non-congressional nominations is assigned to a congressional authority. Designation of "charged" cadets (those filling a Vice-Presidential, congressional, or U.S. Possessions quota) also is accomplished by USAFA/RRS according to § 901.18. USAFA/RRS notifies HQ USAF/DPPA of these assignments which are audited and verified by HQ USAF/DPPA. The Vice Presidential and nominating authorities in Congress and U.S. Possessions are notified of their charged appointees and other nominees who win appointments by HQ USAF/DPPA.

§ 901.28 OMB approval of information collection requirements.

The information collection requirements in this Part 901 have been approved by the Office of Management and Budget under Control numbers 0701-0026, 0701-0063, 0701-0064, 0701-0066 and 0701-0087.

Patsy J. Conner,

Air Force Federal Register Liaison Officer.

[FR Doc. 86-14406 Filed 6-25-86; 8:45 am]

BILLING CODE 3910-01-M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[CGD8-86-03]

Safety Zone; Mississippi River Along the Right Descending Bank at Mile 145.9 Above Head of Passes

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: The Coast Guard is establishing a safety zone in the Mississippi River along the right descending bank at Mile 145.9, above Head of Passes, in the area of the Gramercy-Wallace bridge construction site. This safety zone is needed to protect persons from possible injury and to safeguard the bridge construction site from damage. Entry into this zone is prohibited unless authorized by the Captain of the Port.

DATES: This regulation becomes effective on June 15, 1986 and will terminate when the construction of the Gramercy-Wallace bridge is complete. Comments on this regulation must be received on or before August 1, 1986.

ADDRESS: Comments should be mailed to Captain of the Port, 4640 Urquhart Street, New Orleans, LA. The comments will be available for inspection and copying at 4640 Urquhart Street, Room A-303, New Orleans, LA. Normal office hours are between 7:00 a.m. and 3:30 p.m., Monday through Friday, except holidays.

FOR FURTHER INFORMATION CONTACT: LCDR Larry L. Hereth or LT Scott A. Newsham at (504) 589-7117.

SUPPLEMENTARY INFORMATION: In accordance with 5 U.S.C. 553, a Notice of Proposed Rulemaking was not published for this regulation and good cause exists for making it effective in less than 30 days from the date of publication. Following normal rulemaking procedures would have been contrary to the public interest since immediate action is needed to prevent injury to anyone in the area or damage to the construction site.

Although this regulation is published as a final rule without prior notice, an opportunity for public comment is nevertheless desirable to ensure that the regulation is both reasonable and workable. Accordingly, persons wishing to comment may do so by submitting written comments to the office listed under "**ADDRESS**" in this preamble. Commenters should include their names and addresses, identify the docket number for the regulations, and give reasons for their comments. Based upon comments received, the regulation may be changed.

Drafting Information

The drafters of this regulation are LCDR Larry L. Hereth, Port Safety Officer, and LT Scott A. Newsham, Project Officer for the Captain of the Port, and LCDR James J. Vallone, Project Attorney, Eighth Coast Guard District Legal Office.

Discussion of Regulation

This is a revision to 33 CFR 165.T849. This revision is necessary to protect persons and equipment associated with the construction of the Gramercy-Wallace bridge at Mile 145.9 above the head of passes on the Mississippi River. The area between pier two and the right descending bank will be used as a staging area and a site for falsework which is necessary to erect the bridge. Therefore, it will be closed to all river traffic.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Security measures, Vessels, Waterways.

Final Regulation

PART 165—[AMENDED]

In consideration of the foregoing, Part 165 of Title 33, Code of Federal Regulations is amended as follows:

1. The authority citation for Part 165 of Title 33, Code of Federal Regulations continues to read as follows:

Authority: 33 U.S.C. 1225 and 1231; 50 U.S.C. 191; 49 CFR 1.46; and 33 CFR 1.05-1(g), 6.04-1, 6.04-6, and 160.5.

2. Section 165.T849 is revised to read as follows:

§ 165.T849 Mississippi River Mile 145.9 RDB.

(a) In accordance with the general regulations in 165.23 of this part, entry

into the zone between Pier 2 of the Gramercy-Wallace Bridge and the Right Descending Bank at Mile 145.9 of the Lower Mississippi River is prohibited unless authorized by the Captain of the Port. Section 165.23 also contains other general requirements.

Dated: May 28, 1986.

J.E. Lindak,

Captain, U.S. Coast Guard, Captain of the Port, New Orleans, LA.

[FR Doc. 86-14471 Filed 6-25-86; 8:45 am]

BILLING CODE 4910-14-M

VETERANS ADMINISTRATION

38 CFR Parts 2 and 14

Delegations of Authority; General Counsel et al.

AGENCY: Veterans Administration.

ACTION: Final regulation amendments.

SUMMARY: The VA (Veterans Administration) is amending its regulations to delegate to the VA General Counsel and designees the authority to compromise, settle, or waive a claim to recover the costs of health care from a third party. This authority was granted to the Administrator in an amendment to 38 U.S.C. 629 contained in Pub. L. 99-272, the Veterans' Health Care Amendments of 1986.

DATES: The amendments will be effective June 19, 1986.

FOR FURTHER INFORMATION CONTACT: E. Douglas Bradshaw, Jr., Deputy Assistant General Counsel, Veterans Administration, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 389-2252.

SUPPLEMENTARY INFORMATION:

Section 19013 of Pub. L. 99-272 amended 38 U.S.C. 629 which concerns VA recovery of costs of health care from third parties. Section 629. as amended, authorizes the Administrator to compromise, settle, or waive any VA claim for reimbursement of the cost of health care.

This amendment to 38 CFR 2.6(e)(5) delegates to the General Counsel, Deputy General Counsel, Assistant General Counsel (Professional Staff Group I), Deputy Assistant General Counsel of said staff group, and District Counsels, or those authorized to act for them, authority to collect in full, compromise, settle, or waive any claim and execute the release thereof. The District Counsel's authority is limited to claims not exceeding $40,000.

This amendment to 38 CFR 14.619(c) will, in a case where the District Counsel determines that a claim is appropriate under the provisions of 38 CFR 17.48(g) or 38 U.S.C. 629 for the cost of medical, hospital, or surgical care, authorize the District Counsel to assert a claim and collect payment in full. The District Counsel will have authority to compromise, settle, waive, suspend or terminate collection activity on any claim not exceeding $40,000. Claims in excess of $40,000 could only be compromised, settled, or waived with the approval of the General Counsel. Any such claim not compromised, settled, or waived or where collection action was not suspended or terminated would be referred to the appropriate United States Attorney with sufficient data to enable that office to protect the interest of the Government. A copy of all materials referred to the United States Attorney will be furnished to the General Counsel.

Under 38 CFR 1.12 prior publication of these delegations of authority for public comment is unnecessary since they concern only internal VA management. Because a prior notice of proposed rule making is not required and will not be published, these changes do not come within the term "rule" as defined in and made subject to the requirements of the Regulatory Flexibility Act, 5 U.S.C. 601(2).

In any case, these amendments will not have a significant economic impact on a substantial number of small entities as they are defined in that Act. No regulatory or administrative burdens are imposed upon small entities. Also, since these regulation amendments are related solely to internal agency management, they do not come within the term "rule" as defined in section 1.(a)(3) of Executive Order 12291 entitled Federal Regulation; consequently they are not subject to requirements of that Order.

There are no Catalog of Federal Domestic Assistance numbers associated with these amendments.

List of Subjects in 38 CFR Parts 2 and 14

Authority delegations, Claims, Government employees, Lawyers, Legal Services, Organization and functions.

Approved: June 19, 1986.

Thomas K. Turnage,

Administrator.

38 CFR Part 2, Delegations of Authority, and Part 14, Legal Services, General Counsel, are amended as follows:

PART 2—DELEGATIONS OF AUTHORITY

1. In § 2.6(e), new paragraph (e)(10) is added to read as follows:

§ 2.6 Administrator's delegations of authority to certain officials (38 U.S.C. 212(a)).

* * * * *

(e) * * *

(10) Under the provisions of 38 U.S.C. 629(c)(1), authority is delegated to the General Counsel, Deputy General Counsel, Assistant General Counsel (Professional Staff Group I), Deputy Assistant General Counsel of said staff group, and District Counsel, or those authorized to act for them, to collect in full, compromise, settle, or waive any claim and execute the release thereof; however, claims in excess of $40,000 may only be compromised, settled, or waived with the prior approval of the General Counsel, Deputy General Counsel, Assistant General Counsel (Professional Staff Group I), or Deputy Assistant General Counsel of said staff group, or those authorized to act for them. (38 U.S.C. 629(c)(1))

PART 14—LEGAL SERVICES, GENERAL COUNSEL

2. In § 14.619, paragraph (c) is revised to read as follows:

§ 14.619 Collection action.

* * * * *

(c) In a case where the District Counsel determines that a claim is appropriate under the provisions of § 17.48(g) of this chapter or 38 U.S.C. 629, for the cost of medical, hospital, or surgical care, the District Counsel may assert the claim and collect payment in full. The District Counsel may compromise, settle, waive, suspend or terminate collection activity on any claim not exceeding $40,000. Claims in excess of $40,000 may only be compromised, settled, or waived with the approval of the General Counsel. Any such claim not compromised, settled, or waived or where collection action is not suspended or terminated will be referred to the appropriate United States Attorney with sufficient data to enable that office to protect the interest of the Government. A copy of all materials referred to the United States Attorney will be furnished the General Counsel. (38 U.S.C. 629(c)(1))

[FR Doc. 86-14473 Filed 6-25-86; 8:45 am]

BILLING CODE 8320-01-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[A-10-FRL-3037-1]

Approval and Promulgation of Implementation Plans; Washington

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: In this action EPA is promulgating federal regulations for visibility new source review (NSR) for the State of Washington. The regulations were proposed for 34 States, including Washington, at 49 FR 42670 on October 23, 1984. Washington subsequently submitted state implementation plan (SIP) revisions for visibility which included visibility NSR provisions. However, EPA has determined that the visibility NSR provisions are inadequate and has proposed disapproval in a separate notice (51 FR 17208, May 9, 1986). Under the terms of a settlement agreement between EPA and the Environmental Defense Fund (EDF), EPA is therefore promulgating federal visibility NSR regulations for Washington.

EFFECTIVE DATE: This action will be effective on July 28, 1986.

ADDRESSES: Copies of the materials submitted to EPA may be examined during normal business hours at:

Public Information Reference Unit, Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460

Air Programs Branch (10A-86-3), Environmental Protection Agency, 1200 Sixth Avenue, Seattle, Washington 98101

State of Washington, Department of Ecology, 4224 Sixth Avenue SE., Rowe Six, Building #4, Lacey, Washington 98504

Copies of the State's submittal may be examined at:

The Office of Federal Register, 1101 L Street NW., Room 8401, Washington DC

Comments should be addressed to:

Laurie M. Kral, Air Programs Branch, M/S 532, Environmental Protection Agency, 1200 Sixth Avenue, Seattle, Washington 98101

FOR FURTHER INFORMATION CONTACT: David C. Bray, Air Programs Branch, M/S 532, Environmental Protection Agency, 1200 Sixth Avenue, Seattle, Washington 98101, Telephone: (206) 442-4253, FTS: 399-4253.

SUPPLEMENTARY INFORMATION:

I. Background

Section 169A of the Clean Air Act (Act), 42 U.S.C. 7491, requires visibility protection for mandatory Class I federal areas where EPA has determined visibility is an important value. "Mandatory Class I federal areas" are certain national parks, wilderness areas, and international parks as described in section 162(a) of the Act, 42 U.S.C. 7472(a). The mandatory Class I federal areas where visibility is an important value are identified in EPA regulations at 40 CFR 81.400-437. Section 169A specifically requires EPA to promulgate regulations requiring certain States to amend their SIP's to provide visibility protection. On December 2, 1980, EPA promulgated the required visibility regulations at 45 FR 80084, codified at 40 CFR 51.300 et seq. In December 1982, the Environmental Defense Fund (EDF) filed a citizen suit alleging that EPA failed to perform a nondiscretionary duty under section 110(e) of the Act to promulgate visibility SIP's for States that had failed to submit such SIP revisions to EPA. The EPA and EDF negotiated a settlement agreement for deficient States which the court approved on April 20, 1984.

The settlement agreement requires EPA to promulgate visibility SIP's on a specified schedule for those States that have not submitted visibility SIP revisions to EPA and for those States which EPA determines that submitted SIP revisions are not adequate. (For more information on the settlement agreement, see 49 FR 20647 on May 16, 1984.) The EPA proposed SIP revisions for 34 States including Washington on October 23, 1984 at 49 FR 42670. The settlement agreement requires EPA to approve the State submittal or to promulgate federal programs.

II. Summary of Action

On September 6, 1983, January 5, 1984, and April 15, 1985, Washington submitted final SIP revisions to EPA. Washington's submittals included revisions to its attainment area and nonattainment area NSR programs designed to meet the federal visibility NSR requirements of § 51.307. EPA found the revisions to Washington's NSR program inadequate to meet the requirements of § 51.307 and has proposed to disapprove them in a separate notice (51 FR 17208, May 9, 1986). EPA has already promulgated the federal visibility provisions for attainment areas (40 CFR 52.21, promulgated July 12, 1985, at 50 FR 28544) for Washington codified at 40 CFR 52.2497. EPA is today, therefore, promulgating the federal visibility NSR program for nonattainment areas for Washington.

III. Comments

The EPA took comment on the proposed disapprovals and federal programs in the fall of 1984. These comments can be obtained through Docket A-84-32 at the Public Information Reference Unit address given in the beginning of this notice. All major issues raised during the comment period with regard to the federal programs were addressed in the promulgation notice of July 12, 1985, at 50 FR 28544. No comments were submitted that were specific to Washington.

Administrative Review

The rules have been submitted to the Office of Management and Budget (OMB) for review under Executive Order 12291.

Under 5 U.S.C. 605(b), I certify that this promulgation will not have a significant economic impact on a substantial number of small entities.

The rules promulgated today do not contain any information collection requirements subject to OMB review under the Paperwork Reduction Act of 1980, U.S.C. 3501 et. seq.

Under section 307(b)(1) of the Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by August 25, 1986. This action may not be challenged later in proceedings to enforce its requirements (see 307(b)(2)).

List of Subjects in 40 CFR Part 52

Air pollution control, Ozone, Sulfur oxides, Nitrogen dioxide, Lead, Particulate matter, Carbon monoxide, Hydrocarbons, Intergovernmental relations. Reporting and Recordkeeping requirements.

Dated: June 16, 1986.

Lee M. Thomas,

Administrator.

PART 52—[AMENDED]

Part 52, Chapter I of Title 40, Code of Federal Regulations, is amended as follows:

Subpart WW—Washington

1. The authority citation for Part 52 continues to read as follows:

Authority: 42 U.S.C. 7401-7642.

2. Section 52.2498 is added to read as follows:

§ 52.2498 Visibility protection.

(a) The requirements of section 169A of the Clean Air Act are not met, because the plan does not include

approvable procedures for protection of visibility in mandatory Class I Federal areas.

(b) *Regulations for visibility new source review.* The provisions of § 52.28 are hereby incorporated and made a part of the applicable plan for the State of Washington.

[FR Doc. 86-14470 Filed 6-25-86; 8:45 am]

BILLING CODE 6560-50-M

GENERAL SERVICES ADMINISTRATION

41 CFR Part 105-53

Statement of Organization and Functions

AGENCY: General Services Administration.

ACTION: Final rule.

SUMMARY: The General Services Administration (GSA) is revising its statement of organization and functions to reflect its current organizational structure. This revision reflects the abolishment of the Office of Program Control and the Office of Policy and Management Systems; establishment of the Office of Congressional Affairs, the Office of Policy Analysis, and the Office of Public Affairs; retitling of the Office of the Associate Administrator for Administration as the Office of Administration, the Office of Federal Supply and Services as the Federal Supply Service, and the Office of Information Resources Management as the Information Resources Management Service; and adds responsibility for operating the Federal Computer Performance Evaluation and Simulation Center (FEDSIM). This regulation is informational in nature and is published in accordance with the Freedom of Information Act.

EFFECTIVE DATE: June 26, 1986.

FOR FURTHER INFORMATION CONTACT: Sylvester H. Kish, Director, Organization and Staff Utilization Division (202-566-0086).

SUPPLEMENTARY INFORMATION: The General Services Administration (GSA) has determined that this rule is not a major rule for the purposes of E.O. 12291 of February 17, 1981, because it is not likely to result in an annual effect on the economy of $100 million or more; a major increase in costs to consumers or others; or significant adverse effects. Therefore, a Regulatory Impact Analysis has not been prepared. GSA has based all administrative decisions underlying this rule on adequate information concerning the need for, and the consequence of, this rule; has determined that the potential benefits to society from this rule outweigh the potential costs and has maximized the net benefits; and has chosen the alternative approach involving the least net cost to society.

List of Subjects in 41 CFR Part 105-53

Information Resources Management Service, Computer technology, Federal buildings and facilities, Federal Supply Service, Government property, Government property management, Organization and functions (Government agencies), Public Buildings Service, Surplus Government property, and Strategic materials.

PART 105-53—STATEMENT OF ORGANIZATION AND FUNCTIONS

1. The authority citation for Part 105-53 continues to read as follows:

Authority: 5 U.S.C. 552(a)(1), Pub. L. 90-23, 81 Stat. 54 sec. (a)(1); 40 U.S.C. 486(c), Pub. L. 81-152, 63 Stat. 390, sec. 205(c).

2. The table of contents for Part 105-53 is amended by revising three entries, adding three entries, removing § 105-53.130-6, and removing and reserving § 105-53.136 as follows:

Sec.
105-53.134 Office of Administration.
105-53.136 [Reserved]
105-53.140 Office of Congressional Affairs.
105-53.141 Office of Policy Analysis.
105-53.142 Office of Public Affairs.
105-53.143 Information Resources Management Service.
105-53.145 Federal Supply Service.

Subpart A—General

3. Section 105-53.118 is amended by revising paragraphs (e) and (f) to read as follows:

§ 105-53.118 Location of material available for public inspection.

* * * * *

(e) Business Service Center, General Services Administration, Ninth & Market Streets, Room 5151, Philadelphia, PA 19107, Telephone: 215/597-7613.

(f) Business Service Center, General Services Administration, Richard B. Russell Federal Building, U.S. Courthouse, 75 Spring Street, SW., Atlanta, GA 30303, Telephone: 404/331-5103.

* * * * *

4. Section 105-53.120 is revised as follows:

§ 105-53.120 Address and telephone numbers.

The Office of the Administrator; Office of Ethics; Office of the Executive Secretariat; Office of Small and Disadvantaged Business Utilization; Office of Inspector General; GSA Board of Contract Appeals; Information Security Oversight Office; Office of Administration; Office of Operations; Office of Acquisition Policy; Office of the Comptroller; Office of Congressional Affairs; Office of Policy Analysis; Office of Public Affairs; Information Resources Management Service; Federal Property Resources Service; and Public Buildings Service are located at 18th and F Streets, NW., Washington, DC 20405. The Federal Supply Service is located at Crystal Mall Building 4, 1941 Jefferson Davis Highway, Washington, DC 20406. The telephone number for the above addresses is 202/655-4000. The addresses of the eleven regional offices are provided in § 105-53.151.

Subpart B—Central Office

§ 105-53.130-6 [Removed]

5. Section 105-53.130-6 is removed.

6. Section 105-53.134 is revised to read as follows:

§ 105-53.134 Office of Administration.

The Office of Administration, headed by the Associate Administrator for Administration, participates in the executive leadership of the agency; providing advice on major policies and procedures, particularly those of a critical or controversial nature, to the Administrator and Deputy Administrator. The office plans and administers programs in equal employment opportunity, organization and staff utilization, training, staffing, position classification and pay administration, employee relations, career development, administrative services, GSA internal security, and the Cooperative Administrative Support Unit (CASU) programs. The office also serves as the central point of control for audit and inspection reports from the Inspector General and the Comptroller General of the United States; manages the GSA internal controls evaluation, improvement, and reporting program; coordinates and provides support to various committees engaged in enhancing the management of GSA; provides leadership for GSA's commitment to excellence in management practices and techniques in interactions with the Congress, other Federal agencies, and the private sector; and is responsible for the overall implementation of OMB Circular A-76 agencywide.

§ 105-53.136 [Removed and Reserved]

7. Section 105-53.136 is removed and reserved.

8. Section 105–53.139 is revised to read as follows:

§ 105–53.139 Office of the Comptroller.

(a) *Functions.* The Office of the Comptroller, headed by the Comptroller, is responsible for centralized agencywide budget and accounting functions; overall allocation and administrative control of agencywide resources and financial management programs.

(b) *Regulations.* Regulations pertaining to the Office of the Comptroller's programs are published in 41 CFR Part 101–2. Information on availability of the regulations is provided in § 1.05–53.116.

9. Section 105–53.140 is added to read as follows:

§ 105–53.140 Office of Congressional Affairs.

The Office of Congressional Affairs, headed by the Associate Administrator for Congressional Affairs, is responsible for directing and coordinating the legislative and congressional activities of GSA.

10. Section 105–53.141 is added to read as follows:

§ 105–53.141 Office of Policy Analysis.

The Office of Policy Analysis, headed by the Associate Administrator for Policy Analysis, is responsible for providing analytical support, independent, objective information concerning management policies and programs, and technical and analytical assistance in the areas of policy analysis and resource allocation to the Administrator, senior officials, and organizations in GSA.

11. Section 105–53.142 is added to read as follows:

§ 105–53.142 Office of Public Affairs.

The Office of Public Affairs, headed by the Associate Administrator for Public Affairs, is responsible for the planning, implementation, and coordination of GSA public information and public events and employee communication activities, and managing and operating the Consumer Information Center.

12. Section 105–53.143 is revised to read as follows:

§ 105–53.143 Information Resources Management Service.

(a) *Creation and authority.* The Information Resources Management Service (IRMS), headed by the Commissioner, Information Resources Management Service, was established as the Office of Information Resources Management on August 17, 1982 and subsequently redesignated as IRMS on November 17, 1985, by the Administrator of General Services. The Information Resources Management Service was assigned responsibility for administering the Governmentwide information resources management program, including records management, and procurement, management, and use of automatic data processing and telecommunications resources.

(b) *Functions.* IRMS is responsible for directing and managing Governmentwide programs for the procurement and use of automatic data processing, office information systems, and telecommunications equipment and services; developing and coordinating Governmentwide plans, policies, procedures, regulations, and publications pertaining to ADP and telecommunications activities; managing and operating the Automatic Data Processing (ADP) Fund and the Federal Telecommunications (FT) Fund; managing and operating the Federal Telecommunications System (FTS); planning and directing programs for improving Federal records and information management practices Governmentwide; managing and operating the Federal Information Centers and the Federal Computer Performance Evaluation and Simulation Center (FEDSIM); publishing the Catalog of Federal Domestic Assistance Programs and operating the Federal Assistance Program retrieval system; and developing and overseeing GSA policy concerning internal automated information systems, equipment, and facilities.

(c) *Regulations.* Regulations pertaining to IRMS programs are published in 41 CFR Chapter 201, Federal Information Resources Management Regulation (FIRMR), and 48 CFR Chapters 1 and 5. Information on availability of the regulations is provided in § 105–53.116.

13. Section 105–53.145 is amended by revising the heading and paragraphs (a) and (b) to read as follows:

§ 105–53.145 Federal Supply Service.

(a) *Creation and authority.* The Federal Supply Service (FSS), headed by the Commissioner, FSS, was established on December 11, 1949, by the Administrator of General Services to supersede the Bureau of Federal Supply of the Department of the Treasury which was abolished by the Federal Property and Administrative Services Act of 1949. The Federal Supply Service has been known previously as the Office of Personal Property and the Office of Federal Supply and Services.

(b) *Functions.* FSS is responsible for determining supply requirements; procuring personal property and nonpersonal services; transferring excess (except ADP equipment) and donating and selling surplus personal property; managing GSA's Governmentwide transportation, traffic management, travel, fleet management, and employee relocation programs; auditing of transportation bills paid by the Government and subsequent settlement of claims; developing Federal standard purchase specifications and Commercial Item Descriptions; standardizing commodities purchased by the Federal Government; cataloging items of supply procured by civil agencies; and ensuring continuity of supply operations during defense emergency conditions.

* * * * *

14. Section 105–53.147 is amended by revising paragraph (b) as follows:

§ 105–53.147 Public Building Service.

* * * * *

(b) *Functions.* PBS is responsible for the design, construction, management, maintenance, operation, alteration, extension, remodeling, preservation, repair, improvement, protection, and control of buildings, both federally owned and leased, in which are provided housing accommodations for Government activities; the acquisition, utilization, custody, and accountability for GSA real property and related personal property; representing the consumer interests of the Federal executive agencies before Federal and State rate regulatory commissions and providing procurement support and contracting for public utilities (except telecommunications); the Governmentwide safety program as it relates to GSA public buildings, and the GSA employee safety and health program; the implementation of Executive Order 11593; the implementation of Executive Order 12512 to provide leadership in the development and maintenance of needed property management information systems for the Government; and coordination of GSA activities towards improving the environment as required by the National Environmental Policy Act of 1959.

* * * * *

Subpart C—Regional Offices

15. Section 105–53.150 is revised to read as follows:

§ 105–53.150 Organization and functions.

Regional offices have been established in 11 cities throughout the United States. Each regional office is

headed by a Regional Administrator who reports to the Associate Administrator for Operations. The geographic composition of each region is shown in § 105-53.151.

16. Section 105-53.151 is revised to read as follows:

§ 105-53.151 Geographic composition, addresses, and telephone numbers.

Regional Offices—General Services Administration

Region and Address

No. 1. (Comprising the States of Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont); John W. McCormack Building, Post Office and Courthouse, Boston, MA 02109. Telephone: 617-223-2601.

No. 2. (Comprising the States of New Jersey and New York, the Commonwealth of Puerto Rico, and the Virgin Islands. Federal Plaza, New York, NY 10007. Telephone: 212-264-2600.

No. 3. (Comprising the States of Maryland, Virginia (except those jurisdictions within the National Capital Region boundaries), West Virginia, Pennsylvania, and Delaware); Ninth and Market Streets, Philadelphia, PA 19107. Telephone 215-597-1237.

No. 4. (Comprising the States of Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, and Tennessee); 75 Spring Street, SW., Atlanta, GA 30303. Telephone: 404-221-3200.

No. 5. (Comprising the States of Illinois, Indiana, Michigan, Minnesota, Ohio, and Wisconsin); 230 South Dearborn Street, Chicago, IL 60604. Telephone: 312-353-5395.

No. 6. (Comprising the States of Iowa, Kansas, Missouri, and Nebraska); 1500 East Bannister Road, Kansas City, MO 64131. Telephone: 816-926-7201.

No. 7. (Comprising the States of Arkansas, Louisiana, New Mexico, Oklahoma, and Texas); 819 Taylor Street, Fort Worth, TX 64131. Telephone: 817-334-2321.

No. 8. (Comprising the States of Colorado, Montana, North Dakota, South Dakota, Utah, and Wyoming); Building 41, Denver Federal Center, Denver, CO 80225. Telephone: 303-236-7329.

No. 9. (Comprising Guam and the States of Arizona, California, Hawaii, and Nevada); 525 Market Street, San Francisco, CA 94105. Telephone : 415-974-9147.

No. 10. (Comprising the States of Alaska, Idaho, Oregon, and Washington); GSA Center, Auburn, WA 98002. Telephone: 206-931-7000.

National Capital Region. (Comprising the District of Columbia; Counties of Montgomery and Prince Georges in Maryland; and the City of Alexandria and the Counties of Arlington, Fairfax, Loudoun, and Prince William in Virginia); Seventh and D Streets, SW., Washington, DC 20407. Telephone: 202-472-1100.

Dated: June 20, 1986.

Jon R. Halsall,

Acting Associate Administrator for Administration.

[FR Doc. 86-14463 Filed 6-25-86; 8:45 am]

BILLING CODE 6820-34-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

48 CFR Part 302

Acquisition Regulations; Definition of Terms

AGENCY: Department of Health and Human Services.

ACTION: Final rule.

SUMMARY: The definition of terms used in the HHS Acquisition Regulations is being revised to reflect a recently approved organizational change at the National Institutes of Health (NIH).

EFFECTIVE DATE: June 26, 1986.

FOR FURTHER INFORMATION CONTACT: Edwin D. Becker, Ph.D., Associate Director for Research Services, National Institutes of Health, Building 1, Room 118, 9000 Rockville Pike, Bethesda, Maryland 20892, (301) 496-2215.

SUPPLEMENTARY INFORMATION: The definition of "Principal official responsible for acquisition" as it concerns the National Institutes of Health is changed to reflect a title change from Director, Division of Administrative Services to Director, Division of Procurement. This technical change has no budgetary impact, has no effect on HHS programs or beneficiaries of those programs, and has no economic impact requiring consideration under the Regulatory Flexibility Act. For these reasons, this technical amendment of HHS regulations has not been referred to the Office of Management and Budget for consultation, is not made available for public comment, and the delay in the effective date has been waived.

PART 302—[AMENDED]

Accordingly, 48 CFR Part 302 is amended as follows:

1. The authority citation for Part 302 continues to read as follows:

Authority: 5 U.S.C. 301, 40 U.S.C. 486(c).

2. In Part 302, Subpart 302.1, Section 302.100, entitled "Definitions of terms," within the definition for "Principal official responsible for acquisition," the designation of the second official for the NIH is revised to read:

302.100 [Amended]

* * * * *

NIH—Director, Division of Procurement, Office of Research Services (For acquisitions assigned to the Division of Procurement).

* * * * *

Otis R. Bowen,

Secretary.

[FR Doc. 86-14459 Filed 6-25-86; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 652

[Docket No. 60229-6072]

Atlantic Surf Clam and Ocean Quahog Fisheries

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Notice of surf clam fishery closure.

SUMMARY: NOAA issues this notice to close the Mid-Atlantic Area surf clam fishery for a two-week period from 0001 hours on June 27, 1986, through 2400 hours on July 10, 1986. The action is required to prevent significant over harvest of surf clam allocations and avoid a prolonged closure of the fishery later in the year. The intended effect is to reduce the rate of harvest from the fishery so that the quarterly quota for surf clams will not be exceeded.

EFFECTIVE DATE: June 27, 1986.

FOR FURTHER INFORMATION CONTACT: Bruce Nicholls, 617 281-3600 ext. 263.

SUPPLEMENTARY INFORMATION: Regulations implementing the Fishery Management Plan for Atlantic Surf Clam and Ocean Quahog Fisheries contain at § 652.22(d) a provision to close the fishery if the Regional Director, upon review of available information and public comment, including current and expected levels of fishing effort, determines during any quarter that the quarterly quota for surf clams will be exceeded.

Logbooks submitted by fishermen and processors show that as of May 30, 1986, surf clam harvests from the Mid-Atlantic Area during the first two quarters of 1986 reached 1,281,000 bushels. Thus, 92% of the 1,400,000 bushel quota for the first two quarters of 1986 was harvested during only 85% of the available fishing time. If harvest continues at this rate, the quota for the first half of the year will be exhausted on or about June 13, 1986. Without a closure, the quota for the first half of the year would be exceeded by about 100,000 bushels.

The Regional Director has determined, in consultation with the Council and representatives of the surf clam industry, that without a two-week closure the quarterly quota for the second quarter of 1986 would be significantly exceeded and a lengthy closure of the fishery could be required later in the year. The problem would be particularly acute because the quota for the second half of the year is 75,000 bushels less than that for the first half because that amount of surf clams, which was not taken during 1985, was added to the 1986 quota for the first quarter. Considering all these factors, the Regional Director determined that a closure from June 27 through July 10, 1986, will reduce the cumulative surf clam harvest to a level acceptable under available quotas.

When the fishery reopens at 0001 hours on July 11, 1986, the current reduced fishing time schedule of 6 hours every other week will continue until further notice.

Other Matters

This action is taken under the authority of 50 CFR Part 652 and is taken in compliance with Executive Order 12291.

List of Subjects in 50 CFR Part 652

Fisheries, Reporting and recordkeeping requirements.

Dated: June 23, 1986.

Carmen J. Blondin,

Deputy Assistant Administrator for Fisheries Resource Management, National Marine Fisheries Service.

[FR Doc. 86-14476 Filed 6-23-86; 3:22 pm]

BILLING CODE 3510-22-M

Proposed Rules

Federal Register
Vol. 51, No. 123
Thursday, June 26, 1986

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.

NUCLEAR REGULATORY COMMISSION

10 CFR Part 51

[Docket No. PRM-51-6]

Denial of Petition for Rulemaking Regarding Use of High Burnup Nuclear Fuel

AGENCY: Nuclear Regulatory Commission.

ACTION: Denial of petition for rulemaking.

SUMMARY: The Nuclear Regulatory Commission is denying a petition for rulemaking submitted on March 17, 1980, by Ms. Catherine Quigg on behalf of Pollution and Environmental Problems, Inc., which requests that 10 CFR Part 51 be amended to require the preparation of an environmental impact statement on the generic environmental impacts of high burnup nuclear fuel as used in commercial nuclear reactors, stored in spent fuel pools or cooling racks, or potentially as processed in reprocessing plants or disposed of in permanent waste disposal sites.

ADDRESSES: Copies of comments and documents cited in this notice are available for public inspection at the NRC Public Document Room, 1717 H Street, NW, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Mr. Morton R. Fleishman, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 443-7616.

SUPPLEMENTARY INFORMATION:

Background

On March 17, 1980, Ms. Catherine Quigg filed a petition for rulemaking with the NRC (Docket No. PRM-51-6) on behalf of Pollution and Environmental Problems, Inc. Notice of receipt of this petition and a request for comments was published in the **Federal Register** on April 15, 1980 (45 FR 25557).

The petitioner contends that the use of high burnup fuel [1] could have the following significant effects upon the human environment:

1. Greater fission gas releases from nuclear reactors.
2. Increased fission gas releases from spent fuel pools.
3. Production of "Inferior grade" spent fuel which can lead to long term environmental hazards.
4. Potential for greater radiological impact from reactor and spent fuel pool accidents.
5. Increased radioactive material releases during reprocessing.

The petitioner requests that 10 CFR Part 51 be amended to require that a full environmental impact statement be prepared covering the generic environmental impacts of high burnup nuclear fuel.

Fourteen public comment letters have been received relative to the subject petition for rulemaking. These may be examined in the NRC public document room. Three commenters were in favor of the petition and eleven commenters opposed the petition. All comment letters have been evaluated by the NRC staff.

Discussion

The request of the petitioner was that the Commission amend 10 CFR Part 51, "Licensing and Regulatory Policy and Procedures for Environmental Protection," of its regulations to require the preparation of an environmental impact statement (EIS) on the subject covered by the petition. At the time the petition was submitted there already existed a requirement (§ 51.5(a)(10)) that mandated an EIS under certain conditions. Furthermore, § 51.5(c) required that a negative declaration and environmental impact appraisal be prepared if it is determined that an EIS is not needed. During 1984, 10 CFR Part 51 was almost completely rewritten and reorganized. New § 51.20(a)(1) and § 51.20(b)(13) include language similar to that in the old § 51.5(a)(10) and new § 51.21 requires an environmental assessment (EA) be made for certain regulatory actions. The Commission concludes that an amendment to the regulations, as requested by the petition, is unnecessary because § 51.20 already provides an adequate basis for the preparation of an EIS with regard to high burnup fuel on a commercial scale by requiring an EIS for "any . . . action which the Commission determines is a major Commission action significantly affecting the quality of the human environment." Furthermore, § 51.21 requires that an EA be performed for all licensing and regulatory actions applicable to NRC's domestic licensing and related regulatory functions. The EA is to "provide sufficient evidence and analysis for determining whether to prepare an environmental impact statement or a finding of no significant impact." Finally, the NRC regulations are already in compliance with the Commission on Environmental Quality (CEQ) guidelines for preparing environmental impact statements.

The Commission, therefore, denies the petition.

However, indications from the nuclear utility industry are that there will be an increasing number of applications for license amendments permitting use of high burnup fuel. The trend is expected to be cautious at first, but if the fuel performs satisfactorily and if current economic parameters remain constant, the trend is expected to continue so that within the next 10 to 12 years most licensees will plan for burnups of 45 Gwd/MtU or more. In view of this trend, the Commission thinks that the petitioner's concern about the environmental impact has merit. The Commission believes that it is both prudent and timely to evaluate the significance of this effect. Therefore, the Commission has initiated preparation of an EA on the potential use of high burnup fuel to provide the information necessary to determine whether a more detailed EIS is warranted. We expect the assessment to be completed by mid-1986.

Dated at Washington, DC, this 20th day of June 1986.

[1] The length of use, or total energy generated, or "burnup" of fuel in a reactor is measured in terms of megawatt days per metric ton of uranium (Mwd/MtU) or Gwd/MtU where 1 Gwd/MtU=1000 Mwd/MtU. Typically, fuel has been removed from reactors after 3 to 5 years with burnup levels of 28 Gwd/MtU for boiling water reactors and 33 Gwd/MtU for pressurized water reactors. "High" or "Extended" burnup nuclear fuel is considered, for the purpose of this discussion, to be fuel that is left in a reactor long enough to achieve a burnup of greater than 40 Gwd/MtU. Burnup levels of up to about 60 Gwd/MtU are being considered.

For the Nuclear Regulatory Commission.
Samuel J. Chilk,
Secretary of the Commission.
[FR Doc. 86-14495 Filed 6-25-86; 8:45 am]
BILLING CODE 7590-01-M

NATIONAL CREDIT UNION ADMINISTRATION

12 CFR Part 706

Member Business Loans by Federally-Insured Credit Unions

AGENCY: National Credit Union Administration (NCUA).

ACTION: Proposed rule.

SUMMARY: The proposed rule establishes conditions under which federally-insured credit unions (FICU's) may grant member business loans. The first section defines the type of loans the NCUA Board considers to be member business loans within the scope of the rule, and the remainder sets out specific limitations, requirements, and prohibitions in making such loans. The rule is considered necessary in light of recent liquidations and other problem cases involving unsound business lending practices by FICU's.

DATE: Comments must be received on or before September 30, 1986.

ADDRESS: Send comments to Rosemary Brady, Secretary, National Credit Union Administration Board, 1776 G Street, NW., Washington, DC 20456.

FOR FURTHER INFORMATION CONTACT: J. Leonard Skiles, Regional Director, Region V (Austin), 611 East 6th Street, Suite 407, Austin, TX 78701, or D. Michael Riley, Director, Office of Examination and Insurance, or Steven R. Bisker, Assistant General Counsel, 1776 G St., NW., Washington, DC 20456, or telephone: (512) 482-5131 (Mr. Skiles) or (202) 357-1065 (Mr. Riley) or (202) 357-1030 (Mr. Bisker).

SUPPLEMENTARY INFORMATION:

Background

The current decline in interest rates and the resulting pressures on credit unions to seek higher-yielding investments, along with the increased public awareness of credit unions, have led a number of federally-insured credit unions to grant member business loans. Many of these credit unions have entered the business lending market lacking the necessary expertise in underwriting and servicing such loans. During the last two years approximately half of the losses sustained by the National Credit Union Share Insurance Fund (NCUSIF), or about 20 to 30 million dollars, were directly or indirectly a result of business lending. Anticipated losses for the current year could result in amounts of at least that much, or more.

It is emphasized that the vast majority of FICU's are not involved in member business lending and the NCUA Board does not anticipate a major change in that respect. This regulation is intended not to foster business lending by credit unions, but rather to ensure that, in the case of those few FICU's that choose to exercise their authority to make loans to members for business purposes, the activity is carried out in a manner that mimimizes risk to the NCUSIF and the credit union system.

With the increased amount of credit union losses and failures attributed to business lending activity, the NCUA Board believes that the proposed rule is necessary. It is recognized that an increase in losses sustained by the NCUSIF translates into lower dividends on FICU deposits in the Fund and increases the likelihood of the assessment of share insurance premiums. The rule is intended to reduce losses by establishing a framework in which member business lending can be undertaken in a safe and sound manner.

The Board has proposed that this regulation apply both to Federal credit unions and to federally-insured state credit unions. It has historically been the policy of NCUA, and it will continue to be NCUA's policy, to regulate the operations of federally-insured state credit unions *only* in those instances considered essential to the safety and soundness of the Insurance Fund. It is pursuant to this policy that federall-insured state credit unions have for several years been required to meet minimum standards in such key areas as reserve transfers (capital), fidelity coverage, and accounting practices. The Board believes that business lending is another area in which the establishment of minimum standards for all federally-insured credit unions is necessary and appropriate. Sustained and projected losses by federally-insured state credit unions related to business lending activities have equalled or exceeded such losses attributable to Federal credit unions.

The Board's authority to regulate federally-insured credit unions (Federal and state charters) is contained in section 209(a) (11) of the FCU Act (12 U.S.C. 1789(a)(11). Further, pursuant to section 201(b)(9) of the Act (12 U.S.C. 1781(b)(9)), all credit unions that apply for and receive NCUSIF insurance agree to comply with Title II of the Act (Sections 201-211) and "regulations prescribed by the Board pursuant thereto."

A sampling of the types of problems and abuses that have resulted in losses is documented below. A review of these cases demonstrates the need for prompt and substantial action in this area.

Selected Problem Cases

Credit Union A (State chartered)
Asset size—$28 million
Status—Conservatorship

The credit union had made member business loans of almost $20 million. Seven millions dollars of those loans were over $40,000 each. Members of one family were granted loans totalling more than $1.5 million. No written loan policy or analysis. No appraisals or documentation of value of collateral. No liens on most of the loans. No loan servicing or collection policy. No financial reports (initially or updated). Unqualified loan officer.

Current estimated loss to NCUSIF—$1.7 million and rising.

Credit Union B (Federally chartered)
Asset size—$10 million ($18 million at the at the time the loans were made)
Status—Operating with Section 208 Assistance

The credit unions made in excess of $5 million in business loans. Numerous loans for amounts ranging from $200,000 to $500,000, with one loan made for $1 million. No written loan policy or analysis. Appraisals grossly overvalued collateral in several instances. Inadequate lien filing. No documentation of financial status of borrower. Unqualified loan officer.

Current estimated loss to NCUSIF—In excess of $1 million.

Credit Union C (State chartered)
Asset size—$550 million
Status—Operating with substantial infusion of Section 208 assistance.

Approximately one-half of the credit union's loan portfolio, or about $226 million, is in business loans. $148 million of the $226 million are classified as substandard. Twenty-two borrowers received loans of $3 million or more, totalling $128 million or about 58 percent of the total business loans. The credit union made twenty-four equity-sharing loans, all of which are problem loans. Inadequate loan policy. Inadequate appraisals, documentation, and lien filings. Inadequate loan servicing and collection procedures. Unqualified loan officer.

Current estimated loss to NCUSIF $25-$30 million.

Credit Union D (Federally chartered)
Asset size—$20 million
Status—Liquidation

Many business loans made in excess of $500,000, including loans to members and associated members (*see* definition in proposed subsection 706.1(c)). Business loans made to insiders and to illegal members. No written loan policy or analysis of borrowers' ability to repay. Little or no lien filings. Loan collection and service procedures lacking. Unqualified loan officer.

Current estimated loss to NCUSIF—$5 million.

Credit Union E (State charerted)
Asset sice—$42 million
Status—Liquidation

The credit union made approximately $23 million in business loans, the vast majority of which were agricultural loans. Individual loans were made for large amounts. Overall poor lending practices, including insufficient analysis, appraisals, documentation, financial reports, lien filing, etc. Possible insider dealings, including actions affecting insiders' pecuniary interests.

Current estimated loss to NCUSIF—$18 million and rising.

Section-by-Section Analysis of the Proposed Rule

Section 706.1.—Definitions

(a) "*Member business loan.*"

Section 706.1(a) provides a definition of "member business loan." Only those FICU loans that meet *all* of the conditions specified in this Section are subject to the proposed rule.

The first condition, Section 706.1(a)(1), provides that the proceeds of the loan be used to acquire or develop assets to produce income to repay the loan. Loans to purchase consumer goods or services, mortgage loans, home improvement loans, student loans, etc., would not satisfy this condition. However, where the proceeds of the loan are used to finance a commercial or business endeavor such as a retail business, real estate venture, leasing business, etc. and the income derived from these sources is used, in whole or in part, to repay the loan, the loan would meet this condition. When repayment of the loan is dependent upon income generated from a business or commercial endeavor, a credit union subjects itself to a higher degree of risk since there is greater uncertainty associated with these sources of income. The Board believes, therefore, that safety and soundness concerns dictate that further safeguards be instituted and sufficient reserves and undivided earnings be available to cover losses that may result from such riskier lending. The Board recognizes that there will be instances where the loan proceeds may be for a dual purpose (business and consumer), for example, the purchase of a second home (vacation house), or a camper, sail boat, etc. that is rented for most of the year with the member's personal use limited to only a few weeks each year. However, if it can be documented that the principal purpose of the loan was not for investment or commercial purposes, it would not fall within this provision and not be subject to this proposed rule.

The second condition, Section 706.1(a)(2), relates to the triggering dollar amount of more than $25,000. If the loan to the member, when combined with other loans to the member which would have been considered member business loans except that each loan did not individually exceed $25,000, exceeds the trigger amount, this second condition is satisfied. Additionally, if the loan, when added to loans made to other members where there is a common ownership, investment, or pecuniary interest in a business or commercial endeavor by the members receiving the loans, (this refers to "associated members" defined in Section 706.1(c)), exceeds $25,000, this condition is again met. Personal consumer loans or other nonbusiness-type loans will *not* be aggregated with a member business loan for purposes of determining whether the trigger amount is reached.

The trigger amount of $25,000 was chosen because member business loans in excess of $25,000 are significantly larger than most credit union loans (except first and second trust real estate loans) and, therefore, require that special considerations and limitations be applied to such loans. Commenters are encouraged to provide their thoughts and opinions on this trigger amount or one that they believe is more appropriate.

The last condition, § 706.1(a)(3), provides that the loan will not be considered a member business loan if it is made to another credit union or credit union service organization (CUSO). Even if the conditions of subsections (a)(1) and (a)(2) are satisfied, if the loan is to another credit union or CUSO, it will not be subject to this proposed rule. It is the Board's opinion that such loans do not present the same dangers and risks that may otherwise exist in member business loans. One significant distinguishing fact is the degree of supervision and regulation to which credit unions are subject as compared to private business enterprises and joint business ventures. Often these other businesses are either unsupervised or are supervised to a considerably lesser extent than credit unions. Therefore, it is the opinion of the Board that loans from one credit union to another need not be further regulated by NCUA by subjecting such loans to his proposed rule. Additionally, loans to CUSO's are already subject to NCUA's Rules and Regulations (*see* Section 701.27) and are limited by section 107(5)(D) of the FCU Act (12 U.S.C. 1757(5)(D)). Further regulation does not appear to be required at this time.

(b) "*Reserves.*"

Section 706.1(b) defines reserves for purposes of the proposed rule as all reserves, including the allowance for loan losses account, and undivided earnings or surplus. The reserves required pursuant to section 116 of the Act (12 U.S.C. 1762) and Part 702 of the NCUA Rules and Regulations (12 CFR Part 702) for Federal credit unions, and the reserves required under state law and pursuant to § 741.4(a) of the Rules and Regulations (12 CFR § 741.4(a)) for state-chartered federally-insured credit unions, comprise the reserves referred to in this section. Surplus refers to the credit balance of the undivided earnings account, after all losses have been provided for and net earnings have been added or net losses have been deducted therefrom. The term surplus does not include reserves.

(c) "*Associated member.*"

Section 706.1(c) describes a member who, along with other members, borrows funds from a FICU where each member has a common ownership, investment or other pecuniary interest in a business or commercial endeavor. In singling out these members, the Board is attempting to properly ascribe the ultimate beneficiary (e.g., the common business enterprise) of the loans obtained from the credit union and sufficiently allocate the *total* exposure that a FICU may have when making loans to one or more associated members. It is not uncommon to see members *individually* obtain loans for the same business venture, with each member assigning (transferring, investing, etc.) the proceeds of the loan to the business. In almost all instances, repayment is directly tied to the success of the business and its ability to repay the loan(s). In order to properly aggregate the total exposure that a group of such loans poses to a FICU, and for purposes of the limitation (§ 706.6) provisions of the proposed rule, the Board has created and defined the term "associated member."

(d) "*Immediate family member.*"

This is the same definition that is found in other sections of the Rules and Regulations. *See* §§ 701.21(c)(8), 701.27(c)(3), 701.36(b)(6), 703.2(1) and 721.2(c). By including this term, the Board intends to limit the circumvention

of the proposed rule in those instances where a loan is structured so that ostensibly it is made to a spouse, or a child, parent, grandchild, grandparent, etc. of an individual who would otherwise be limited or prohibited from receiving the loan.

Section 706.2—Limitations on Member Business Loans

This proposed Section establishes a limit on the aggregate amount of member business loans that can be made to any one member or group of associated members, as well as a ceiling on the total amount of such loans to all members. In addition, it provides that the loan must otherwise comply with other applicable statutes and regulations and the credit union's bylaws.

§ 706.2(a)(1) 10% Limit

In order to limit the amount of loss that may result from a default on business loans to one member or a group of associated members, and to ensure that the loss will not drain all of the FICU's available reserves (as defined in § 706.1(b)), the aggregate amount of member business loans to any one member or group of associated members is limited to 10% of reserves. Included in the calculation are all member business loans on which the member or associated member is primarily or secondarily liable. This would cover those member business loans where the member or associated member is the sole maker or is a comaker (cosigner) or guarantor (accommodation party) on the loan.

§ 706.2(a)(2) 300% Limit

To help foster diversification in loans to members and to minimize the impact of member business loan defaults on a FICU's financial stability, the Board has proposed to establish a ceiling of 300% of reserves as the total amount that may be lent out in member business loans. Inherent in the proposed limit is the recognition that credit unions have an historical place in serving the consumer loan needs of their members (e.g., auto loans, home improvement loans, student loans, etc.). Establishing a cap on member business loans is consistent with the essence of credit unions and the principal purpose of the Federal Credit Union System as reflected in the FCU Act. (*See* 12 U.S.C. 1751 stating the purpose of the FCU System—". . . to make more available to people of small means credit for provident purposes. . . .")

The 300% ceiling, in conjunction with the 10% ceiling (in (a)(1)), addresses the safety and soundness concerns (along with the other subsections of this proposed rule) that the Board has with respect to member business loans. With these two limits in place, the adverse impact on an FICU because of the failure of any one business or commercial endeavor is kept to a minimum. Assuming that an FICU were to be fully loaned out under these ceilings, it would have made loans to fund 30 or more (if each loan is less than the 10% limit) separate business ventures. The credit union would thus be reasonably diversified, such that a failure of any one or more such businesses could be more easily absorbed than if the loans were concentrated in a few businesses or if the aggregate amount of such loans were not limited. Clearly, the greater the number of these loans and/or the dollar amount of such loans, the greater is the risk of loss to the lending credit union. Inasmuch as the risk of loss is not simply borne by the FICU but is ultimately suffered by the NCUSIF and all other FICU's with deposits in the NCUSIF, the Board believes that, for the benefit of all affected parties, the limits proposed in subsections (a)(1) and (a)(2) may be advisable. The Board specifically requests comments from *all* FICU's on whether these limits are prudent and necessary.

(a)(3) Applicability of Other Laws and Bylaws

The proposed rule is intended to govern, in conjunction with all other requirements or limitations imposed by the FCU Act, the NCUA Rules and Regulations, state credit union codes and regulations, and credit union bylaws. If there is a conflict between other sections of the NCUA Rules and Regulations or state law, or the credit union's bylaws, the Board's intention is that this proposed rule (after it is effective as a final rule) supercede or otherwise preempt such conflicting provisions.

Section 706.3—Written Loan Policies

The requirement of a written loan policy is not new. Section 701.21(c)(2) of the Rules and Regulations currently requires the board of directors of all Federal credit unions to establish written policies for loans and lines of credit consistent with the relelvant provisions of the FCU Act, the Rules and Regulations and other applicable laws. Additionally, sections 113(8) and (20) of the Act (12 U.S.C. 1761b(8) and (20)) mandate that the board of directors of a Federal credit union establish lending policies and, among other things, determine the interest rates on loans (consistent with the FCU Act), the security, and the maximum amount which may be loaned. Section 113(19) of the FCU Act requires that the board of directors establish and maintain a system of internal controls consistent with the regulatiuons of the Board. Similar provisions are found throughtout the several state credit union codes and regulations. In light of the complexity and high risk of business lending, the Board believes that a comprehensive written loan policy is essential.

The proposed § 706.3 requires that the written loan policy for member business loans be reviewed and adopted annually. The general purpose of the loan policy is to ensure that no loan is made without proper analysis and documentation of the borrower's ability to repay the loan. To aid federally-insured credit unions in preparing their member business loan policies, the Board has proposed, in § 706.3(a), a list of reviews, analyses, procedures, and documents that, at a minimum, *must* be included in the written loan policy. Section 706.3(a) further provides that, before making a business loan, the credit union shall document the actions taken, pursuant to its written loan policy.

Proposed § 706.3(b) requires that all documentation be accurate and current and that the borrower's financial reports be updated quarterly throughout the term of the loan.

The items to be addressed in the written loan policy, as provided by § 706.3(a)(1)-(6), are typical of those analyses, procedures, and documentation performed by other lenders that grant business loans. For the most part, the list is self explanatory. The Board specifically requests comments on whether the list is sufficiently comprehensive to protect the interests of the lending credit union, or, in the alternative, whether the list contains provisions that are unnecessary, with supporting reasons in either case. It is expected that contempraneous with the promulgation of a final rule, the *Accounting Manual for Federal Credit Unions* will be updated to include a section on member business loans which will further explain the rule and will more particularly address the items required to be included in the written loan policy. The *Manual*, although prepared for Federal credit unions, is available for use by all federally-insured credit unions.

Section 706.4—Qualified Loan Officer

Business lending is a specialized lending that presents problems and risks vastly different than those accompanying consumer-oriented loans.

While credit unions regularly make automobile, vacation, student, home improvement, and other consumer-type loans, and presently have in place good working systems, procedures, and experienced loan officers who underwrite and service these loans, most credit unions currently lack the necessary expertise to safely and soundly involve themselves in member business loans. It is essential that FICU's choosing to enter this market *first* acquire the necessary expertise. Proficiency in evaluating business plans, pro formas, special collateral, and establishing payment schedules, draws, follow ups on financial condition, etc., and familarity with the types of agreements and loan documents used for business loans are indispensable.

This proposed § 706.4 requires that each federally-insured credit union that grants a member business loan retain the services of a qualified loan officer who is experienced in underwiting and servicing business loans. The proposed rule does not expressly specify the number of years of experience, training, educational background, etc., that the loan officer must have. The rule would leave the determination up to the credit union's board of directors. The Board specifically requests that commenters provide their opinions as to whether a more detailed list of qualifications for the loan officer should be included in the final rule.

Section 706.5—Allowance for Loan Losses

This proposed Section contains two subsections. Subsection (a) describes the factors that will be relied on in determining whether a member business loan will be classified as substandard, doubtful, or loss for purposes of the valuation allowance for loan losses. The proposed Appendix to the rule describes the elements used to determine these three classifications. The classifications and descriptions are modeled after those used by the Comptroller of the Currency for national banks. In addition, this subsection stresses that member business loans that are not delinquent or otherwise in default may still be classified, in reliance on other factors, including, but not limited to, the adequacy of the analysis and documentation required as part of a FICU's written loan policy (proposed § 706.3) This is somewhat of a departure from nonbusiness loans where delinquency is the principal factor in determining whether the loan is to be classified. However, because of the volatility of business loans, it is not uncommon for loans to turn bad very quickly. Therefore, it is extremely important to closely monitor such loans. To the extent that a FICU fails to properly comply with its written loan policy, especially in documenting and monitoring its business loans, loans may be classified pursuant to this subsection.

Subsection (b) provides the reserving requirements for loans that are classified pursuant to subsection (a). Loans classified as loss loans shall be reserved at 100%, doubtful loans at 50% of the outstanding amount of the loan, and substandard at 10% of the outstanding amount of the loan unless other factors, such as the history of business loans at the FICU, indicate that a greater or lesser amount is appropriate.

Section 706.6—Prohibitions

This proposed Section establishes certain prohibitions relating to member business loans of FICU's.

§ 706.6(a)—Loans to Insiders Prohibited

This subsection prohibits a FICU from granting a member business loan to any director, official, committee member, employee, or to any associated member or immediate family member of such individual. The Board has proposed this absolute prohibition because of the utmost importance of assuring that complete objectivity will be exercised by a FICU when it grants a member business loan. The individuals prohibited from receiving such loans by this proposed subsection retain a varying degree of influence over the decisions made by a credit union even if they do not directly participate in the decisionmaking process. Given the substantial exposure to FICU's on business loans, it is imperative that such loans be granted only after the credit union is satisfied that the conditions of its written loan policies are met. In many instances this may require a judgment call which could easily be influenced by the relationship of the borrower to the credit union. Additonally, the servicing of member business loans requires that judgment calls be made along the way, and again, the relationship of these individuals to the credit union could detrimentally affect the objectivity of the decisionmaker. Since those individuals prohibited by this subsection exhibit the closest relationships to the credit union, for safety and soundness reasons, the Board has proposed that FICU's not be permitted to make such business loans.

Many of the cases and statistics previously cited, in which credit unions and ultimately the NCUSIF sustained substantial losses, involved business loans made to insiders. Over one-third of the problem cases recently reviewed by NCUA involved loans to insiders (including loans to their family or business). The potential for abuse and the difficulty in remaining completely objective when such individuals are involved necessitate this prohibition.

It would be noted that the proposed prohibition would *not* totally preclude *all* other loans that a FICU can legally make to these individuals. Loans that would satisfy Section 706.1(a)(1), but do not exceed $25,000, would not be prohibited, nor would consumer-type loans. Of course, there may be other limitations applicable to those loans. For example, the limitation in sections 107(5(A) (iv) and (v) of the Act (12 U.S.C. 1757(5)(A) (iv) and (v)) and § 701.21(d) of the Rules and Regulations would apply with respect to loans to FCU officials.

§ 706.6(b)—Anti-kickback Provision

This proposed subsection is similar to other provisions in the NCUA Rules and Regulations which currently affect FCU's. *See* §§ 701.21(c)(8), 701.27(d)(6), 703.4(e), and 721.2(c) of the NCUA Rules and Regulations. Under this subsection, all directors, officials, committee members, employees of credit unions, and immediate family members of such individuals would be prohibited from receiving, either directly or indirectly, any compensation or thing of value (other than items of nominal value, e.g., inexpensive pen, calendar, date book, etc.), in connection with the underwriting, servicing, or collecting of member business loans. As with other sections of the proposed rule, this subsection is intended to ensure that decisions that an FICU makes at the various stages (underwriting, servicing, collecting) of a member business loan will not be influenced by the receipt of things of value by those at the FICU involved in such decisions. This is another practice that was found to exist in a number of the problem credit union cases analyzed by NCUA. As noted in the proposed subsection, it is not intended to prohibit or otherwise restrict reasonable compensation received by employees or others entitled to receive compensation from the FICU in connection with their involvement with member business loans.

§ 706.6(c)—Equity Sharing Prohibited

The Board is aware of a growing business lending practice that is used in instances where the borrower has experienced difficulty in obtaining financing under more conventional terms. Often the difficulty stems from a poor credit history or an extremely risky business venture. To entice the lender, the borrower agrees to pay the lender a

percentage of the profits of the business or commercial endeavor for which the funds are borrowed. This may be in addition to a stated fixed interest rate on the loan, or in lieu of a fixed rate. Because of the prospects of a high yield on such a loan, lenders are unwittingly lured into these loans, with, in many instances, disastrous results.

The Board believes that these loan transactions are inherently unsafe and unsound and has, therefore, proposed by this subsection to prohibit FICU's from making such member business loans. To the extent that a borrower is willing to forego a part of his profit, effectively raising his cost of funds far in excess of normal loan rates (and conceivably pay a rate in excess of the loan interest rate limit in the FCU Act and NCUA Rules and Regulations), he is doing so because of his inability (because of a questionable credit history (creditworthiness) or questionable business venture) to obtain financing from other lenders and not because of his generosity. This should immediately raise red flags to the prudent lender. While the Board believes that the majority of FICU's do not and will not engage in these lending practices, involvement by even a small number of FICU's could have very costly consequences to those FICU's, the NUCSIF, and all FICU's contributing to the NCUSIF. Because of the high risk of such loans, the Board feels that it is necessary to regulate this activity and not rely on the self-policing of the marketplace.

§ 706.6(d)—Limitation on Loans to Nonnatural Persons

This subsection incorporates into the proposed rule language contained in Article XII, Section 1 of the standard Federal Credit Union Bylaws. Article XII, Section 1 provides, in part, that: "Loans to a member other than a natural person shall not be in excess of its shareholdings in this credit union." The proposed rule would subject all FICU's to this provision.

One of the primary reasons for the bylaw is to guarantee that nonnatural person members (e.g., organizations, corporations, partnerships, sole proprietorships, etc.) would not be a drain on a credit union's liquidity, to the detriment of natural person members. By requiring that the loan amount not exceed shares at the credit union, the net effect of a loan to a nonnatural person on the credit union's liquidity would be zero, since the loan would be offset by the liquidity created by the shares placed into the credit union. In light of the typically large dollar amount of member business loans, the liquidity problem becomes even more acute. While the Board is aware that current market conditions have resulted in excess credit union liquidity, it is their belief that this condition is transitory. Any excess liquidity that exists today can very quickly be absorbed by member business loans, and be lost for an extended period of time. Therefore, a limitation that is in place before liquidity again becomes a problem is the logical approach.

Pursuant to this proposed limitation, a loan on which a nonnatural person member cosigns with a natural person member will be treated as a loan to a nonnatural person if the use and benefit of the proceeds are for the nonnatural person. Under those circumstances, the member business loan could not exceed the shares of the nonnatural persons held at the FICU.

Section 706.7—Recordkeeping and Reporting

So that members of FICU's, the state supervisory authority, and NCUA can be apprised of the number and amount of member business loans generated by each FICU, this proposed section requires that monthly financial statements reflect such amounts. The reporting can be accomplished by adding a separate line item on the financial statement or by footnoting the statement. FICU's will not be additionally burdened by this requirement since such information would need to be maintained to assure that the limitations in § 706.2 are complied with.

Section 706.8—Phase-in of Limitations

FICU's not in compliance with proposed § 706.2 would be granted a 90-day period, from the effective date of any final rule, to establish a plan, in consultation and agreement with the Regional Director and the state supervisory authority (state-chartered credit unions), to achieve compliance. The Board realizes that certain FICU's especially agriculturally based FICU's, may not be able to comply with the limits of § 706.2(a)(2) because of their membership base and the types of loans they customarily grant. In those cases, an agreement must be reached as to a substituted level of member business loans in excess of that provided in this proposed rule. The Board requests comments on what specific standards should be applied, if any, in arriving at the appropriate limits in these cases.

Regulatory Procedures

Regulatory Flexibility Act

The NCUA Board has determined and certifies that the proposed amendments, if adopted, will not have a significant economic impact on a substantial number of small credit unions (primarily those under $1 million dollars in assets). According to information available to the NCUA, business loans are not made by a significant number of small credit unions. Accordingly, the Board has determined that a Regulatory Flexibility Analysis is not required.

Paperwork Reduction Act

The proposed regulation does contain two collection of information requirements. Section 706.3 requires that a credit union establish written loan policies that include six specific items before it can make business loans. Section 706.7 requires that a credit union's monthly financial statements shall reflect the total number and aggregate dollar amount of business loans.

These collection requirements will be submitted to the Office of Management and Budget for review under the Paperwork Reduction Act. Written comments and recommendations regarding the collection requirements should be forwarded directly to the OMB Desk Officer indicated below at the following address: OMB Reports Management Branch, New Executive Office Building, Room 3208, Washington, DC 20503. Attn: Robert Neal.

List of Subjects in 12 CFR Part 706

Credit unions, Business loans.

By the National Credit Union Administration Board on June 19, 1986.

Rosemary Brady,

Secretary of the Board.

Accordingly, NCUA proposes to amend its regulations by adding a new Part 706 as follows:

PART 706—MEMBER BUSINESS LOANS BY FEDERALLY-INSURED CREDIT

Sec.
706.1 Definitions.
706.2 Limitations on Member Business Loans.
706.3 Written Loan Policies.
706.4 Qualified Loan Officer.
706.5 Allowance for Loan Losses.
706.6 Prohibitions.
706.7 Recordkeeping and Reporting
706.8 Phase-in of Limitations

Appendix to Part 706.—Loan Classifications

Authority: 12 U.S.C. 1757, 1766(a) and 1789(a)(11).

§ 706.1 Definitions.

(a) "Member business loan" means any loan that meets each of the following conditions:

(1) The proceeds of the loan are used to acquire or develop assets to produce income to repay the loan;

(2) The amount of the loan exceeds $25,000, or the amount of the loan, when added to the balances of other loans which meet paragraph (a)(1) of this section and on which the borrower or an associated member is obligated, exceeds $25,000; and

(3) The loan is not a loan to another credit union or a credit union service organization.

(b) "Reserves" means all reserves, including the Allowance for Loan Losses account, and undivided earnings or surplus.

(c) "Associated member" means any member with a common ownership, investment or other pecuniary interest in a business or commercial endeavor.

(d) "Immediate family member" means a spouse, or a child, parent, grandchild, grandparent, brother or sister, or the spouse of any such individual.

§ 706.2 Limitations on member business loans.

(a) A federally-insured credit union may make member business loans provided:

(1) The aggregate of member business loans to any one member or group of associated members, including any loans on which one or more of the members is primarily or secondarily liable, shall not exceed 10 percent of the credit union's reserves;

(2) The aggregate of all member business loans shall not exceed 300 percent of reserves; and

(3) The loans otherwise comply with applicable Federal or state laws and regulations and the credit union's bylaws.

§ 706.3 Written loan policies.

(a) Prior to granting a member business loan, a federally-insured credit union shall establish written loan policies that are reviewed and adopted annually by the board of directors and that, at a minimum, require that no such loan be disbursed without proper analysis and documentation of the borrower's ability to repay the loan. This shall include:

(1) Balance sheet, trend, and structure analysis;

(2) Ratio analysis of cash flow, income and expense, and tax data;

(3) Analysis of collateral value including, but not limited to, obtaining independent certified appraisals, title searches, and insurance (hazard and title, etc.);

(4) Filing, as necessary, of documents of title, deeds of trust, mortgages, and liens;

(5) Analysis of the credit union's trade area, loan servicing and pricing policy, diversification, loan monitoring, follow up, and collection procedures; and

(6) Maximum loan amounts, maturity limits and appropriate interest rates.

(b) All documentation shall be accurate and current. The borrower's financial reports shall be updated quarterly.

§ 706.4 Qualified loan officer.

(a) Each federally-insured credit union that grants a member business loan must retain the services of a qualified loan officer experienced in underwriting and servicing business loans.

§ 706.5 Allowance for loan losses.

(a) The determination whether a member business loan will be classified as substandard, doubtful, or loss, for purposes of the valuation allowance for loan losses, will rely on factors not limited to the delinquency of the loan. Nondelinquent loans may be classified, depending on an evaluation of factors, including, but not limited to, the adequacy of the analysis and documentation required by the credit union's written loan policies as provided in § 706.3.

(b) Loans classified shall be reserved as follows:

(1) Loss loans at 100% of outstanding amount;

(2) Doubtful loans at 50% of outstanding amount; and

(3) Substandard loans at 10% of outstanding amount unless other factors (e.g., history of such loans at the credit union) indicate a greater or lesser amount is appropriate.

§ 706.6 Prohibitions.

(a) A federally-insured credit union shall not grant a member business loan to any director, official, committee member, employee, or to any associated member of any such individual, or to an immediate family member of any such individual.

(b) No director, official, committee member, employee, or immediate family member of any such individual shall receive, either directly or indirectly, any pecuniary consideration in connection with the underwriting, servicing or collecting of member business loans. However, reasonable compensation for employees and others entitled to compensation is not prohibited by this paragraph.

(c) A federally-insured credit union shall not grant a member business loan where a portion of the amount of income to be received by the credit union in conjunction with such loan is tied to the profit of the business or commercial endeavor for which the funds are lent.

(d) A federally-insured credit union shall not grant a member business loan to a nonnatural person member in excess of its shares at the credit union.

§ 706.7 Recordkeeping and reporting.

(a) Monthly financial statements shall reflect the total number and aggregate dollar amount of loans covered by this rule. This reporting may be by a line item or by a footnote on the financial statement.

§706.8 Phase-in of limitations.

(a) Any federally-insured credit union not in compliance with § 706.2 of this regulation as of [effective date] shall, within 90 days after that date, establish, in consultation and agreement with the NCUA Regional Director, or, in the case of a federally-insured state-chartered credit union, in consultation and agreement with both the state supervisory authority and the NCUA Regional Director, a plan for achieving compliance. If compliance with the aggregate limits of § 706.2(a)(2) cannot be reasonably achieved, such as in some agriculture-based credit unions, then an agreement must be reached as to an acceptable level of member business loans.

Appendix to Part 706—Loan Classifications

Substandard—Loan is inadequately protected by the current sound worth and paying capacity of the obligor or of the collateral pledged, if any. Loans classified must have a well-defined weakness or weaknesses that jeopardize the liquidation of the debt. They are characterized by the distinct possibility that the credit union will sustain some loss if the deficiencies are not corrected. Loss potential, while existing in the aggregate amount of substandard loans, does not have to exist in individual loans classified substandard.

Doubtful—A loan classified doubtful has all the weakness inherent in one classified substandard, with the added characteristic that the weaknesses make collection or liquidation in full, on the basis of currently existing facts, conditions, and values, highly questionable and improbable. The possibility of loss is extremely high, but because of certain important and reasonably specific pending factors which may work to the advantage and strengthening of the loan, its classification as an estimated loss is deferred until its more exact status may be determined. Pending factors include: proposed merger, acquisition, or liquidation

actions, capital injection, perfecting liens on additional collateral, and refinancing plans.

Loss—Loans classified loss are considered uncollectible and of such little value that their continuance as loans is not warranted. This classification does not necessarily mean that the loan has absolutely no recovery or salvage value, but rather it is not practical or desirable to defer writing off this basically worthless loan even though partial recovery may occur in the future.

[FR Doc. 86-14298 Filed 6-25-86; 8:45 am]

BILLING CODE 7535-01-M

DEPARTMENT OF TRANSPORTION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 86-ANM-19]

Proposed Alteration of Portland, Oregon, Transition Area

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This notice proposes to redefine the current geographical boundaries of the Portland, Oregon, 700 foot transition area. This action is necessary to ensure segregation of aircraft using approach procedures in instrument weather conditions and other aircraft operating in visual weather conditions.

DATES: Comments must be received on or before September 8, 1986.

ADDRESSES: Send comments on the proposal to: Manager, Airspace & System Management Branch, ANM-530, Federal Aviation Administration, Docket No. 86-ANM-19, 17900 Pacific Highway South, C-68966, Seattle, Washington 98168.

The official docket may be examined in the Office of Regional Counsel, at the same address.

An informal docket may also be examined during normal business hours at the address listed above.

FOR FURTHER INFORMATION CONTACT: Robert L. Brown, ANM-534, Federal Aviation Administration, Docket No. 86-ANM-19, 17900 Pacific Highway South, C-68966, Seattle, Washington 98168, Telephone: (206) 431-2534.

SUPPLEMENTARY INFORMATION:.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposal. Communications should identify the airspace docket and be submitted in duplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to Airspace Docket No. 86-ANM-19". The postcard will be date/time stamped and returned to the commenter. All communications received before the specified closing date for comments will be considered before taking any action on the proposed rule. The proposal contained in this notice may be changed in the light of comments received. All comments submitted will be available for examination at the address listed above both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM's

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, Airspace & System Management Branch, 17900 Pacific Highway South, C-68966, Seattle, Washington, 98168. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRM's should also request a copy of Advisory Circular 11-2 which describes the application procedure.

The Proposal

The FAA is considering an amendment to § 71.181 of Part 71 of the Federal Aviation Regulations (14 CFR Part 71) to provide additional controlled airspace to accommodate aircraft executing the VOR/DME-B approach to McMinnville Municipal Airport, McMinnville, Oregon.

Section 71.181 of Part 71 of the Federal Aviation Regulations was republished in Handbook 7400.68 dated January 2, 1986.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) Is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Aviation safety, Transition areas.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend Part 71 of the Federal Aviation Regulations (14 CFR Part 71) as follows:

1. The authority citation for Part 71 continues to read as follows:

Authority: 49 U.S.C. 1348(a), 1354(a), 1510; Executive Order 10854; 49 U.S.C. 106(g) (Revised Pub. L. 97-449, January 12, 1983); 14 CFR 11.69.

§ 71.181 [Amended]

2. Section 71.181 is amended as follows:

Portland, Oregon, Transition Area (Amended)

That airspace extending upward from 700 feet above the surface bounded on the north by lat. 46°00'00" N, on the east by long. 122°00'00" W; thence via a line to lat. 45°51'00" N, long 122°00'00 W; to lat. 45°51'00" N, long. 122° 05'00" W; bounded on the south by lat. 45° 10'00" N, and on the west by long. 123° 30'00" W; including that airspace 2.26 miles either side of the Newburg VORTAC 215° (T) radial between a point 13.5 nautical miles and 19.78 nautical miles of the Newburg VORTAC 215° (T) radial; that airspace extending upward from 1,200 feet above the surface bounded on the north by a line beginning at a point 3 miles offshore at lat. 46°30'30" N, extending easterly via lat. 46°30'30" N, to long. 121° 40'00" W; thence easterly along the south edge of V-204 to lat 46° 30'40"N, long. 120° 36'00"W; on the east by V-25, on the south by V-536 to Corvallis, VOR; thence via lat. 44° 30'00"N, to a point 3 miles offshore and on the west by a line 3 miles offshore to the point of beginning.

Issued in Seattle, Washington, June 13, 1986.

David E. Jones,

Manager, Air Traffic Division, Northwest Mountain Region.

[FR Doc. 86-14397 Filed 6-25-86; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF COMMERCE

15 CFR Part 22

[Docket No. 60468-6068]

Salary Offset for Federal Employees Indebted to the United States Under Programs Administered by the Secretary of Commerce

AGENCY: Department of Commerce.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Secretary proposes regulations for offsetting a debt against the Federal pay of a current Federal employee who is indebted to the United States under a program administered by the Secretary of the Department of Commerce. These proposed regulations implement debt collection procedures provided for under the Debt Collection Act of 1982 (5 U.S.C. 5514).

DATES: Comments must be received on or before July 28, 1986.

ADDRESS: Send comments to Sonya G. Stewart, Director, Office of the Secretary, Office of Finance and Federal Assistance, Department of Commerce, Room 6827, H.C. Hoover Building, 14th and Constitution Avenue, NW., Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Roger J. Mallet, telephone (202) 377-2324.

SUPPLEMENTARY INFORMATION:

Background

Section 5 of the Debt Collection Act of 1982 (5 U.S.C. 5514) authorizes the Federal Government to collect debts owed to it by a Federal employee. Like administrative offset, agencies are directed to cooperate with one another when one agency is owed the debt, but the debtor is the employee of another agency.

Under the law, when the head of a Federal agency determines that one of the agency's employees is indebted to the United States, or is notified by the head of another Federal agency that one of the agency's employees is indebted to the United States, the employee's debt may be repaid by offsetting the debt against the employee's pay. The amount of the offset may not exceed 15 percent of the employee's disposable pay. The employee also has certain due process rights which must be afforded before salary offset deductions are begun.

Executive Order 12291

This proposed action has been reviewed and has been determined not to be a "major rule" as defined in Executive Order 12291 dated February 17, 1981, because it will not result in:

(1) An annual effect on the economy of $100 million or more;

(2) A major increase in costs or prices for consumers, individual industries, Federal, State, or local Government agencies, or geographic regions; or

(3) Significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

Regulatory Flexibility Act

The Department believes that the proposed rule will have no "significant economic impact upon a substantial number of small entities" within the meaning of section 3(a) of the Regulatory Flexibility Act, Pub. L. 96-354, Stat. 1164 (5 U.S.C. 605(b)). The General Counsel has certified to the Chief Counsel for Advocacy of the Small Business Administration to this effect. This conclusion is reached because the proposed rule does not, in itself, impose any additional requirements upon small entities. The proposed rules will affect only individual Federal employees. Accordingly, no regulatory flexibility analysis is required.

Paperwork Reduction Act

Under Section 3518 of the Paperwork Reduction Act of 1980 and 5 CFR 1320.3(c), the information collection provisions contained in this proposed regulation are not subject to the Office of Management and Budget review and approval.

List of Subjects in 15 CFR Part 22

Claims, Debt collection, Government employees, Wages.

For the reasons set forth above, it is proposed that Part 22 be added to 15 CFR Subtitle A to read as follows:

PART 22—SALARY OFFSET

Sec.
22.1 Scope.
22.2 Definitions.
22.3 Pay subject to offset.
22.4 Determination of indebtedness.
22.5 Notice requirements before offset.
22.6 Request for hearing—prehearing submission(s).
22.7 Hearing procedures.
22.8 Written decision following a hearing.
22.9 Standards for determining extreme financial hardship.
22.10 Review of departmental records related to the debt.
22.11 Coordinating offset with another Federal agency.
22.12 Procedures for salary offset—when deductions may begin.
22.13 Procedures for salary offset—types of collection.
22.14 Procedures for salary offset—methods of collection.
22.15 Procedures for salary offset—imposition of interest, penalties, and adminstrative costs.
22.16 Non-waiver of rights.
22.17 Refunds.

Authority: 5 U.S.C. 5514; 5 CFR 550.1104.

§ 22.1 Scope.

(a) These regulations provide Department procedures for collection by salary offset of a Federal employee's pay to satisfy certain debts owed the Government.

(b) These regulations apply to collections by the Secretary from:

(1) Federal employees who owe debts to the Department; and

(2) Current employees of the Department who owe debts to other agencies.

(c) These regulations do not apply to debts or claims arising under the Internal Revenue Code of 1954, as amended (26 U.S.C. 1 *et. seq.*); the Social Security Act (42 U.S.C. 301 *et. seq.*); the tariff laws of the United States; or to any case where collection of a debt by salary offset is explicitly provided for or prohibited by another statute (e.g., travel advances in 5 U.S.C. 5705 and employee training expenses in 5 U.S.C. 4108).

(d) These regulations do not apply to any adjustment to pay arising out of an employee's election of coverage or a change in coverage under a Federal benefits program requiring periodic deductions from pay, if the amount to be recovered was accumulated over four pay periods or less.

(e) Nothing in these regulations precludes the compromise, suspension, or termination of collection actions where appropriate.

§ 22.2 Definitions.

(a) "Agency" means:

(1) An Executive department, military department, Government corporation, or independent establishment as defined in 5 U.S.C. 101, 102, 103, and 104, respectively;

(2) The United States Postal Service;

(3) The Postal Rate Commission;

(4) An agency or court of the judicial branch; and

(5) An agency of the legislative branch, including the U.S. Senate and the U.S. House of Representatives.

(b) "Creditor agency" means the agency to which the debt is owed.

(c) "Days" means calendar days.

(d) "Debt" means:

(1) An amount of money owed the United States from sources which include loans insured or guaranteed by

the United States; from fees, leases, rents, royalties, services, sales or real or personal property, overpayments, penalties, damages, fines and forfeitures (except those arising under the Uniform Code of Military Justice);

(2) An amount owed to the United States by an employee for pecuniary losses, including, but not limited to:

(i) Theft, misuse, or loss of Government funds;

(ii) False claims for services and travel;

(iii) Illegal or unauthorized obligations and expenditures of Government appropriations;

(iv) Authorization of the use of Government owned or leased equipment, facilities, supplies, and services for other than official or approved purposes;

(v) Vehicle accidents where the employee is determined to be liable for the repair or replacement of a Government owned or leased vehicle; and

(vi) Erroneous entries on accounting records or reports for actions for which the employee can be held liable.

(e) "Department" or "DOC" means the United States Department of Commerce.

(f) "Disposable pay" means the amount that remains from an employee's Federal pay after required deductions for Federal, State and local income taxes; Social Security taxes, including Medicare taxes; Federal retirement programs; premiums for life and health insurance benefits; and such other deductions that are required by law to be withheld.

(g) "Employee" means:

(1) A civilian employee as defined in 5 U.S.C. 2105;

(2) A member of the Armed Forces or Reserves of the United States, or of a uniformed service, including a commissioned officer of the National Oceanic and Atmospheric Administration;

(3) An employee of the United States Postal Service or the Postal Rate Commission;

(4) An employee of an agency or court of the judicial branch; and

(5) An employee of the legislative branch, including the U.S. Senate and the U.S. House of Representatives.

(h) "FCCS" means the Federal Claims Collection Standards jointly published by the Justice Department and the General Accounting Office at 4 CFR 101.1 *et. seq.*

(i) "Offset" means a deduction from the disposable pay of an employee to satisfy a debt with or without the employee's consent.

(j) "Pay" means basic pay, special pay, incentive pay, retired pay, retainer pay, or, in the case of an employee not entitled to basic pay, other authorized pay.

(k) "Paying agency" means the agency employing the individual and authorizing his or her current pay.

(l) "Payroll office" means the Departmental or other office providing payroll services to the employee.

(m) "Secretary" means the Secretary of Commerce, or his/her designee.

§ 22.3 Pay subject to offset.

(a) An offset from an employee's pay may not exceed 15 percent of the employee's disposable pay, unless the employee agrees in writing to a larger offset amount.

(b) An offset from pay shall be made at the officially established pay intervals from the employee's current pay account.

(c) If an employee retires, resigns, or is discharged, or if his or her employment period or period of active duty otherwise ends, an offset may be made from subsequent payment on any amount due to the individual from the Federal Government.

§ 22.4 Determination of indebtedness.

In determining that an employee is indebted, the Secretary will review the debt to make sure that it is valid and past due.

§ 22.5 Notice requirements before offset.

Except as provided in § 22.1, deductions will not be made unless the Secretary provides the employee with a minimum of 30 calendar days written notice. This Notice of Intent to offset an employee's salary (Notice of Intent) will state:

(a) That the Secretary has reviewed the records relating to the claim and has determined that a debt is owed, the amount of the debt, and the facts giving rise to the debt;

(b) The Secretary's intention to collect the debt by means of deduction from the employee's current disposal pay account until the debt and all accumulated interest are paid in full;

(c) The amount, frequency, approximate beginning date, and duration of the intended deductions;

(d) An explanation of the Department's requirements concerning interest, penalties and administrative costs unless such payments are excused in accordance with §§ 22.9 an 22.15;

(e) The employee's right to inspect and to request and receive a copy of Department records relating to the debt;

(f) The right to a hearing conducted by an administrative law judge of the Department or a hearing official, not under the control of the Secretary, on the Secretary's determination of the debt, the amount of the debt, or the repayment schedule (i.e., the percentage of disposable pay to be deducted each pay period), so long as a petition is filed by the employee as prescribed by the Secretary.

(g) The method and time period for requesting a hearing;

(h) That the timely filing of a petition for hearing will stay the collection proceedings; (§ 22.6);

(i) That a final decision on the hearing will be issued at the earliest practical date, but not later than 60 days after the filing of the petition requesting the hearing, unless the employee requests and the hearing official grants a delay in the proceedings;

(j) Any other rights and remedies available to the employee under statutes or regulations governing the program for which the collection is being made; and

(k) That any knowingly false or frivolous statements, representations, or evidence may subject the employee to:

(1) Disciplinary procedures appropriate under 5 U.S.C. 7501 *et seq.*, 5 CFR Part 752, or any other applicable statutes or regulations;

(2) Penalties under the False Claims Act, 31 U.S.C. 3729–3731, or any other applicable statutory authority; or

(3) Criminal penalties under 18 U.S.C. 286, 287, 1001, and 1002 or any other applicable statutory authority.

(l) Unless there are applicable contractual or statutory provisions to the contrary, amounts paid on or deducted for the debt which are later waived or found not owed to the United States will be promptly refunded to the employee.

§ 22.6 Request for hearing—prehearing submission(s).

(a) An employee must file a petition for a hearing in accordance with the instructions in the Notice of Intent. This petition must be filed by the time stated in the notice described in § 22.5 if an employee wants a hearing concerning:

(1) The existence or amount of the debt; or

(2) The Secretary's proposed offset schedule.

(b) If the employee files his or her required submissions within 5 days after the deadline date established under § 22.5 and the hearing official finds that the employee has shown good cause for failure to comply with the deadline date, the hearing official may find that an employee has not waived his or her right to a hearing.

§ 22.7 Hearing procedures.

(a) The hearing will be presided over by either:

(1) A Department administrative law judge; or

(2) A hearing official not under the control of the Secretary.

(b) The hearing shall conform to § 102.3(c) of the Federal Claims Collection Standards (4 CFR 102.3(c)).

(c)(1) If the Secretary's determination regarding the existence or amount of the debt is contested, the burden is on the employee to demonstrate that the Secretary's determination was erroneous.

(2) If the hearing official finds the Secretary's determination of the amount of the debt was erroneous, the hearing official shall indicate the amount owed by the employee, if any.

(d)(1) If the Secretary's offset schedule is contested, the burden is on the employee to demonstrate that the payments called for under the Secretary's schedule will produce an extreme financial hardhship for the employee under § 22.9.

(2) If the hearing official finds that the payments called for under the Secretary's offset schedule will produce an extreme financial hardship for the employee, the hearing official shall establish an offset schedule that will result in the repayment of the debt in the shortest period of time without procuring an extreme financial hardship for the employee.

§ 22.8 Written decision following a hearing.

(a) The hearing official shall issue to the Secretary and the employee a written opinion stating his or her decision, with a rationale supporting that decision, as soon as practicable after the hearing, but not later than 60 days after the employee files the petition requesting the hearing as provided in § 22.5(i).

(b) The written decision following a hearing will include:

(1) A statement of the facts presented to support the nature and origin of the alleged debt;

(2) The hearing official's analysis, findings, and conclusions, in light of the hearing, concerning the employee's or the Department's grounds;

(3) The amount and validity of the alleged debt; and

(4) The repayment schedule if applicable.

(c) In determining whether the Secretary's determination of the existence or amount of the employee's debt was erroneous, the hearing official is governed by the relevant Federal statutes and regulations authorizing and implementing the programs giving rise to the debt, and by State law, if relevant.

§ 22.9 Standards for determining extreme financial hardship.

(a)(1) An offset produces an extreme financial hardship for an employee if the offset prevents the employee from meeting the costs necessarily incurred for essential subsistence expenses of the employee and his or her spouse and dependents.

(2) Ordinarily, essential subsistence expenses include only costs incurred for food, housing, clothing, transportation, and medical care.

(b) In determining whether an offset would prevent the employee from meeting the essential subsistence expenses described in paragraph (a) of this section, the hearing official shall require that the employee submit a detailed financial statement showing assets, liabilities, income and expenses.

§ 22.10 Review of departmental records related to the debt.

(a) Notification by employee. An employee who intends to inspect or copy Departmental records related to the debt must make arrangements in conformance with the instructions in the Notice of Intent.

(b) Secretary's response. In response to a timely request submitted by the debtor, as described in paragraph (a) of this section, the Secretary will notify the employee of the location and time when the employee may inspect and copy Department records related to the debt.

§ 22.11 Coordinating offset with another Federal agency.

(a) When Commerce is owed the debt. When the Department is owed a debt by an employee of another agency, the Department will submit a written request to the paying agency to begin salary offset. This request will include certification as to the debt (including the amount and basis of the debt and the due date of the payment) and that the Department has complied with these regulations.

(b) When another agency is owed the debt. The Department will use salary offset against one of its employees who is indebted to another agency if requested to do so by that agency. Such a request must be accompanied by a certification by the requesting agency that the person owes the debt (including the amount) and that the procedural requirements of 5 U.S.C. 5514 and 5 CFR Part 550, Subpart K, have been met.

Requests by another Federal Department or agency for Department cooperation in offsetting the salary of one of its employees must be directed to the Director for Personnel and Civil Rights, Room 5001, U.S. Department of Commerce, Herbert C. Hoover Building, 14th and Constitution Ave., NW., Washington, DC 20230

§ 22.12 Procedures for salary offset—when deductions may begin.

(a) Deductions to liquidate an employee's debt will be by the method and in the amount stated in the Secretary's Notice of Intent to collect from the employee's current pay.

(b) If the employee filed a timely petition for hearing, deductions will begin after the hearing official has provided the employee with a hearing, and the final written decision is in favor of the Secretary.

(c) If an employee retires or resigns before collection of the amount of the indebtedness is completed, the remaining indebtedness will be collected according to the procedures for administrative offset (15 CFR 21).

§ 22.13 Procedures for salary offset—types of collection.

A debt will be collected in a lump-sum or in installments. Collection will be by lump-sum collections unless the amount of the debt exceeds 15 percent of disposable pay. In these cases, deduction will be by installments.

§ 22.14 Procedures for salary offset—methods of collection.

(a) *General.* A debt will be collected by deductions at officially established pay intervals from an employee's current pay account, unless the employee and the Secretary agree to alternative arrangements for repayment.

(b) *Installment deductions.* Installment deductions will be made over a period not greater than the anticipated period of employment. The size and frequency of installment deductions will bear a reasonable relation to the size of the debt and the employee's ability to pay. However, the amount deducted for any period will not exceed 15 percent of the disposable pay from which the deduction is made; unless the employee has agreed in writing to the deduction of a greater amount. If possible, the installment payment will be sufficient in size and frequency to liquidate the debt in three years. Installment payments of less than $25 per pay period or $50 a month will be accepted only in the most unusual circumstances.

(c) Sources of deductions. The Department will make deductions from the employee's pay.

§ 22.15 Procedure for salary offset—imposition of interest, penalties, and administrative costs.

These charges will be made on installment payments in accordance with the Office of Personnel Management regulations (5 CFR 550.1104 (n)) and the requirements contained in the FCCS (4 CFR 1002.13).

§ 22.16 Non-waiver of rights.

So long as there are no statutory or contractual provisions to the contrary, no employee involuntary payment (of all or a portion of a debt) collected under these regulations will be interpreted as a waiver of any rights that the employee may have under 5 U.S.C. 5514 and these implementing regulations.

§ 22.17 Refunds.

The Department will refund promptly to the appropriate individual amounts offset under these regulations when:

(a) A debt is waived or otherwise found not owing the United States (unless expressly prohibited by statute or regulation); or.

(b) The Department is directed by an administrative or judicial order to refund amounts deducted from the employee's current pay.

Dated: June 23, 1986.

Sonya G. Stewart,

Director, Office of Finance and Federal Assistance.

[FR Doc. 86-14485 Filed 6-25-86; 8:45 am]

BILLING CODE 3510-FA-M

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 270

[IC-15155; S7-14-86]

Proposed Amendment to Investment Company Act Recordkeeping Rule

AGENCY: Securities and Exchange Commission.

ACTION: Proposed amendment to Investment Company Act Recordkeeping Rule.

SUMMARY: The Commission is publishing for comment a proposed amendment to the recordkeeping rule under the Investment Company Act of 1940 to permit registered investment companies to preserve required records on magnetic tape, disk, or other computer storage medium. By enlarging the range of acceptable storage media, the amendment would create more flexibility for investment companies in their recordkeeping. The amendment also would result in savings of time and cost to registered investment companies and Commission examiners.

DATE: Comments must be received on or before August 22, 1986.

ADDRESS: Comments shouled be sent in triplicate to Shirley E. Hollis, Acting Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Wasington, DC 20549. Comment letter should refer to File No. S7-14-86. All comments will be available for public inspection and copying in the Commission's Public Reference Room, 450 Fifth Street, NW., Washighton, DC 20549.

FOR FURTHER INFORMATION CONTACT: R. Michael Parker, Senior Compliance Examiner, (202) 272-2025, or Jay Gould, Attorney, (202) 272-2107, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549.

SUPPLEMENTARY INFORMATION: Section 31(a) of the Investment Company Act of 1940 (the "1940 Act") [15 U.S.C. 80a-1 *et seq.*] gives the Commission authority, by rulemaking and regulations, to prescribe the books and records which an investment company, and its investment adviser, depositor, and principal underwriter must maintain. Rule 31a-1 [17 CFR 270.31a-1] under the 1940 Act specifies what sorts of records must be kept. Rule 31a-2 [17 CFR 270.31a-2] under the 1940 Act generally specifies where and for how long these records must be kept.[1] Paragraph (f) of Rule 31a-2 specifies in what format records may be kept.[2]

In 1985, the Commission amended the recordkeeping rule for investment advisers, Rule 204-2 [17 CFR 275.204-2], under the Investment Advisers Act of 1940 [15 U.S.C. 80b-1 *et seq.*] to permit investment advisers, among other things, to store certain records on computer tape or disk or other computer storage medium, provided certain conditions are met.[3] Rule 204-2 limits the types of records which can be stored in computer systems to those which exist in original form in a computer storage medium.

The Commission now proposes to amend Rule 31a-2(f) under the 1940 Act to permit the records of investment companies, required to be preserved pursuant to Rules 31a-1 and 31a-2, to be stored in a computer storage medium. The proposed amendment would be consistent with Advisers Act Rule 204-2 in that only those records which exist in original form in a computer storage medium may be stored in computer systems. Moreover, the amendment would, like its Advisers Act counterpart, require that records stored on a computer storage medium be capable of immediate access and retrieval, that printouts of the records or copies of the computer tape or disk be immediately available to Commission examiners, that one other copy of the computer storage medium be stored separately from the original, and that procedures be used for maintenance and preservation of, and access to, records so as to reasonably safeguard them from loss, alteration, or destruction.

Cost/Benefit of Proposal

The Commission requests comment on the specific costs and benefits that investment companies and their agents perceive will result from this proposal. The Commission believes that due to the permissive nature of the proposed amendment, no additional long-term costs will be incurred by investment companies or their agents if the proposal is adopted. It is possible that some investment companies may incur short-term costs if, as a result of the rule change, they determine to convert to a computer storage medium. It is expected that investment companies would use a computer storage medium only if the long-term benefits make such costs economically feasible.

The Commission expects that the proposed amendment would provide an overall benefit for both investment companies and Commission examiners. Generally, it is easier to store and access computer records than microfilm or hardcopy records. Many investment companies already make extensive use of computers in their business activities. The Commission estimates that a significant cost associated with compliance with recordkeeping requirements consists of storage expenses. Because records created by computer must now be stored in microfilm or hardcopy, the amendment to Rule 31a-2 would substantially eliminate the storage expense for those records which exist in original form in computer medium. Because Commission examiners have begun using portable computers, the Commission would also benefit from the proposal. Examiners would be able to download records stored on magnetic tape or disk directly onto their personal computers and reproduce needed records. This would

[1] Generally, records must be maintained for at least six years after the end of the fiscal year in which the last entry is made.

[2] Under Rule 31a-2(f), records required to be maintained and preserved pursuant to Rule 31a-1 and Rule 31a-2 may be immediately produced or reproduced on photographic film and can be maintained or preserved for the required time in that form.

[3] Investment Advisers Act Rel. No. 952 (January 11, 1985) [50 FR 2542 (January 17, 1985)].

reduce the time necessary to conduct an investment company examination, thereby increasing examiner productivity, while reducing disruption to the investment company.

Summary of Regulatory Flexibility Act Analysis

The Commission has prepared an Initial Regulatory Flexibility Act Analysis in accordance with 5 U.S.C. 603 regarding the proposed amendment to Rule 31a-2. The analysis considers the impact that allowing investment companies to maintain required records on magnetic tape or disk or other computer storage medium for the required period of time would have on small investment companies. The Analysis notes that the proposed amendment, if adopted, would result in cost savings by eliminating the need for investment companies to make and store either hard copy or photographic film copy of information which is already in a computer storage medium. However, the Analysis states that it is not possible to estimate the significance of the economic impact on small investment companies, in part because it is not possible to estimate the extent to which investment companies will choose to preserve required records on computer storage medium rather than in hard copy or on photographic film. A copy of the Initial Regulatory Flexibility Act Analysis may be obtained by contacting R. Michael Parker, Division of Investment Management, 450 Fifth Street, NW., Washington, DC 20549.

List of Subjects in 17 CFR Part 270

Investment companies, Reporting and recordkeeping requirements, Securities.

Text of Proposal

Title 17, Chapter II of the Code of Federal Regulations is proposed to be amended as follows:

PART 270—RULES AND REGULATIONS, INVESTMENT COMPANY ACT OF 1940

1. The authority citation for Part 270 continues to read in part as follows:

Authority: Secs. 38, 40, 54, Stat. 841, 842; (15 U.S.C. 80a-37 * * * § 270.31a-2 also issued under 15 U.S.C. 80a-31(a)).

2. Section 270.31a-2 is amended by revising paragraph (f)(1), redesignating (f)(2) as (f)(3), and adding (f)(2) as follows:

§ 270.31a-2 Records to be preserved by registered investment companies, certain majority-owned subsidiaries thereof, and other persons having transactions with registered investment companies.

* * * * *

(f)(1) The records required to be maintained and preserved under paragraphs (a) through (d) of § 270.31a-1 and paragraphs (a) through (c) of § 270.31a-2 may be immediately produced or reproduced on photographic film or, as provided in paragraph (f)(2) of this section, on magnetic tape, disk, or other computer storage medium, and be maintained and preserved for the required time in that form. If such records are produced or reproduced by photographic film or computer storage medium by, or on behalf of, an investment company, such investment company shall:

(i) Arrange the records and index and file the films or computer storage medium in such a manner as to permit the immediate access and retrieval of any particular record;

(ii) Be ready at all times to provide, and immediately provide, any facsimile enlargement of film or computer printout or copies of the computer storage medium which the Commission, by its examiners or other representatives, or the directors of such investment company may request;

(iii) Store separately from the original one other copy of the photographic film or computer storage medium for the time required;

(iv) With respect to records stored on computer storage medium, maintain procedures for maintenance and preservation of, and access to, records so as to reasonably safeguard records from loss, alteration, or destruction; and

(v) With respect to records stored on photographic film, at all times have available for examination of its records by the Commission, pursuant to section 31 of the Investment Company Act of 1940 or by the directors of such investment company, facilities for immediate, easily readable projection of the photographic film and for producing easily readable facsimile enlargements.

(f)(2) Under paragraph (f)(1) of this section, an investment company may maintain and preserve on computer tape or disk or other computer storage medium records which, in the ordinary course of the investment company's business, are created by, or on behalf of, the investment company on electronic media or are received by, or on behalf of, the investment company solely on electronic media or by electronic data transmission.

* * * * *

By the Commission.

Shirley E. Hollis,

Acting Secretary.

June 19, 1986.

[FR Doc. 86-14443 Filed 6-25-86; 8:45 am]

BILLING CODE 8010-01-M

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 935

Reopening and Extension of Public Comment Period on Proposed Amendments to the Ohio Permanent Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSMRE), Interior.

ACTION: Reopening and extension of public comment period.

SUMMARY: By letter dated November 6, 1984, Ohio submitted a program amendment consisting of a revision to Ohio Administrative Code rule 1501.13-14-03 concerning civil penalties and alternative enforcement. OSMRE published a notice in the **Federal Register** on December 12, 1984, announcing receipt of the amendment and inviting public comment on the adequacy of the proposed amendment (49 CFR 48324).

Following a review of the Ohio amendment, OSMRE notified the State on March 11, 1985, of its concerns about the amendment relating to alternative enforcement. On June 21, 1985, the State responded by submitting a policy statement addressing the implementation of alternative enforcement measures.

OSMRE reopened and extended the public comment period on July 19, 1985, for 15 days (50 FR 29438).

Additional review of Ohio's amendment and policy statement resulted in a second letter to the State dated September 25, 1985, identifying concerns and seeking clarification. The State responded on December 19, 1985, with a letter clarifying its policy statement. OSMRE reopened and extended the comment period on this new information on February 3, 1986, for 15 days (51 FR 4188). At the close of the public comment period, the State informed OSMRE that it was drafting the proposed amendment and would submit it to OSMRE when it was completed.

By letter dated May 19, 1986, Ohio submitted a revised amendment to OSMRE. Accordingly, OSMRE is reopening and extending the comment period on Ohio's November 6, 1984 amendment as reproposed by the State on May 19, 1986. This action is being taken to provide the public an opportunity to reconsider the adequacy of the reproposed amendment.

DATE: Written comments, data or other relevant information relating to this rulemaking not received on or before 4:00 p.m. July 11, 1986 will not necessarily be considered in the Director's decision to approve or disapprove the amendment.

ADDRESSES: Written comments should be mailed or hand delivered to: Ms. Nina Rose Hatfield, Director, Columbus Field Office, Office of Surface Mining Reclamation and Enforcement, Room 202, 2242 South Hamilton Road, Columbus, Ohio 43227. Telephone: (614) 866-0578.

Copies of the Ohio program, the proposed modification to the program, and all written comments received in response to this notice will be available for public review at the OSMRE Field Office listed above and at the OSMRE Headquarters Office of the State regulatory authority listed below during normal business hours Monday through Friday, excluding holidays. Each requestor may receive, free of charge, one single copy of the amendment by contacting the OSMRE Columbus Field Office listed above.

Office of Surface Mining Reclamation and Enforcement, Adminstrative Record, 100 "L" Street, NW., Washington, DC 20240

Ohio Division of Reclamation, Building B, Fountain Square, Columbus, Ohio 43224

FOR FURTHER INFORMATION CONTACT: Ms. Nina Rose Hatfield, Director, Columbus Field Office, Office of Surface Mining Reclamation and Enforcement, Room 202, 2242 South Hamilton Road, Columbus, Ohio 43227. Telephone: (614) 866-0578.

SUPPLEMENTARY INFORMATION:

I. Background

The Ohio program was conditionally approved effective Augsut 16, 1982, by notice published in the August 10, 1982 **Federal Register** (47 FR 34688). Information pertinent to the general background, revisions, modifications, and amendments to the Ohio program submission, as well as the Secretary's findings, the disposition of comments, and a detailed explanation of the conditions of approval of the Ohio program can be found in the August 10, 1982 **Federal Register.** Subsequent actions concerning the Ohio program amendments and conditions of approval can be found at 30 CFR 935.11 and 935.15.

II. Proposed Amendment

By letter dated November 6, 1984 Ohio submitted a proposed program amendment consisting of a revision to rule 1501:13-14-03 concerning civil penalties, setting a 30-day cap on failure-to-abate cessation order assessments and establishing assessment conference procedures. The proposed amendment also provides for alternative enforcement actions to be taken if a violation has not been abated withing 30 days.

OSMRE announced receipt of the amendment and initiated a public comment period on December 12, 1984 (49 FR 48324). The comment period closed on January 11, 1985.

During review of the amendment, OSMRE identified one concern. The proposed amendment did not specify how alternative enforcement measures will be implemented at the end of the 30-day abatement period to ensure that violations will be corrected. OSMRE notified Ohio about this concern by letter dated March 11, 1985. On June 21, 1985, Ohio responded by providing a policy statement on the implementation of alternative enforcement measures.

OSMRE announced receipt of the policy statement and initiated a public comment period on July 19, 1985 (50 FR 29438). The comment period closed on August 5, 1985.

OSMRE's review of Ohio's policy statement identified additional concerns. They included a limit on the types of violations for which alternative enforcement would be considered, clarification of the public interests which may obviate the need for civil action, lack of documentation as to alternative enforcement actions taken. Ohio was notified of these concerns in a letter dated September 25, 1985. On December 19, 1985, Ohio responded with a letter providing the clarification OSMRE had requested.

OSMRE announced receipt of the amendment and subsequent material and initiated a public comment period on February 3, 1986 (51 FR 4188). The comment period closed on February 18, 1986. Following the close of the comment period, Ohio informed OSMRE that it was rewriting the proposed amendment and would submit it to OSMRE when it was completed.

By letter dated May 19, 1986, Ohio submitted the redrafted amendment. The full text of the proposed amendment is available for review at the locations listed above under "**ADDRESSES.**" OSMRE is now seeking comment on the November 6, 1984 amendment as reproposed on May 19, 1986. If the Director determines that the proposed amendment is no less stringent than SMCRA and no less effective than the Federal regulations, the amendment will be approved and become part of the approved permanent program.

List of Subjects in 30 CFR Part 935

Coal mining, Intergovernmental relations, Surface mining, Underground mining.

Dated: June 23, 1986.

Arthur W. Abbs,

Acting Assistant Director, Program Operations.

[FR Doc. 86-14486 Filed 6-25-86; 8:45 am]

BILLING CODE 4310-OS-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[A-5-FRL-3038-5]

Approval and Promulgation of Implementation Plans; Illinois

AGENCY: U.S. Environmental Protection Agency (USEPA).

ACTION: Proposed rulemaking.

SUMMARY: USEPA proposes to approve a revision to the Illinois State Implementation Plan (SIP) for ozone. The revision, if finally approved, would provide an extended compliance schedule for National Can Corporation's (National Can) Rockford facility which is located in Rockford, Illinois. This SIP revision would allow National Can additional time to reformulate the coatings used in manufacturing cans for the general line can market. This action is taken in response to a May 6, 1985, request from the State of Illinois.

DATE: Comments on this revision and on the proposed USEPA action must be received by July 28, 1986.

ADDRESSES: Copies of the SIP revision are available at the following addresses for review: (It is recommended that you telephone Uylaine E. McMahan, at (312) 886-6031, before visiting the Region V office.)

U.S. Environmental Protection Agency, Region V, Air and Radiation Branch, 230 South Dearborn Street, Chicago, Illinois 60604

Illinois Environmental Protection Agency, Division of Air Pollution Control, 2200 Churchill Road, Springfield, Illinois 62706

Comments on this proposed rule should be addressed to: (Please submit an original and three copies, if possible.) Gary Gulezian, Chief, Regulatory Analysis Section, Air and Radiation Branch (5AR-26), U.S. Environmental Protection Agency, Region V, 230 South Dearborn Street, Chicago, Illinois 60604.

FOR FURTHER INFORMATION CONTACT: Uylaine E. McMahan, (312) 886-6031.

SUPPLEMENTARY INFORMATION: On May 6, 1985, the Illinois Environmental Protection Agency (IEPA) submitted a proposed revision to its ozone SIP for National Can's Rockford facility located in Rockford, Illinois. This SIP revision is in the form of an April 1, 1982, Opinion and Order of the Illinois Pollution Control Board (IPCB), PCB 81-189, and a January 24, 1985, Opinion and Order of the IPCB, PCB 84-108. These Orders grant National Can a variance from the existing SIP requirements from December 31, 1982, until December 31, 1983, and from December 31, 1983, until December 31, 1985, respectively.

Under the existing federally approved SIP, Illinois Can Coating limitations are:

(i) Sheet basecoat and overvarnish—2.8 lbs/gal.

(ii) Exterior base coat and overvarnish—2.8 lbs/gal.

(iii) Interior body spray coat—4.2 lbs/gal.

(iv) Exterior end coat—4.2 lbs/gal.

(v) Side seam spray coat—5.5 lbs/gal.

(vi) End sealing compound coat—3.7 lbs/gal.

National's can coating lines are subject to the above emission limitations, which are contained in Rule 205(n)(1)(B) of Chapter 2: Air Pollution, of the Illinois Pollution Control Board Rules and Regulations. Final compliance with these emission limitations on a line-by-line basis, was required by December 31, 1982. National's Rockford facility is currently emitting at higher levels consistent with the State variances. This SIP revision will not produce any increase in emissions. National has failed to achieve compliance with the interior body spray coat final emission limit.

USEPA's policy on approving compliance date extensions for controlling VOC emissions from certain can manufacturing processes was published in the March 10, 1982, **Federal Register** (47 FR 10293). The policy states that USEPA will approve compliance date extensions for control of VOC emissions from can coating operations in those cases where the extension will facilitate the expeditious conversion to low solvent technology. These extensions may be granted for a period up to December 31, 1985, where an expeditious, legally enforceable compliance program has been developed. In addition, an approvable compliance date extension must be consistent with the reasonable further progress (RFP) requirements of the Clean Air Act and must not prevent the area from attaining the ozone national ambient air quality standard by the area's attainment date.

National Can is located in Winnebago County which is an attainment area for ozone.

USEPA believes that this SIP revision provides for an expeditious, legally enforceable compliance program to convert to low solvent coatings which is in accordance with the provisions contained in USEPA's policy relating to time extensions for can coating operations. USEPA considers the 3-year extension request to be reasonable and expeditious because of the difficulty associated with the reformulation of coatings used for the general line can market. In addition, because the area presently attains the NAAQS for ozone, the compliance date extension does not jeopardize RFP.

It should be noted that National Can may either demonstrate final compliance with the SIP emission limitations for each individual can coating operation or it may use the procedure described in the December 8, 1980, **Federal Register** (45 FR 80824), entitled "Compliance with VOC Emission Limitations for Can Coating Operations." This compliance method allows the use of a daily weighted average in conjunction with a plantwide emission limitation. USEPA issued the December 8, 1980, interpretative statement to notify State and local agencies that, in USEPA's view, State and local regulations may be interpreted as allowing the use of daily weighted averages for approving permits and compliance plans, without further regulatory changes or the need for a SIP revision. This policy memorandum allows the use of a standardized equation to express the weight of VOC per gallon of coating, less water, in terms of weight of VOC per gallon of solids to determine compliance.

It should further be noted that Illinois' test methods for demonstrating compliance for surface coating operations consist of methods of analyzing the solvent content of coatings, and are essentially instantaneous. Rule 205(n)(4) of the Illinois SIP allows use of a daily weighted average bubble and is a vehicle for implementing the daily weighted average can coating policy. However, on July 11, 1985 (50 FR 28224), USEPA proposed to disapprove Rule 205(n)(4) because the equations for determining compliance with emission limits are deficient. Therefore, the method set forth in USEPA's December 8, 1980, interpretative statement must be used by National Can to demonstrate compliance with the SIP emission limits.

If National Can's reformulation program fails, it must begin procedures for construction of add-on control equipment by the third quarter of the variance period, have installed add-on control equipment by December 31, 1985, and have achieved and demonstrated final compliance with the Illinois Ozone SIP limitations control in Rule 205(n)(1)(B) on or before the same date.

USEPA is providing a 30-day comment period on this notice of proposed rulemaking. Public comments received on or before July 28, 1986 will be considered in USEPA's final rulemaking. All comments will be available for inspection during normal business hours at the Region V office listed at the front of this notice.

Under 5 U.S.C. 605(b), the Administrator has certified that SIP approvals do not have a significant economic impact on a substantial number of small entities. (See 46 FR 8709).

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12291.

Authority: 42 U.S.C. 7401-7642.

Dated: December 27, 1985.

Valdas V. Adamkus,

Regional Administrator.

[FR Doc. 86-14469 Filed 6-25-86; 8:45 am]

BILLING CODE 6560-50-M

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40 CFR Part 52

[A-7-FRL-3038-6]

Approval and Promulgation of State Implementation Plan for Missouri

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of Inadequacy for the State Implementation Plan (SIP) for lead and call for revisions.

SUMMARY: In this document, EPA gives notice that it has notified the Governor of Missouri that the SIP is inadequate to attain the National Ambient Air Quality Standards for lead in Herculaneum, Missouri. The Governor has been requested to revise the plan and submit the revisions within one year. The purpose of this notice is to advise the public of EPA's action.

DATE: The final plan revision must be submitted to EPA by June 3, 1987.

ADDRESSES: The information on which this decision was based is available from the Environmental Protection Agency, 726 Minnesota Avenue, Kansas City, Kansas 66101.

FOR FURTHER INFORMATION CONTACT: Dewayne E. Durst (913) 236-2893, FTS 757-2893.

SUPPLEMENTARY INFORMATION: On October 5, 1978, EPA promulgated an ambient air quality standard for lead. The standard was set at a level of 1.5 micrograms per cubic meter, maximum arithmetic mean averaged over a calendar quarter. On the same date, regulations were promulgated which contained requirements for preparation, adoption, and submittal of implementation plans for lead. On September 2, 1980, Missouri submitted a SIP which was designed to attain the lead standard throughout the State. EPA approved that plan with exceptions on April 27, 1981 (46 FR 23412).

The plan indicated that the ambient lead standard was exceeded in Herculaneum during a three-month sampling period in 1979. Because there was urgency in completing and submitting the lead plan, Missouri used only one quarter of data on which to base the original plan. The plan contained a control strategy which required the St. Joe primary lead smelter located in Herculaneum to install certain controls which were calculated to provide sufficient emission reductions to meet the lead standard. It also required the company to establish a monitoring network which would be used to determine if the standards were actually met after all of the controls were in place. The monitors have been in place since 1982. The monitors have shown that there are still violations of the lead standard even though all the controls which were contained in the plan have been implemented at the St. Joe smelter. This indicates that additional controls are needed in order to meet the standard.

On June 3, 1986, EPA notified Governor John Ashcroft of Missouri that the Missouri SIP for lead is substantially inadequate. In order to cure the problem, EPA requested the State to revise the plan as it pertains to the area in the immediate vicinity of the St. Joe lead smelter in Herculaneum, Missouri. This is the only portion of the State where EPA has determined that the Missouri lead SIP is substantially inadequate. The call for the plan revision was issued pursuant to the authority of section 110(a)(2)(H) of the Clean Air Act (42 U.S.C. 7410(a)(2)(H). The revision must meet the requirements of section 110 of the Clean Air Act and the regulations in 40 CFR Part 51 issued pursuant thereto (section 110 and section 301 of the Clean Air Act (U.S.C. 7410 and 7601)).

Dated: June 3, 1986.

Morris Kay,

Regional Administrator.

[FR Doc. 86-14468 Filed 6-25-86; 8:45 am]

BILLING CODE 6560-50-M

GENERAL SERVICES ADMINISTRATION

41 CFR Part 201-8

Implementation and Revision of Federal Information Processing Standards (FIPS) and Federal Telecommunications Standards (FED-STDS) in the Federal Information Resources Management Regulation (FIRMR)

AGENCY: Information Management Service, GSA.

ACTION: Notice of proposed rulemaking.

SUMMARY: The proposed final regulation updates and implements FIRMR provisions for twelve Federal Information Processing Standards (FIPS) and two Federal Telecommunications Standards (FED-STDS) to provide associated standard terminology that shall be used as solicitation documents and requirements documents as applicable. The general terminology of FIPS PUBS 68, 69, and 111 is updated; FIPS PUBS 109 and 112 through 119, INT-FED-STD 1031, and FED-STD 1033 are inserted: and, FIPS PUBS 46 and 81 are relocated to a new section that reflects the National Bureau of Standards' categorization of operation standards. The intended effect of this regulation is to enhance economy and efficiency in the acquisition of automatic data processing/telecommunications equipment and services.

DATE: Comments are due: July 28, 1986.

ADDRESS: Comments should be submitted to the General Services Administration (KMPP), Washington, DC 20405.

FOR FURTHER INFORMATION CONTACT: Mary B. Anderson, Policy Branch (KMPP), Information Resources Management Service, telephone (202) 566-0194 or FTS, 566-0194. The full text of the proposed rule is available upon request.

SUPPLEMENTARY INFORMATION: The General Services Administration (GSA) has determined that this rule is not a major rule for purposes of Executive Order 12291 of February 17, 1981. GSA decisions are based on adequate information concerning the need for, and the consequences of the rule. The rule is written to ensure maximum benefits to Federal agencies. This is a Governmentwide management, acquisition, and use regulations that will have little or no net cost effect on society.

List of Subjects in 41 CFR Chapter 201-8

Computer technology, Telecommunications, Information resources activities, and Standards for information resources.

Dated: May 29, 1986.

Francis A. McDonough,

Deputy Commissioner for Federal Information Resources Management Service.

[FR Doc. 86-14502 Filed 6-25-86; 8:45 am]

BILLING CODE 6820-25-M

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 6, 8, 15, 41, and 52

Federal Acquisition Regulation (FAR); Extension of Comment Period on Proposed Revision of Acquisition of Utility Services

AGENCIES: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Proposed rule (Extension of comment period).

SUMMARY: The Civilian Agency Acquisition Council and the Defense Acquisition Regulatory Council have approved a revision to FAR Subpart 8.3, Acquisition of Utility Services, and its redesignation as FAR Part 41, Utility Services. The proposed revision was published in the **Federal Register** on May 7, 1986 (51 FR 16988). The original date for submission of comments was July 7, 1986. In response to requests from utility suppliers and from regulatory utility commissioners, the Councils have decided to extend the period for public comment to ensure the adequacy of the time made available for public consideration of the proposed rule.

DATE: Comments should be submitted to the FAR Secretariat at the address shown below on or before September 7, 1986, to be considered in the formulation of a final rule.

ADDRESS: Interested parties should submit written comments to: General Services Administration, FAR Secretariat (VRS), 18th & F Streets NW., Room 4041, Washington, DC 20405.

Please cite FAR Case 85-10 in all correspondence related to this issue.

FOR FURTHER INFORMATION CONTACT: Ms. Margaret A. Willis, FAR Secretariat, Telephone (202) 523-4755.

List of Subjects in 48 CFR Parts 6, 8, 15, 41, and 52

Government procurement.

Dated: June 20, 1986.

Lawrence J. Rizzi,

Director, Office of Federal, Acquisition and Regulatory Policy.

[FR Doc. 86-14387 Filed 6-25-86; 8:45 am]

BILLING CODE 6820-61-M

Notices

Federal Register
Vol. 51, No. 123
Thursday, June 26, 1986

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Soil Conservation Service

Big Sandy Salinity Control Plan, Colorado River Salinity Control Program, WY

AGENCY: Soil Conservation Service, USDA.

ACTION: Notice of a Finding of No Significant Impact.

SUMMARY: Pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969; the Council on Environmental Quality Guidelines (40 CFR Part 1500); and the Soil Conservation Service Guidelines (7 CFR Part 650); the Soil Conservation Service, U.S. Department of Agriculture, gives notice that an environmental impact statement is not being prepared for the Big Sandy River Salinity USDA Salinity Control Plan in Sweetwater County, Wyoming.

FOR FURTHER INFORMATION CONTACT: Mr. Frank S. Dickson, Jr., State Conservationist, Soil Conservation Service, Room 3124, 100 East B Street, Casper, Wyoming 82601, telephone 307-261-5201.

SUPPLEMENTARY INFORMATION: The environmental assessment of this federally assisted action indicates that the project will not cause significant local, regional, or national impacts on the environment. As a result of these findings, Frank S. Dickson, Jr., State Conservationist, has determined that the preparation and review of an environmental impact statement are not needed for this project.

The Selected Plan calls for the following structures to be installed on a maximum of 15,700 acres of irrigated land to reduce salinity in the Colorado River Basin.

Distribution Pipeline and Risers
Motor, Pumps, and Valves
Low Pressure Sprinkler Irrigation Systems
Irrigation Wasteway System
Voluntary Wildlife Habitat Development and Enhancement (Wetland and Upland)

Actual acreage would vary depending on individual participation in the program. Participation would be voluntary and implemented through long-term contracts administered by the USDA Agricultural Stabilization and Conservation Service. Technical assistance for conservation planning, implementation of planned practices, assistance to realize irrigation water management objectives, and installation of wildlife practices would be provided by the Soil Conservation Service. A project team would consist of soil conservationlists, an irrigation water management specialist, engineers, a biologist, civil engineering technicians, and soil conservation technicians.Additional irrigation water management assistance would be provided by the Cooperative Extension Service.

Implementation of the Selected Plan will result in a reduction of an estimated 52,900 tons of salt annually entering the Big Sandy River. This would amount to a decrease in salinity in the Green River at the town of Green River, Wyoming, of 26.67 milligrans per liter or a decrease of 5.49 milligrams per liter at Imperial Dam on the lower Colorado River.

The Selected Plan would also increase hay production by an average yield greater than 2 tons annually. In addition to the increased yields, irrigators will be able to go to pure stands of alfalfa and realize a higher value crop. Other benefits would include: stands maturing earlier, remaining productive longer, and producing a second cutting yearly.

If all eligible acres were converted to sprinkler irrigation, about 3,775 acres of irrigation water induced and suplemented wetlands (USFWS Circ. 39, Types 1, 2, 3, 4, 9, and 10) would be affected. Reduced water supply would occur on about 1,010 acres of wetlands, and 2,765 acres of wetlands may be eliminated. The majority of these wetlands are lower value Types 1, 2, and 9. To replace wildlife habitat values foregone, the habitat quality of about 860 acres of higher value welands (Types 3, 4, and 10) would be preserved and enhanced by pond lining, livestock exclusion, seeding, and installation of nesting islands. Various conservation practices would be installed and implemented that would also create and enhance wildlife habitat (vegetation) around ponds, regulating reservoirs, wasteways, ditches, field edges, and odd area. All wildlife habitat (wetlands and vegetation) will be inventoried in the before- and after-plan conditions in order to determine the wildlife habitat values needed to replace values foregone. The Habitat Evaluation Procedures (HEP) developed by the U.S. Fish and Wildlife Service will be used by the team biologist or other HEP certified team members for these inventories.

Excess water in the reservoir resulting from improved efficiencies could be released on a schedule that would enhance fish habitat and reduce downstream flood damages. Release schedules could be developed by the Wyoming Game and Fish Department and need concurrence from the Wyoming State Engineer.

Implementation of the salinity control project will cause flows in Bone Draw to cease. Bone Draw, located about 5 miles below the project, is a small tributary that flows 0.5 to 1.5 cfs of water from saline seeps. During drought years, Bone Draw has ceased to flow. Aware of these and propsed project flow regimes, the Bureau of Land Management and a local sportsmen's group fenced and developed Bone Draw for a trout fry nursery.

Installation of the selected plan is not expected to have any adverse effects on endangered species that may occur in the project area.

There are several cultural resource sites and areas of high potential located on or near the irrigated lands. Since participation in the project would be voluntary, cultural resource surveys would be conducted, where appropriate, when specific construction sites are identified.

The installation of structures would have short-term adverse impacts as a result of construction activities. Disturbed areas would be reseeded with adaptable vegetative cover favorable to wildlife. Shor-term impacts are not considered significant. Long-term impacts are either beneficial or not significant.

The initial work for the Big Sandy River salinity study was done in 1978 and 1979. A report entitled *Big Sandy*

River, Colorado River Basin Salinity Control Study, USDA Report, was completed in November 1980. However, the USDA report did not identify a viable alternative which could be supported by the State of Wyoming, the Soil Conservation Service, and the irrigators in the area. The report did discuss environmental effects of several alternatives.

Early in 1984, the State of Wyoming asked that the Soil Conservation Service evaluate an additional alternative, installation of a low pressure sprinkler irrigation system. Consensus from the State of Wyoming, Soil Conservation Service, and the irrigators was favorable to the low pressure sprinkler alternative. The State of Wyoming and Big Sandy Conservation District asked the SCS to prepare a USDA Selected Onfarm Low Pressure Sprinkler Plan. This Findings of No Significant Impact addresses that alternative.

Preliminary environmental information and cumulative impacts for the 16 original units in Title II of the Colorado River Basin Salinity Control Act have been presented in a final environmental statement on the Colorado River Water Quality Improvement Program (FES 77-15). The statement was prepared by the Bureau of Reclamation, Department of the Interior, and the Soil Conservation Service, Department of Agriculture, and was filed with the Council on Environmental Quality on May 16, 1977.

The Finding of No Significant Impact (FONSI) and Environmental Assessment Summary (EAS) have been forwarded to the Environmental Protection Agency and to various Federal, State, and local agencies and intrested parties. A limited number of copies of the FONSI and the EAS are available to fill single copy requests at the above address. Basic data developed during the environmental assessment are on file and may be reviewed by contacting Mr. Frank S. Dickson, Jr.

No administrative action on implementation of the proposal will be taken until 30 days after the date of this publication in the **Federal Register.**

(Catalog of Federal Domestic Assistance Program No. 10.902, Conservation Operations Program. Executive Order No. 12372 regarding State and local clearinghouse review of Federal and federally assisted programs and projects is applicable)

Dated: June 19, 1986.

Frank S. Dickson,

State Conservationist.

[FR Doc. 86-14500 Filed 6-25-86; 8:45 am]

BILLING CODE 4310-16-M

Moonlight Lateral Farm Irrigation RC&D Measure, CO

AGENCY: Soil Conservation Service, USDA.

ACTION: Notice of finding of no significant impact.

SUMMARY: Pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969; the Council on Environmental Quality Guidelines (40 CFR Part 1500); and the Soil Conservation Service, U.S. Department of Agriculture, gives notice that an Environmental Impact Statement is not being prepared for the Moonlight Lateral Farm Irrigation RC&D Measure, Montezuma County, Colorado.

FOR FURTHER INFORMATION CONTACT: Mr. Sheldon G. Boone, State Conservationist, Soil Conservation Service, 2490 West 26th Avenue, Denver, Colorado 80211, telephone (303) 964-0292.

SUPPLEMENTARY INFORMATION: The Environmental Assessment of this federally assisted action indicates that the measure will not cause significant local, regional or national impacts on the environment. As a result of these findings, Mr. Sheldon G. Boone, State Conservationist, has determined that the preparation and review of an Environmental Impact Statement are not needed for this measure.

This farm irrigation measure concerns a plan to improve the irrigation system. The planned works of improvement include installing 16,200 feet of concrete ditch, replacing a severely eroding earthen ditch. The measure will reduce erosion and sedimentation, prevent interruption of irrigation water delivery, and reduce salinization downstream.

The Notice of Finding of No Significant Impact (FONSI) has been forwarded to the Environmental Protection Agency and to various federal, state and local agencies and interested parties. A limited number of copies of the FONSI are available at the above address to fill single-copy requests. Basic data developed during the Environmental Evaluation are on file and may be reviewed by contacting Mr. Sheldon G. Boone. No administrative action on implementation of the proposal will be taken until 30 days after the date of this publication in the **Federal Register.**

(This activity is listed in the Catalog of Federal Domestic Assistance under No. 10.901, Resource Conservation and Development, and is subject to the provisions of Executive Order 12372 which requires intergovernmental consultation with state and local officials.)

Dated: June 16, 1986.

Kenneth A. Pitney,

Assistant State Conservationist (Programs).

[FR Doc. 86-14381 Filed 6-25-86; 8:45 am]

BILLING CODE 3410-16-M

ARCHITECTURAL AND TRANSPORTATION BARRIERS COMPLIANCE BOARD

DEPARTMENT OF THE TREASURY

INTERAGENCY COORDINATING COUNCIL

A Federal TDD Relay Service

The U.S. Architectural and Transportation Barriers Compliance Board (Board), the Department of the Treasury, and the Interagency Coordinating Council announce that the Treasury Department is establishing, in cooperation with the Board, a pilot relay service as a method to facilitate communication between users of telecommunication devices for deaf persons (TDDs) and telephone users, for calls between the Federal Government and the general public.

The pilot service, funded by the Board and provided by the Office of the Secretary's Telecommunications Center at the Treasury Department, is expected to be operating by June. The telephone numbers will be: (202) 566-2673 (TDD); and (202) 377-9555 (voice). These numbers are not toll free. During the trial period, the TDD relay service will operate from 9 a.m. to 5 p.m., Eastern Standard Time, Monday through Friday, excluding government holidays. The TDD's will automatically record incoming TDD calls (but not voice calls) during other hours.

Any member of the public needing to contact an agency of the Executive, Legislative, or Judicial branches of the Federal Government may initiate a call to the TDD relay service. The Treasury operator will relay messages between the conversing parties—via the TDD in one direction and orally in the other direction—until the conversation has ended. Also, any employee of a Federal agency needing to contact a member of the public by TDD may use the TDD relay service.

TDDs enable persons with hearing and/or speech impairments to communicate through the telephone system. To have an effective TDD communication, both the transmitting and the receiving parties must have TDDs, unless a TDD relay is used. Instead of talking into a telephone receiver, a TDD user transmits a

message across telephone lines by typing the message on the keyboard, and receives a typed message on a display screen.

The use of TDDs to facilitate communication between the Federal Government and members of the public who rely on TDDs has been increasing. Many agencies have already installed TDDs in their offices. For example, the Internal Revenue Service and the Social Security Administration provide toll free TDD "800" service. The pilot relay service will supplement the TDDs already in place.

The Interagency Coordinating Council (Council) was established by section 507 of the Rehabilitation Act of 1973, as amended in 1978 (29 U.S.C. 794c), to promote efficiency among the various agencies responsible for the implementation of title V of the Act. Section 501 of the Act (29 U.S.C. 791) requires Federal agencies to structure their procedures and programs so as to ensure that qualified handicapped individuals are afforded equal employment opportunity. The section 501 regulation promulgated by the Equal Employment Opportunity Commission (EEOC) requires Federal agencies to make reasonable accommodations to the known physical or mental limitations of a qualified handicapped applicant or employee, 29 CFR 1613.704. Under this regulation, many agencies have provided, as reasonable accommodations, TDDs in their offices to provide TDD communication with applicants and employees with hearing and/or speech impairments as well as to enable employees with these impairments to communicate by telephone.

Section 504, 29 U.S.C. 794, as amended in 1978, prohibits discrimination on the basis of handicap in programs or activities conducted by Executive agencies or the United States Postal Service. Numerous agencies, including the Department of Justice, have issued final regulations implementing this section, requiring them to take appropriate steps to ensure effective communication with personnel of other Federal entities, applicants, participants, and members of the public (e.g., 49 FR 35736–35737 (1984), to be codified at 28 CFR 39.160 (18 other agencies)). These regulations require the agencies to provide auxiliary aids to ensure that handicapped people have an equal opportunity to participate in, and enjoy the benefit of, their programs or activities. *Id.* Specifically, they provide that where the agency communicates with applicants and beneficiaries by telephone, TDDs or equally effective telecommunication systems be used. *Id.* In carrying ut these section 504 responsibilities, some agencies have installed TDDs in their offices to provide effective communication with those who use TDDs.

The Board is charged by section 502, among other things, with responsibility to investigate and examine alternative approaches to the "communication . . . barriers confronting handicapped individuals, particularly with respect to telecommunication devices" (29 U.S.C. 794(b)(2)). It also has a responsibility to ". . . develop standards and provide appropriate technical assistance to any public or private activity, person, or entity affected by regulations prescribed pursuant to this subchapter (title V) with respect overcoming to (sic) . . . communication barriers" (*Id.* at section (d)(3)). In carrying out these responsibilities, the Board agreed to finance the pilot project, to be operated by the Department of the Treasury.

The Council has endorsed the use of the TDD relay service by agencies in order to provide increased communication accessibility to the public as well as within the government. The Council, however, emphasizes that it does not endorse this service as the *sole* means for all agencies to meet their responsibilities under title V. In some instances, a Federal agency, because of its size, or the number and nature of calls, may need to have its own TDD capability or relay services, or the use of the Treasury relay service and its own TDD system.

The pilot test, to extend for a period of approximately one year, will allow the Board and Treasury to assess the level of interest among departments and agencies throughout the Federal Government in continuing the service beyond the trial period on a reimbursable basis.

Further information on the project, contact Mr. Rollin M. Westwood, Treasury Department, at (202) 377–9313 (voice) or (202) 566–1672 (TDD), or Dr. Frank Bowe, the Board, at (202) 472–2700 (voice or TDD). These numbers are not toll free.

Charles R. Hauser,

Chairperson, Architectural and Transportation Barriers Compliance Board.

May 22, 1986.

John F. W. Rogers,

Assistant Secretary of the Treasury (Management).

May 16, 1986.

Wm. Bradford Reynolds,

Chairperson, Interagency Coordinating Council.

June 19, 1986.

[FR Doc. 86–14405 Filed 6–25–96; 8:45 am]

BILLING CODE 4410–01–M

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Docket No. 20–86]

Foreign-Trade Zone 84, Harris County, TX (Houston POE); Amendment of Zone Plan

An application has been submitted to the Foreign-Trade Zones Board (the Board) by the Port of Houston Authority (PHA), grantee of Foreign-Trade Zone 84, requesting an amendment to its zone plan to add a petroleum and chemical storage and blending facility in Harris County, Texas, within the Houston Customs port of entry. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 USC 81a–81u), and the regulations of the Board (15 CFR 400). It was formally filed on June 9, 1986.

PHA received authority from the Board to establish a multi-site foreign-trade zone in Harris County, Texas, on July 15, 1983 (Board Order 214, 48 FR 34792, August 1, 1983. While 5 PHA sites were approved as conventional ones, the remaining sites were approved for 5 years, subject to special conditions. The zone plan was amended in 1985 to delete 8 and add 10 non-PHA sites subject to the same time limitation and conditions as the original ones (Board Order 303, 50 FR 20252). This amendment would also be subject to the same time limitation and conditions as the other non-PHA sites.

The proposed amendment would involve adding to the zone the public petroleum product and chemical storage terminal and blending facilities of Intercontinental Terminals Company, located on a 125-acre parcel at Mile Point 35.4 on the Houston Ship Channel in the Deer Park area. With a 4 million barrel capacity, the facility stores and blends industrial chemicals, petrochemicals, motor fuels, and blendstocks. The company would use zone procedures for motor fuel blending for export only.

In accordance with the regulations, an examiners committee has been appointed to investigate the application and report to the Board. The committee consists of: John J. Da Ponte, Jr. (Chairman), Director, Foreign-Trade Zones Staff, U.S. Department of Commerce, Washington, DC 20230; Donald Gough, Deputy Assistant Regional Commissioner, U.S. Customs Service, Southwest Region, 5850 San Felipe Street, Houston, TX 77057; and Colonel Gordon M. Clarke, District Engineer, U.S. Army Engineer District Galveston, P.O. Box 1229, Galveston, TX 77553.

Comments concerning the proposed amendment of the zone plan are invited in writing from interested parties. They should be addressed to the Board's Executive Secretary at the address below and postmarked on or before July 29, 1986.

A copy of the application is available for public inspection at each of the following locations:

U.S. Dept. of Commerce District Office, 2625 Federal Courthouse, 515 Rusk Street, Houston, TX 77002

Office of the Executive Secretary, Foreign-Trade Zones Board, U.S. Dept. of Commerce, Room 1529, 14th and Pennsylvania, NW., Washington, DC 20230

Dated: June 20, 1986.

John J. Da Ponte, Jr.,

Executive Secretary.

[FR Doc. 86-14484 Filed 6-25-86; 8:45 am]

BILLING CODE 3510-25-M

International Trade Administration

Johns Hopkins University; Decision on Application for Duty-Free Entry of Scientific Instrument

This decision is made pursuant to section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89-651, 80 Stat. 897; 15 CFR 301). Related records can be viewed between 8:30 AM and 5:00 PM in Room 1523, U.S. Department of Commerce, 14th and Constitution Avenue, NW., Washington, DC.

Docket Number: 86-049. Applicant: The Johns Hopkins University, Baltimore, MD 21218. Instrument: Eight-channel Pulse Generator, Model Master-8-cp. Manufacturer: A.M.P.I., Israel. Intended Use: See notice at 50 FR 52821.

Comments: None received. Decision: Approved. No instrument of equivalent scientific value to the foreign instrument, for such purposes as it is intended to be used, is being manufactured in the United States.

Reasons: The foreign instrument provides computer controlled generation of digital electrical pulses with eight independently programmable channels. The National Institutes of Health advises in its memorandum dated May 1, 1986 that (1) this capability is pertinent to the applicant's intended purpose and (2) it knows of no domestic instrument or apparatus of equivalent scientific value to the foreign instrument for the applicant's intended use.

We know of no other instrument or apparatus of equivalent scientific value to the foreign instrument which is being manufactured in the United States.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials)

Frank W. Creel,

Director, Statutory Import Programs Staff.

[FR Doc. 86-14480 Filed 6-25-86; 8:45 am]

BILLING CODE 3510-DS-M

Johns Hopkins University Decision on Application for Duty-Free Entry of Scientific Instrument

This decision is made pursuant to section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89-651, 80 Stat. 897; 15 CFR 301). Related records can be viewed between 8:30 AM and 5:00 PM in Room 1523, U.S. Department of Commerce, 14th and Constitution Avenue, NW., Washington, DC.

Docket No.: 86-037. Applicant: The Johns Hopkins University, Baltimore, MD 21218. Instrument: Two Multi-electrode Recording Systems. Manufacturer: Philipps-Universitat Marburg, West Germany. Intended use: See notice at 50 FR 48451.

Comments: None received. Decision: Approved. No instrument of equivalent scientific value to the foreign instrument, for such purposes as it is intended to be used, is being manufactured in the United States.

Reasons: The foreign instrument provides a unique seven-channel fiberoptical microelectrode advancer with high precision drives and stepper motor assemblies. The National Institutes of Health advises in its memorandum dated May 1, 1986 that (1) this capability is pertinent to the applicant's intended purpose and (2) it knows of no domestic instrument or apparatus of equivalent scientific value to the foreign instrument for the applicant's intended use.

We know of no other instrument or apparatus of equivalent scientific value to the foreign instrument which is being manufactured in the United States.

Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials.

Frank W. Creel,

Director, Statutory Import Programs Staff.

[FR Doc. 86-14481 Filed 6-25-86; 8:45 am]

BILLING CODE 3510-DS-M

Montana State University; Decision on Application for Duty-Free Entry of Scientific Instrument

This decision is made pursuant to section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89-651, 80 Stat. 897; 15 CFR 301). Related records can be viewed between 8:30 AM and 5:00 PM in Room 1523, U.S. Department of Commerce, 14th and Constitution Avenue, NW., Washington, DC.

Docket No.: 85-191R. Applicant: Montana State University, Bozeman, MT 59717. Instrument: Electron Loss Spectrometer, Model ELS-22 with Accessories. Manufacturer: Leybold-Heraeus, West Germany. Intended use: Original notice of this resubmitted application was published in the **Federal Register** of June 26, 1985.

Comments: None received. Decision: Approved. No instrument of equivalent scientific value to the foreign instrument, for such purposes as it is intended to be used, is being manufactured in the United States.

Reasons: The foreign instrument provides a resolution of 5 meV and an extremely low background ($S/B10^8$). The capability is pertinent to the applicant's intended purpose. We know of no domestic instrument or apparatus of equivalent scientific value to the foreign instrument for the applicant's intended use.

Catalog of Federal Domestic Assistance Programs No. 11.105, Importation of Duty-Free Educational and Scientific Materials.

Frank W. Creel,

Director, Statutory Import Programs Staff.

[FR Doc. 86-14483 Filed 6-25-86; 8:45 am]

BILLING CODE 3510-OS-M

University of Colorado Health Sciences Center; Decision on Application for Duty-Free Entry of Scientific Instrument

This decision is made pursuant to section 6(c) of the Educational Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89-651, 80 Stat. 897; 15 CFR 301). Related records can be viewed between 8:30 AM and 5:00 PM in Room 1523, U.S. Department of

Commerce, 14th and Constitution Avenue, NW., Washington, DC.

Docket No.: 86-043. Applicant: University of Colorado Health Sciences Center, Denver, CO 80262. Instument: Counter Current Distribution Apparatus. Manufacturer: Kemicentrum, Lunds Universitet, Sweden. Intended use: See notice at 50 FR 48451.

Comments: None received. Decision: Approved. No instrument of equivalent scientific value to the foreign instrument, for such purposes as it is intended to be used, is being manufactured in the United States. Reasons: The foreign instrument provides precise sequential phase separation (120 steps) of cell membranes. The National Institutes of Health advises in its memorandum dated May 1, 1986 that (1) this capability is pertinent to the applicant's intended purpose and (2) it knows of no domestic instrument or apparatus of equivalent scientific value to the foreign instrument for the applicant's intended use.

We know of no other instrument or apparatus of equivalent scientific value to the foreign instrument which is being manufactured in the United States.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials)

Frank W. Creel,

Director, Statutory Import Programs Staff.

[FR Doc. 86-14479 Filed 6-25-86; 8:45 am]

BILLING CODE 3510-DS-M

University of Massachusetts Medical Center; Decision on Application for Duty-Free Entry of Scientific Instrument

This decision is made pursuant to section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89-651, 80 Stat. 897; 15 CFR 301). Related records can be viewed between 8:30 AM and 5:00 PM in Room 1523, U.S. Department of Commerce, 14th and Constitution Avenue, NW., Washington, DC.

Docket No.: 86-025. Applicant: University of Massachusetts Medical Center, Worcester, MA 01605. Instrument: Dual Wave Length Fluorescence Stop-Flow Spectrophotometer. Manufacturer: Hi-Tech Scientific Limited, United Kingdom. Intended use: See notice at 50 FR 46149.

Comment: None received. Decision: Approved. No instrument of equivalent scientific value to the foreign instrument, for such purposes as it is intended to be used, is being manufactured in the United States. Reasons: The foreign instrument provides rapid multimixing of four substances over a wide temperature range (−100 to +100 degrees centigrade with an accuracy of ± 0.1 degrees). The National Institutes of Health advises in its memorandum dated May 1, 1986 that (1) this capability is pertinent to the applicant's intended purpose and (2) it knows of no domestic instrument or apparatus of equivalent scientific value to the foreign instrument for the applicant's intended use.

We know of no other instrument or apparatus of equivalent scientific value to the foreign instrument which is being manufactured in the United States.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials)

Frank W. Creel,

Director, Statutory Import Programs Staff.

[FR Doc. 86-14482 Filed 6-25-86; 8:45 am]

BILLING CODE 3510-DS-M

[A-507-502]

Certain In-Shell Pistachios From Iran; Clarification of Scope in Antidumping Duty Investigation

AGENCY: International Trade Administration, Import Administration, Commerce.

ACTION: Notice.

SUMMARY: We have determined that roasted in-shell pistachios should not be included within the scope of the antidumping duty investigation of in-shell pistachios from Iran. This is based upon statements by petitioners' representatives before the International Trade Commission that petitioners did not include roasted pistachios within their request for an antidumping duty investigation of sales or in-shell pistachios.

EFFECTIVE DATE: June 26, 1986.

FOR FURTHER INFORMATION CONTACT: Mary S. Clapp, Office of Investigations, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230, telephone (202) 377-1769.

Background

On May 9, 1986, the Department of Commerce (the "Department") published a notice of clarification of scope in its antidumping duty investigation of in-shell pistachios from Iran (51 FR 17220). In that notice, the Department stated that roasted in-shell pistachios were within the scope of the investigation and noted that roasted and raw pistachios were part of the same class or kind of merchandise. On May 23, 1986, the Department published its final determination of sales at less than fair value, a determination which included roasted in-shell pistachios.

The Department has since learned that, in testimony before the International Trade Commission (ITC) during its injury investigation in this case, the petitioners, domestic growers of pistachios, specifically stated that they were not requesting the inclusion of roasted in-shell pistachios within the scope of the investigation. As a result of this testimony, the ITC specifically did not include roasted in-shell pistachios within its preliminary determination of the likelihood of injury to a domestic industry by virtue of imports of in-shell pistachios.

Based upon petitioners' ITC testimony, the Department has decided not to include roasted in-shell pistachios within the scope of the antidumping proceeding. We are, therefore, rescinding our notice of clarification of scope and amending our notice of final determination insofar as it involves roasted in-shell pistachios. We will continue to include raw in-shell pistachios, currently classified under item 145.2600 of the Tariff Schedules of the United States Annotated (TSUSA), within the scope of the proceeding.

We view the testimony of the petitioners at the ITC as determinative of the petitioners' intent with regard to scope in this case. The statements by the petitioners' representatives, which were not prior to this time a part of the Department's record, were a clear indication of the petitioners' intended scope and were a major factor in the ITC's decision not to include roasted in-shell pistachios within its investigation.

For these reasons, the Department's final determination of sales at less than fair value will not include roasted pistachios.

Suspension of Liquidation

The Department will instruct the United States Customs Service to discontinue suspension of liquidation of entries of roasted in-shell pistachios, classifiable under TSUSA item 145.5300, covered under the Department's clarification of May 9, 1986, and its final determination of May 23, 1986, and to liquidate those entries without regard to antidumping duties. We will instruct the Customs Service to continue to suspend liquidation of entries of all shipments of raw in-shell pistachios classifiable under TSUSA item 145.2600 entered, or withdrawn from warehouse, for consumption on or after December 11, 1985.

This notice is published pursuant to section 735(d) of the Act, as amended (19 U.S.C. 1673d(d)).

Dated: June 18, 1986.

Gilbert B. Kaplan,

Deputy Assistant Secretary for Import Administration.

[FR Doc. 86-14426 Filed 6-25-86; 8:45 am]

BILLING CODE 3510-DS-M

Consolidated Decision on Applications for Duty-Free Entry of Electron Microscopes; Rush-Presbyterian-St. Luke's Medical Center et al.

This is a decision consolidated pursuant to section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89-651, 80 Stat. 897; 15 CFR Part 301). Related records can be viewed between 8:30 A.M. and 5:00 P.M. in Room 1523, U.S. Department of Commerce, 14th and Constitution Avenue, NW., Washington, DC.

Docket No.: 86-155. Applicant: Rush-Presbyterian-St. Luke's Medical Center, Chicago, Il 60612. Instrument: Electron Microscope System, Model JEM-1200EX. Manufacturer: JEOL, Ltd., Japan. Intended Use: See notice at 51 FR 16729. Instrument Ordered: October 15, 1985.

Docket No.: 86-156. Applicant: Howard Hughes Medical Institute, Coconut Grove, FL 33133. Instrument: Electron Microscope, Model EM 430 with Accessories. Manufacturer: N.V. Philips, The Netherlands. Intended Use: See notice at 51 FR 12905. Application Received by Commissioner of Customs: March 13, 1986.

Docket No.: 86-170. Applicant: Washington University, St. Louis, MO 63130-4899. Instrument: Electron Microscope, Model JEM-2000FX. Manufacturer: JEOL, Ltd., Japan. Intended Use: See notice at 51 FR 13275. Instrument Ordered: January 28, 1986.

Docket No.: 86-173. Applicant: Northeastern University, Boston, MA 02115. Instrument: Electron Microscope, Model H-600-5. Manufacturer: Hitachi, Ltd., Japan. Intended Use: See notice at 51 FR 13275. Instrument Ordered: December 2, 1985.

Comments: None received.

Decision: Approved. No instrument of equivalent scientific value to the foreign instrument, for such purposes as these instruments are intended to be used, was being manufactured in the United States at the time the instruments were ordered.

Reasons: Each foreign instrument is a conventional transmission electron miscroscope (CTEM) and is intended for research or scientific educational uses requiring a CTEM. We know of no CTEM, or any other instrument suited to these purposes, which was being manufactured in the United States either at the time of order of each instrument or at the time of receipt of application by the U.S. Customs Service.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials.)

Frank W. Creel,

Director, Statutory Import Programs Staff.

[FR Doc. 86-14428 Filed 6-25-86; 8:45 am]

BILLING CODE 3510-DS-M

Consolidated Decision on Applications for Duty-Free Entry of Interferometers; State University of New York et al.

This is a decision consolidated pursuant to section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89-651, 80 Stat. 897; 15 CFR Part 301). Related records can be viewed between 8:30 A.M. and 5:00 P.M. in Room 1523, U.S. Department of Commerce, 14th & Constitution Avenue, NW., Washington, DC.

Docket No. 86-152. Applicant: SUNY at Buffalo, Buffalo, NY 14260. Intended Use: See notice at 51 FR 12906.

Docket No. 86-167. Applicant: Brown University, Providence, RI 02912. Intended Use: See notice at 51 FR 13275.

Article: Fourier Transform Interferometer.

Manufacturer: Bomen, Canada.

Comments: None received. Decision: Approved. No instrument of equivalent scientific value to the foreign instrument, for such purposes as each is intended to be used, is being manufactured in the United States. Reasons: Each foreign instrument to which the foregoing applications relate provides an unapodized resolution of 0.02 cm^{-1}. This capability is pertinent to each applicant's intended purpose. We know of no domestic instrument or apparatus of equivalent scientific value for the intended use of each instrument.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Education and Scientific Materials.)

Frank W. Creel,

Director, Statutory Import Programs Staff.

[FR Doc. 86-14430 Filed 6-25-86; 8:45 am]

BILLING CODE 3510-DS-M

Applications for Duty-Free Entry of Scientific Instruments; University of Michigan Hospitals et al.

Pursuant to section 6(c) of the Educational, Scientific and Cultural Materials Importation Act of 1966 (Pub. L. 89-651; 80 Stat. 897; 15 CFR Part 301), we invite comments on the question of whether instruments of equivalent scientific value, for the purposes for which the instruments shown below are intended to be used, are being manufactured in the United States.

Comments must comply with § 301.5(a) (3) and (4) of the regulations and be filed within 20 days with the Statutory Import Programs Staff, U.S. Department of Commerce, Washington, DC 20230. Applications may be examined between 8:30 A.M. and 5:00 P.M in Room 1523, U.S. Department of Commerce, 14th and Constitution Avenue, NW., Washington, DC.

Docket No. 86-031R. Applicant: The University of Michigan Hospitals, 1405 East Ann Street, Ann Arbor, MI 48109. Instrument: Extracorporeal Shock Wave Lithotripter. Manufacturer: Dornier Systems GmbH, West Germany. Original notice of this resubmitted application was published in the **Federal Register** of November 25, 1985.

Docket No. 86-229. Applicant: Cornell University, Section of Neurobiology & Behavior, NB&B, Mudd Hall, Ithaca, NY 14853. Instrument: Portable Analog Pulse Logger. Manufacturer: Helpware Computer Consultancy, United Kingdom. Intended Use: The instrument will be used to digitize individual electric organ discharges from electric fish from South America both in the field and in make-shift laboratories in the field. After digitization the signals are played back to individual fish in a series of experiments designed to test for the significance of pulse waveform in species recognition. All experiments will be done using standard behavioral methods. The instrument will also be used to teach students about analog signal digitization and about the use of electronic instruments in behavioral experimentation. Application Received by Commissioner of Customs: June 5, 1986.

Docket No. 86-230. Applicant: Norwich University, Northfield, VT 05663. Instrument: Electromagnetic Geophysical Instrument, Model EM-16. Manufacturer: Genoics Limited, Canada. Intended Use: The instrument will be used for educational purposes in the courses:

(1) Field Geology: a course teaching basic mapping methods and an introduction to the use of various geophysical instruments and

(2) Physical Geology—an introduction to the materials and processes of the earth.

Application Received by Commissioner of Customs: June 6, 1986.

Docket No. 86-231. Applicant: The University of Texas System Cancer Center, M.D. Anderson Hospital & Tumor Institute, Department of Pathology, 6723 Bertner, Houston, TX 77030. Instrument: Electron Microscope, Model JEM-1200EX. Manufacturer: JEOL Ltd., Japan. Intended Use: The instrument is intended to be used for the study of the ultrastructure of tumor cells. The experiments to be conducted will include:

—Characterization of the fine structure of cells of soft tissue sarcomas
—Ultrastructural morphometric analysis of poorly differentiated and undifferentiated lung carcinomas
—Evaluation of cytologic features of fine needle aspiration biopsies
—Correlative studies (with immunocytochemical methods) of cytoskeletal components in epithelial neoplasms
—Ultrastructural changes in anthracylcine-induced cardiotoxicity
—Pathologic alterations in rat peripheral nerves induced by cis-platinum.

The objectives of the investigations are to define the pathologic alterations occuring in the various tissues, compare and contrast them with normal (control) tissues and relate the observed changes to the etiologic factors.

Application Received by Commissioner of Customs: June 6, 1986.

Docket No. 86-232. Applicant: Michigan State University, Department of Metallurgy, Mechanics and Materials Science, 330 Engineering Building, East Lansing, MI 48824-1226. Instrument: LAB_6 Modification Kit and Accessories for Electron Microscope. Manufacturer: Hitachi Scientific Instruments, Japan. Intended Use: The instrument is intended to be used for studies of microstructure and electron diffraction patterns of metals, alloys, and some organic compounds. Dislocation contrast, diffraction, high-temperature deformation experiments will be conducted with the objective of understanding high-temperature behavior of metal-matrix composities. In additon, the instrument will be used for educational purposes in the courses: MMM 832: Electron Microscopy, MMM 899: Masters Thesis Research and MMM 999 Ph.D. Thesis Research.

Application Received by Commissioner of Customs: June 6, 1986.

Docket No. 86-234. Applicant: The Ohio State University, Campus Chemical Instrument Center, 176 W. 19th Avenue, Columbus, OH 43210. Instrument: Mass Spectrometer/Gas Chromatograph Data System, Model VG-70250S. Manufacturer: VG Instruments, United Kindgdom. Intended Use: The instrument is intended to be used for the analysis of chemical compounds isolated or synthesized by faculty research groups from several departments and colleges of the University. The experiments to be conducted include but are not limited to: accurate-mass measurement to determine chemical formula, gas chromatograph/mass spectrometry, fast atom bombardment for detection of involatile and/or polar species and chemical ionization.

Application Received by Commissioner of Customs: June 11, 1986.

Docket No. 86-235. Applicant: University of California, Lawrence Livermore National Laboratory, P.O. Box 5012, Livermore, CA 94550. Instrument: ICP Mass Spectrometer, Model Plasma Quad. Manufacturer: V.G. Isotopes, Ltd., United Kingdom. Intended Use: The intrument is intended to be used for research and development in support of the LLNL Atomic Vapor Laser Isotope Separation (AVLIS) program. Specifically, the instrument is to be used to perform the following analysis:

(a) High throughput isotopic ratio determinations of enriched and depleted uranium.
(b) Qualitative and quantitative determination of elemental impurity levels in AVLIS feedstock and product.

The objective of these investigations is to develop highly sensitive methods for both isotopic and elemental analysis of dissolved material suitable for the analysis of large numbers of samples of interest to the program.

Application Received by Commissioner of Customs: June 11, 1986.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials.)

Frank W. Creel,

Director, Statutory Import Programs Staff.

[FR Doc. 86-14429 Filed 6-25-86; 8:45 am]

BILLING CODE 3510-DS-M

[Case No. OEE-1-86]

La Physique Appliquee Industrie et al.; Order Renewing Temporary Denial of Export Privileges

In the matter of la Physique Appliquee Industrie, 5 Rue de Pacalaire, 38170 Seyssinet-Pariset, France, and Les Accessoires Scientifiques, Varigney, 70800 Conflans-Sur-Lanterne, France, Respondents.

On June 2, 1986, the Office of Export Enforcement, International Trade Administration, United States Department of Commerce (Department), pursuant to the provisions of § 388.19 of the Export Administration regulations, 15 CFR Parts 368-399 (1986) (the Regulations), issued pursuant to the Export Administration act of 1979, 50 U.S.C. app. 2401-2420 (1982), as amended by the Export Administration Amendments Act of 1985, Pub. L. 99-64, 99 Stat. 120 (July 12, 1985) (the Act), asked the Deputy Assistant Secretary for Export Enforcement to renew an order temporarily denying all United States export privileges to La Physique Appliquee Industrie [1] of Seyssinet-Pariset, France, and Les Accessoires Scientifique of Conflans-Sur-Lanterne, France (hereinafter collectively referred to as respondents). The initial order was issued on April 23, 1986 (51 FR 15955, April 29, 1986).

On June 16, 1986, respondents filed an opposition to the Department's request for renewal of the temporary denial order and requested a hearing. On June 20, 1986, a hearing was held before me. The issue presented to me for decision is whether the temporary denial order should be renewed to prevent an imminent violation, as defined in § 388.19 of the Regulations.

It is important to note that this matter is still under investigation by the Department. Nevertheless, based on my review of the record before me, including the submissions of the parties and their presentations at the hearing, I find that the Department has established that a violation is imminent.

The material facts out of which this proceeding arose are not seriously disputed by the parties. What is disputed between the parties is the conclusions to be drawn from those facts. Based on the record before me, I find that the Department's investigation is focusing on serious violations which may have been committed by the respondents. The Department's investigation to date has given it sufficient reason to believe that respondents herein may have participated in a scheme to divert highly sensitive U.S.-origin goods and technology to the Union of Soviet Socialist Republics (U.S.S.R) and other Eastern bloc countries. Further, there is sufficient reason to believe that respondents may continue to seek to obtain U.S.-origin goods and technoloyy which they may divert to the U.S.S.R. or other Eastern bloc countries.

The evidence presented to me established a very strong basis for the

[1] The initial order denying export privileges to the respondents identified this company as "La Physique Applique Industrie". This order reflects the correct spelling of that company's name.

Department's belief that: (1) On at least two occasions, LPAI, acting in response to an order from LAS, purchased U.S.-origin goods; (2) The ultimate destination of those U.S.-origin goods was intended to be the U.S.S.R.; (3) If an export license or reexport authorization request had been requested by either respondent identifying the U.S.S.R. as the country of ultimate destination, which it was not, the Department would not have authorized that export or reexport; (4) Further, LAS currently has a contract with the U.S.S.R. which calls for LAS to supply equipment of a smilar type and nature to equipment in the two transactions which are the principal focus of the Department's investigation; (5) Again, export or reexport of this equipment to the U.S.S.R. would not be authorized by the Department; (6) That the respondents have had substantial business experience in import and export transactions involving scientific and technical products; (7) A violation may be likely to occur in the future unless action is taken to prevent respondents from gaining access to U.S.-origin goods and technical data.

Therefore, based on the record before me, I find that renewal of the order temporarily denying export privileges to respondents is necessary in order to prevent an imminent violation and to give notice to companies in the United States and abroad to cease dealing with respondents in goods and technical data subject to the Act and the Regulations in order to reduce the substantial likelihood that respondents will continue to engage in activities which are in violation of the Act and the Regulations.

Accordingly, it is hereby

Ordered

I. All outstanding validated export licenses in which any respondent appears or participates, in any manner or capacity, are hereby revoked and shall be returned forthwith to the Office of Export Licensing for cancellation.

II. the respondents, their successors or assignees, officers, partners, representatives, agents, and employees hereby are denied all privileges of participating, directly or indirectly, in any manner or capacity, in any transaction involving commodities or technical data exported or to be exported from the United States in whole or in part, or that are otherwise subject to the Regulations. Without limiting the generality of the foregoing, participation, either in the United States or abroad, shall include participation, directly or indirectly, in any manner or capacity: (a) As a party or as a representative of a party to any export license application submitted to the Department, (b) in preparing or filing with the Department any export license application or reexport authorization, or any document to be submitted therewith, (c) in obtaining or using any validated or general export license or other export control document, (d) in carrying on negotiations with respect to, or in receiving, ordering, buying, selling, delivering, storing, using, or disposing of, in whole or in part, any commodities or technical data exported from the United States, or to be exported, and (e) in financing, forwarding, transporting, or other servicing of such commodities or technical data. Such denial of export privileges shall extend only to those commodities and technical data which are subject to the Act and the Regulations.

III. After notice and opportunity for comment, such denial may be made applicable to any person, firm, corporation, or business organization with which any respondent is now or hereafter may be related by affiliation, ownership, control, position of responsibility, or other connection in the conduct of trade or related services.

IV. No person, firm, corporation, partnership or other business organization, whether in the United States or elsewhere, without prior disclosure to and specific authorization from the Office of Export Licensing shall, with respect to U.S.-origin commodities and technical data, do any of the following acts, directly or indirectly, or carry on negotiations with respect thereto, in any manner or capacity, on behalf of or in any association with any respondent or any related party, or whereby any respondent or any related party may obtain any benefit therefrom or have any interest or participation therein, directly or indirectly: (a) Apply for, obtain, transfer, or use any license, Shipper's Export Declaration, bill of lading, or other export control document relating to any export, reexport, transshipment, or diversion of any commodity or technical data exported in whole or in part, or to be exported by, to, or for any respondent or any related party denied export privileges; or (b) order, buy, receive, use, sell, deliver, store, dispose of, forward, transport, finance, or otherwise service or participate in any export, reexport, transshipment, or diversion of any commodity or technical data exported or to be exported from the United States.

V. In accordance with the provisions of § 388.19(e) of the Regulations, any respondent may, at any time, appeal this temporary denial order by filing with the Office of Administrative Law Judges, U.S. Department of Commerce, Room H-6716, 14th Street and Constitution Avenue, NW., Washington, DC 20230, a full written statement in support of the appeal.

VI. This order shall become effective on June 22, 1986 and shall remain in effect for 60 days.

VII. In accordance with the provisions of § 388.19(d) of the Regulations, the Department may seek renewal of this temporary denial order by filing a written request not later than 20 days before the expiration date. Any respondent may oppose any request to renew this temporary denial order by filing a written submission with the Deputy Assistant Secretary for Export Enforcement, which must be received not later than seven days before the expiration date of this order.

A copy of this order renewing the temporary denial of export privileges shall be served upon the respondents and published in the **Federal Register.**

Dated: June 20, 1986.

Theodore W. Wu,

Deputy Assistant Secretary for Export Enforcement.

[FR Doc. 86-14464 Filed 6-25-86: 8:45 am]

BILLING CODE 3510-DS-M

National Oceanic and Atmospheric Administration

Coastal Zone Management Programs and Estuarine Sanctuaries, State Programs; Maryland et al.

AGENCY: National Oceanic and Atmospheric Administration, National Ocean Service, Office of Ocean and Coastal Resource Management, Commerce.

ACTION: Notice of intent to evaluate.

SUMMARY: The National Oceanic and Atmospheric Administration, National Ocean Service, Office of Ocean and Coastal Resource Management (OCRM), announces its intent to evaluate the performance of the Maryland Coastal Management Program (CMP); North Carolina CMP; Puerto Rico CMP; New Jersey CMP; Delaware CMP; California's Elkhorn Slough National Estuarine Reserve (NER); and Florida's Apalachicola NER; through September 30, 1986. These reviews will be conducted pursuant to section 312 of the

Coastal Zone Management Act (CZMA) which requires a continuing review of the performance of the states with respect to coastal management, and their adherence to the terms of financial assistance awards funded under the CZMA. Coastal zone management is under under CZMA section 306, and the National Estuarine Reserve Program is authorized by CZMA section 315. The reviews involve consideration of written submissions, a site visit to the state, and consultations with interested Federal, state and local agencies and members of the public. Public meetings will be held as part of the site visits. The state will issue notice of these meetings. Copies of each state's most recent performance report, as well as the OCRM's notification letter and supplemental information request letter to the state are available upon request from the OCRM. A subsequent notice will be placed in the **Federal Register** announcing the availability of the Final Findings based on each evaluation once these are completed.

FOR FURTHER INFORMATION CONTACT: John H. McLeod, Evaluation Officer, Policy Coordination Division, Office of Ocean and Coastal Resource Management, National Ocean Service, NOAA, 3300 Whitehaven, St., NW., Washington, DC 20235 (telephone: 202/673-5104).

(Federal Domestic Assistance Catalog 11.419, Coastal Zone Management Program Administration)

Dated: June 20, 1986.

[FR Doc. 86-14501 Filed 6-25-86; 8:45 am]

BILLING CODE 3510-08-M

National Marine Fisheries Service; Caribbean Fishery Management Council; Public Meeting

The Caribbean Fishery Management Council's Administrative Subcommittee will convene a public meeting, June 26, 1986, from 9:30 a.m. to approximately 4 p.m., at the conference room of the Hotel Pierre, de Diego Avenue, Santurce, PR, to discuss issues related to its regular administrative operations. For further information contact the Caribbean Fishery Management Council, Banco de Ponce Building, Suite 1108, Hato Rey, PR 00918; telephone: (809) 753-4926.

Dated: June 20, 1986.

Richard B. Roe,

Director, Office of Fisheries Management, National Marine Fisheries Service.

[FR Doc. 86-14458 Filed 6-25-86; 8:45 am]

BILLING CODE 3510-22-M

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Limits for Certain Cotton Textile Products Produced or Manufactured in Portugal

June 24, 1986.

The Chairman of the Committee for the Implementation of Textile Agreements (CITA), under the authority contained in E.O. 11651 of March 3, 1972, as amended, as issued the directive published below to the Commissioner of Customs to be effective on June 26, 1986. For further information contact Ann Fields, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 377-4212.

Background

On November 26 and December 20, 1985, notices were published in the **Federal Register** (50 FR 48621 and 51896), which established import restraint levels for women's, girls' and infants' cotton knit shirts in Category 339 and men's and boys' cotton shirts in Category 340, produced or manufactured in Portugal and exported during the twelve-month period which began on June 26, 1985 and extends through June 25, 1986. The limits filled on April 29, 1986 (Category 339) and January 6, 1986 (Category 340).

On December 24, 1984 a notice was published in the **Federal Register** (49 FR 49879) announcing that, as of January 1, 1985, the Committee for the Implementation of Textile Agreements, in order to prevent market disruption, would direct the U.S. Customs Service, as appropriate, to permit entry into the United States for consumption, or withdrawal from warehouse for consumption, of such goods, which were exported during a prior restraint period in excess of the restraint limit established for that period, at a prescribed rate during the following period. CITA has decided, in the case of imports in Categories 339 and 340, exported from Portugal on and after June 26, 1985 and extending through June 25, 1986, to direct Customs to permit entry in amounts not to exceed 51,571 dozen and 26,747 dozen, respectively, during each of the thirty-day periods stipulated in the letter to the Commissioner of Customs which follows this notice.

A description of the textile categories in terms of T.S.U.S.A. numbers was published in the **Federal Register** on December 13, 1982 (47 FR 55709), as amended on April 7, 1983 (48 FR 15175), May 3, 1983 (48 FR 19924), December 14, 1983 (48 FR 55607), December 30, 1983 (48 FR 57584), April 4, 1984 (49 FR 13397), June 28, 1984 (49 FR 26622), July 16, 1984 (49 FR 28754), November 9, 1984 (49 FR 44782), and in Statistical Headnote 5, Schedule 3 of the Tariff Schedules of the United States Annotated (1986).

William H. Houston III,

Chairman, Committee for the Implementation of Textile Agreements.

June 24, 1986.

June 24, 1986.

Committee for the Implementation of Textile Agreements

Commissioner of Customs,

Department of the Treasury, Washington, DC 20229.

Dear Mr. Commissioner: Under the terms of Section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854), and the Agreement Regarding International Trade in Textiles done at Geneva on December 20, 1973, as extended on December 15, 1977 and December 22, 1981; and in accordance with the provisions of Executive Order 11651 of March 3, 1972, as amended, you are directed to prohibit, effective on June 26, 1986, entry into the United States for consumption and withdrawal from warehouse for consumption of cotton textile products in Categories 339 and 340, produced or manufactured in Portugal and exported during the twelve-month period which began on June 26, 1985 and extends through June 25, 1986, which were in excess of the limits established for that period, in the following amounts during each specified thirty-day period:

Category	Amount to be entered
339	51,571 dozen.
340	26,747 dozen.

The thirty-day periods shall be as follows: June 26—July 25, 1986; July 26—August 24, 1986; August 25—September 23, 1986; September 24—October 23, 1986; October 24, 1986—November 22, 1986.

A description of the textile categories in terms of T.S.U.S.A. numbers was published in the **Federal Register** on December 13, 1982 (47 FR 55709), as amended on April 7, 1983 (48 FR 15175), May 3, 1983 (48 FR 19924), December 14, 1983, (48 FR 55607), December 30, 1983 (48 FR 57584), April 4, 1984 (49 FR 13397), June 28, 1984 (49 FR 26622), July 16, 1984 (49 FR 28754), November 9, 1984 (49 FR 44782), and in Statistical Headnote 5, Schedule 3 of the Tariff Schedules of the United States Annotated (1986).

In carrying out the above directions, the Commissioner of Customs should construe entry into the United States for consumption to include entry for consumption into the Commonwealth of Puerto Rico.

The Committee for the Implementation of Textile Agreements has determined that these actions fall within the foreign affairs exception to the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,

William H. Houston III,

Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 86-14522 Filed 6-25-86; 8:45 am]

BILLING CODE 3510-DR-M

Adjusting Import Limits for Certain Wool Apparel Products, Produced or Manufactured in Hungary

June 23, 1986.

The Chairman of the Committee for the Implementation of Textile Agreements (CITA), under the authority contained in E.O. 11651 of March 3, 1972, as amended, has issued the directive published below to the Commissioner of Customs to be effective on June 27, 1986. For further infomation contact Eve Anderson, International Trade Specialist, Office of Textiles and apperal, U.S. Department of Commerce, (202) 377-4212.

Background

A CITA directive dated December 16, 1985 (50 F.R. 51739) established limits for certain categories of wool textile products, including Catagories 435 and 448, produced or manufactured in Hungary and exported during the agreement year which began on January 1, 1986. Under the terms of the Bilateral Wool Textile Agreement of February 15 and 25, 1983, as amended between the Governments of the United States and the Hungarian People's Repubic, and at the request of the Government of the Hungarian People's Republic, the limit for Category 435 is being increased from 9,946 dozen to 10,443 dozen by the application of swing. The limit for Category 448, is being reduced from 22,023 dozen to 20,073 dozen to account for the swing applied to Category 435, as provided in the bilateral agreement.

A description of the textile categories in terms of T.S.U.S.A. numbers was published in the **Federal Register** on December 13, 1982 (47 FR 55709), as amended on April 7, 1983 (48 FR 15175), May 3, 1983 ((48 FR 19924), December 14, 1983, (48 FR 55607), December 30, 1983 (48 FR 57584), April 4, 1984 (49 FR 13397), June 28, 1984 (49 FR 26622), July 16, 1984 (49 FR 28754), November 9, 1984 (49 FR 44782), and in Statistical Headnote 5, Schedule 3 of the Tariff Schedule of the United Annotated (1986).

William H. Houston III,

Chairman, Committee for the Implementation of Textile Agreements.

June 23, 1986.

Committee for the Implementation of Textile Agreements

Commissioner of Customs,

Department of the Treasury, Washington, DC 20229.

Dear Mr. Commissioner: This directive amends, but does not cancel, the directive of December 16, 1985 from the Chairman of the Committee for the Implementation of Textile Agreements concerning imports into the United States of certain wool textile products, produced or manfactured in Hungary and exported during 1986.[1]

Effective on June 27, 1986, paragraph 1 of the directive of December 16, 1986 is hardly amended to include adjusted restraint limits for the following categories:

Category	Adjusted restraint limit [1]
435	10,443 dozen.
448	20,023 dozen.

[1] The limits have not been adjusted to reflect any imports exported after December 31, 1985.

The Committee for the Implementation of Texile Agreement has determined that these actions fall within the foreign affairs exception to the rulemaking provisions of 5 U.S.C. 553.

Sincerely,

William H. Houston III,

Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 86-14478 Filed 6-25-86; 8:45 am]

BILLING CODE 3510-DR-M

Adjusting the Import Limit for Certain Man-Made Fiber Textile Products Produced or Manufactured in the People's Republic of China

June 23, 1986.

The Chairman of the Committee for the Implementation of Textile Agreements (CITA), under the authority contained in E.O. 11651 of March 3, 1972, as amended, has issued the directive published below to the Commissioner of Customs to be effective on June 27, 1986. For further information contact Diana Solkoff, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 377-4212.

[1] The agreement provides, in part, that: (1) specific limits may be exceeded during the agreement year by designated percentages; (2) specific limits may be adjusted for carryover and carryforward; and (3) administrative arrangements or adjustments may be made to resolve minor problems arising in the implementation of the agreement.

Background

On June 4, 1986 a notice as published in the **Federal Register** (51 FR 20332) announcing the application of swing to increase the restraint limit established for women's, girls' and infants' cotton skirts in Category 342, produced or manufactured China and exported during the twelve-month period which began on January 1, 1986 and extends through December 31, 1986. According to the terms of the Bilateral Cotton, Wool and Man-Made Fiber Textile Agreement of August 19, 1983, as amended, between the Governments of the United States and the People's Republic of China, the amount of that increase in equivalent square yards is being deducted from the limit established for women's, girls' and infants' man-made fiber coats in Category 635, reducing it from 446,563 dozen to 442,585 dozen for the agreement year which began on January 1, 1986 and extends through December 31, 1986.

Accordingly, in the letter which follows this notice the Chairman of CITA directs the Commissioner of Customs to reduce the current-year limit for man-made fiber textile products in Category 635 to the designated amount.

A description of the textile categories in terms of T.S.U.S.A. numbers was published in the **Federal Register** on December 13, 1982 (47 FR 55709), as amended on April 7, 1983 (48 FR 15175), May 3, 1983 (48 FR 19924), December 14, 1983 (48 FR 55607), December 30, 1983 (48 FR 57584), April 4, 1984 (49 FR 13397), June 28, 1984 (49 FR 26622, July 16, 1984, (49 FR 28754), November 9, 1984 (49 FR 44782), and in Statistical Headnote 5, Schedule 3 of the Tariff Schedules of the United States Annotated (1986).

William H. Houston III,

Chairman, Committee for the Implementation of Textile Agreements.

June 23, 1986.

Committee for the Implementation of Textile Agreements

Commissioner of Customs,

Department of the Treasury, Washington, DC 20229.

Dear Mr. Commissioner: This directive further amends, but does not cancel, the directive of December 24, 1985, as amended, from the Chairman of the Committee for the Implementation of Textile Agreements, which established restraint limits for certain specified categories of cotton, wool and man-made fiber textile products, produced or manufactured in the People's Republic of China and exported during 1986.

Effective on June 27, 1986, the directive of December 24, 1985 is hereby further amended to reduce the previously established restraint limit for man-made fiber textile products in

Category 635 to 442,585 dozen[1] under the terms of the Bilateral Cotton, Wool and Man-Made Fiber Textile Agreement of August 19, 1983, as amended, between the Governments of the United States and the People's Republic of China.[2]

The Committee for the Implementation of Textile Agreements has determined that this action falls within the foreign affairs exception to the rulemaking provisions of 5 U.S.C. 553.

Sincerely,

William H. Houston III,

Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 86-14477 Filed 6-25-86; 8:45 am]

BILLING CODE 3510-DR-M

[1] The limit has not been adjusted to reflect any imports exported after December 31, 1985.

[2] The agreement provides, in part, that: (1) with the exception of Category 315, any specific limit may be exceeded by not more than 5 percent of its square yards equivalent total, provided that the amount of the increase is compensated for by an equal square yard equivalent decrease in one or more other specific limits in that agreement year; (2) the specific limits for certain categories may be increased for carryforward; and (3) administrative arrangments or adjustments may be made to resolve minor problems arising in the implementation of the agreement.

DEPARTMENT OF DEFENSE

Office of the Secretary

Graduate Medical Education Advisory Committee

AGENCY: Department of Defense Graduate Medical Education Advisory Committee, Defense.

ACTION: Notice of open meeting.

SUMMARY: Pursuant to the provisions of Pub. L. 92-463, notice is hereby given that an open meeting of the Department of Defense Graduate Medical Education Advisory Committee has been scheduled as follows:

DATE: July 24, 1986, 8:00 a.m. to 5:00 p.m.

ADDRESS: Crystal City Marriott, 1999 Jefferson Davis Highway, Arlington, Virginia.

FOR FURTHER INFORMATION CONTACT: Lieutenant Colonel Michael Herndon, Executive Secretary, DoD Graduate Medical Education Advisory Committee, Office of the Assistant Secretary of Defense (Health Affairs), Room 1B657, the Pentagon, Washington, DC, 20301 (202) 694-0748.

SUPPLEMENTARY INFORMATION: This will be the second meeting of the Committee. Presentations of current and projected Service programs will be made. A DoD analysis of current GME resource utilization will be presented.

Patricia H. Means,

OSD Federal Register Liaison Officer, Department of Defense.

June 23, 1986.

[FR Doc. 86-14449 Filed 6-25-86; 8:45 am]

BILLING CODE 3810-01-M

Department of the Air Force

Termination of Application; Slick Airways, Division of Airlift International in the Vietnam Conflict (1965-1967)

Consideration of the application on behalf of Slick Airways Division of Airlift International in the Vietnam Conflict (1965-1967) under section 401, Pub. L. 95-202 and DOD Directive 1000.20 has been terminated. The applicant for the group is now deceased and no other persons have responded to the solicitation for information about this group which appeared in the original acceptance announcement in the **Federal Register** on December 17, 1985, 50 FR 51449. Should any other individual or group wish to sponsor the application on behalf of this group, contact the DOD Civilian/Military Service Review Board, Secretary of the Air Force (SAF/MIPC), Washington, DC 20330. For further information, contact Lt Col Michael Dandar, (202) 692-4744, or Lt Col Mary Todd, (202) 692-4746.

Patsy J. Conner,

Air Force Federal Register Liaison Officer.

[FR Doc. 86-14407 Filed 6-25-86; 8:45 am]

BILLING CODE 3910-01-M

Department of the Navy

Naval Research Advisory Committee; Closed Meeting

Notice was published June 13, 1986, at 51 FR 21590, that the Naval Research Advisory Committee Panel on Under Ice Warfare Requirements will meet on July 1 and 2, 1986. The meeting location on July 1 and 2 has been changed to R&D Associates, 1401 Wilson Boulevard, Arlington, Virginia. All other information in the previous notice remains effective.

Dated: June 20, 1986.

Harold L. Stoller, Jr.,

Commander, JAGC, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. 86-19465 Filed 6-25-86; 8:45 am]

BILLING CODE 3810-AE-M

DEPARTMENT OF ENERGY

National Petroleum Council, Coordinating Subcommittee on U.S. Petroleum Refining; Meeting

Notice is hereby given that the Coordinating Subcommittee on U.S. Petroleum Refining will meet in July 1986. The National Petroleum Council was established to provide advice, information, and recommendations to the Secretary of Energy on matters relating to oil and natural gas or the oil and natural gas industries. The Coordinating Subcommittee on U.S. Petroleum Refining will be addressing the current activities of all task groups and providing guidance for future studies. Its analysis and findings will be based on information and data to be gathered by the various task groups.

The Coordinating Subcommittee on U.S. Petroleum Refining will hold its thirteenth meeting on Thursday, July 17, 1986, starting at 9:00 a.m., in the Austin Room of the Four Seasons Hotel, 1300 Lamar Street, Houston, Texas.

The tentative agenda for the Coordinating Subcommittee on U.S. Petroleum Refining meeting follows:

1. Opening remarks by the Chairman and Government Cochairman.
2. Review draft report.
3. Discuss any other matters pertinent to the overall assignment from the Secretary of Energy.

The meeting is open to the public. The Chairman of the Coordinating Subcommittee on U.S. Petroleum Refining is empowered to conduct the meeting in a fashion that will, in his judgment, facilitate the orderly conduct of business. Any member of the public who wishes to file a written statement with the Coordinating Subcommittee on U.S. Petroleum Refining will be permitted to do so, either before or after the meeting. Members of the public who wish to make oral statements should inform Ms. Pat Dickinson, Office of Oil, Gas, Shale and Coal Liquids, Fossil Energy, 301/353-2430, prior to the meeting and reasonable provision will be made for their appearance on the agenda.

Summary minutes of the meeting will be available for public review at the Freedom of Information Public Reading Room, Room 1E-190, DOE Forrestal Building, 1000 Independence Avenue, SW., Washington, DC, between the hours of 9:00 a.m. and 4:00 p.m., Monday through Friday, except Federal holidays.

Issued at Washington, DC, on June 19, 1986.

Donald L. Bauer,

Acting Assistant Secretary for Fossil Energy.

[FR Doc. 86-14456 Filed 6-25-86; 8:45 am]

BILLING CODE 6450-01-M

Economic Regulatory Administration

[Docket No. ERA-FC-85-007; OFP Case Nos. 61053-9271-20, 21-24]

Order Granting to American Cogen Technology, Inc., Exemption From the Prohibitions of the Powerplant and Industrial Fuel Use Act of 1978

AGENCY: Economic Regulatory Administration, DOE.

ACTION: Order granting to American Cogen Technology, Inc., exemption from the prohibitions of the Powerplant and Industrial Fuel Use Act of 1978.

SUMMARY: The Economic Regulatory Administration (ERA) of the Department of Energy (DOE) hereby gives notice that it has granted a permanent cogeneration exemption from the prohibitions of Title II of the Powerplant and Industrial Fuel Use Act of 1978, 42 U.S.C. 8301 *et seq.* ("FUA" or "the Act") to American Cogen Technology, Inc. (Cogen or "the petitioner"). The permanent cogeneration exemption permits the use of natural gas as the primary energy source for a 54.19 MW (net, approximate) combined cycle cogeneration facility designed to produce electricity and process steam at the Spreckels Agri-Business Center, Spreckels, California. The final exemption order and detailed information on the proceeding are provided in the **SUPPLEMENTARY INFORMATION** section, below.

DATES: The order shall take effect on August 25, 1986.

The public file containing a copy of the order, other documents, and supporting materials on this proceeding is available upon request through DOE, Freedom of Information Reading Room, 1000 Independence Avenue, SW., Room 1E-190, Washington, DC 20585, Monday through Friday, 9:00 a.m. to 4:00 p.m., except Federal holidays.

FOR FURTHER INFORMATION CONTACT:

George G. Blackmore, Office of Fuels Programs, Economic Regulatory Administration, 1000 Independence Avenue, SW., Room GA-093, Washington, DC 20585, Telephone (202) 252-1774

Steven E. Ferguson, Esq., Office of General Counsel, Department of Energy, Forrestal Building, Room 6A-113, 1000 Independence Avenue, SW., Washington, DC 20585, Telephone (202) 252-6947.

SUPPLEMENTARY INFORMATION: On March 26, 1985, Cogen petitioned ERA under section 212(c) of FUA and 10 CFR 503.37 for a permanent cogeneration exemption to permit the use of natural gas in a 54.19 MW (net, approximate) combined cycle cogeneration facility consisting of two gas turbine generators, two waste heat recovery steam generators, a steam extraction turbine generator and ancillary equipment. Action on the petition was delayed until the petitioner resolved certain issues with the California Energy Commission. As all of the net annual generation of electric power from the unit will be sold to Pacific Gas and Electric Company, the unit is, by definition, an electric powerplant under 10 CFR 500.2. The facility will produce approximately 45,900 pounds of steam per hour which will supply Spreckels Agri-Business Center's needs.

Basis for Permanent Exemption Order

The permanent exemption order is based upon evidence in the record including Cogen's certification to ERA, in accodance with 10 CFR 503.37(a)(1), that:

1. The oil or natural gas to be consumed by the cogeneration facility will be less than that which would otherwise be consumed in the absence of such cogeneration facility, in accordance with 10 CFR 503.37(a)(1)(i);
2. The use of a mixture of natural gas and coal or oil and coal in the cogeneration facility will not be technically feasible, in accordance with 10 CFR 503.37(a)(1)(ii); and
3. Prior to operation, all applicable environmental certifications will be secured.

The last certification is required under 10 CFR 503.13(b)(1). In further compliance with that section, Cogen submitted and certified as accurate the information required by the environmental checklist in § 503.13(b), as amended (51 FR 18866, May 22, 1986).

Procedural Requirements

In accordance with the procedural requirements of section 701(c) of FUA and 10 CFR 501.3(b), ERA published its Notice of Acceptance of Petition and Availability of Certification in the **Federal Register** on May 1, 1985 (50 FR 18550), commencing a 45-day public comment period.

A copy of the petition was provided to the Environmental Protection Agency for comments as required by section 701(f) of the Act. During the comment period, interested persons were afforded an opportunity to request a public hearing. The comment period closed on June 17, 1985; no comments were received and no hearing was requested.

Order Granting Permanent Cogeneration Exemption

Based upon the entire record of this proceeding, ERA has determined that Cogen has satisfied the eligibility requirements for the requested permanent cogeneration exemption, as set forth in 10 CFR 503.37 and 503.13. Therefore, pursuant to section 212(c) of FUA, ERA hereby grants a permanent cogeneration exemption to Cogen to permit the use of natural gas as the primary energy source for its cogeneration facility at the Spreckels Agri-Business Center, Spreckels, California.

Pursuant to section 702(c) of the Act and 10 CFR 501.69, any person aggrieved by this order may petition for judicial review thereof at any time before the 60th day following the publication of this order in the **Federal Register.**

Issued in Washington, DC, on June 16, 1986.

Robert L. Davies,

Director, Office of Fuels Programs, Economic Regulatory Administration.

[FR Doc. 86-14457 Filed 6-25-86; 8:45 am]

BILLING CODE 6450-01-M

[ERA Docket No. 86-28-NG]

NHP Energy, Inc.; Order Granting Blanket Authorization To Import Gas from Canada

AGENCY: Economic Regulatory Administration, DOE.

ACTION: Notice of Order Granting Blanket Authorization To Import Natural Gas from Canada.

SUMMARY: The Economic Regulatory Administration (ERA) of the Department of Energy (DOE) gives notice that it has issued an order granting blanket authorization to import natural gas from Canada to NHP Energy, Inc. (NHP). The order issued in ERA Docket No. 86-28-NG authorizes HNP to import up to 3 Bcf over a two-year period for sale in the domestic spot market.

A copy of this order is available in the Natural Gas Division Docket Room, GA-076, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 252-9478. The docket room is open between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, except holidays.

Issued in Washington, DC, on June 20, 1986.

Robert L. Davies,

Director, Office of Fuels Programs, Economic Regulatory Administration.

[FR Doc. 86-14454 Filed 6-25-86; 8:45 am]

BILLING CODE 6450-01-M

[ERA Docket No. 86-06-NG]

Tennessee Gas Pipeline Co.; Order Extending Authorization To Import Natural Gas from Canada and Amending Contract

AGENCY: Economic Regulatory Administration, DOE.

ACTION: Notice of order granting extension of authorization to import natural gas from Canada, modifying contract terms and conditions, and providing for spot sales.

SUMMARY: The Economic Regulatory Administration (ERA) of the Department of Energy (DOE) gives notice that it has issued an order extending the present authorization of Tennessee Gas Pipeline Company (Tennessee) to import up to 75,000 Mcf of natural gas per day from Canada from November 1, 1987, through October 21, 2000. The original authorization for the importation was granted in DOE/ERA Opinion and Order No. 32. Tennessee has also renegotiated the terms and conditions of its contract with its supplier, ProGas Limited (ProGas), to bring them into conformity with the DOE policy guidelines for natural gas imports (49 FR 6684, February 22, 1984) and asked that the new contract supersede all prior agreements.

DATE: The new contract also provides that ProGas, from time to time, may offer certain volumes of the contract gas as "special purchase gas" for sale at a commodity charge less than the commodity charge otherwise in effect under the agreement. Tennessee may assign its rights and obligations with respect to the purchase, receipt and payment for any or all of this special purchase gas to third parties through spot sales. The duration of Tennessee's authority to utilize the "special purchase gas" provision has been restricted to two years from the date of first delivery to conform to other such blanket authorizations.

A copy of this order is available for inspection and copying in the Natural Gas Division Docket Room, GA-076, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 252-9478. The docket room is open between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, except holidays.

Issued in Washington, DC, June 20, 1986.

Robert L. Davies,

Director, Office of Fuels Programs, Economic Regulatory Administration.

[FR Doc. 86-14455 Filed 6-25-86; 8:45 am]

BILLING CODE 6450-01-M

Office of Energy Research

Energy Research Advisory Board; Renewal

Pursuant to section 14(a)(2)(A) of the Federal Advisory Committee Act, and § 101-6.1015 of the Interim Rule on Advisory Committee Management, (41 CFR 101-6.1015) and following consultation with the Committee Management Secretariat, General Services Administration, notice is hereby given that the Energy Research Advisory Board has been renewed for a 2-year period ending June 19, 1988. The Committee will continue to provide advice to the Secretary of Energy on the research and development activities of the Department of Energy.

The renewal of the Energy Research Advisory Board has been determined to be necessary and in the public interest in connection with the performance of duties imposed upon the Department of Energy by law. The Committee will operate in accordance with the provisions of the Federal Advisory Committee Act (Pub. L. No. 92-463), the Department of Energy Organization Act (Pub. L. No. 95-91), and regulations and directives implementing those statutes.

Further information regarding this advisory committee can be obtained from Gloria Decker (202/252-8990).

Issued in Washington, DC, on June 20, 1986.

Charles R. Tierney,

Advisory Committee Management Officer.

[FR Doc. 86-14453 Filed 6-25-86; 8:45 am]

BILLING CODE 6450-01-M

Federal Energy Regulatory Commission

[Docket Nos. CP86-526-000 et al.]

Natural Gas Certificate Filings: United Gas Pipe Line Company et al.

Take notice that the following filings have been made with the Commission:

1. United Gas Pipe Line Company

June 17, 1986.

[Docket No. CP86-526-000]

Take notice that on May 30, 1986, United Gas Pipe Line Company (Applicant), P.O. Box 1478, Houston, Texas 77251-1478, filed in Docket No. CP86-526-000, and application pursuant to section 7 of the Natural Gas Act for a certificate of public convenience and necessity along with pregranted abandonment authorization, authorizing a contract demand reduction/conversion program for its firm sales customers under Rate Schedules G-N, G-S, DG-N, DG-S and PL-N and a transportation program under new Rate Schedules ITS and FTS which would provide self-implementing interruptible and firm transportation services on an "open-access" basis, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Applicant states that it is proposing its "open access" transportation program and contract demand revision program as a result of the Commission's Order Nos. 436 and 436-A. Applicant further asserts that its proposed programs meet the substantive objectives of the Commission's Order Nos. 436 and 436-A.

Applicant states that revised service agreements would be required to establish its base service level obligations and that the revised service agreements would have proposed terms extending to October 31, 1991. Applicant further states that any customer redesignating its maximum daily delivery quantity (CDQ) would be offered the following basic service level options exercisable over a five-year period beginning November 1, 1986: (1) Retain or reduce the current CDQ level; (2) convert a portion of the current CDQ level to firm transportation; or, (3) combine the above CDQ reduction and conversion options. Applicant proposes the following annual percentage limitations:

Year	CDQ reduction (percent)	CDQ conversion (percent)	Reduction/Conversion combination (percent)
1	10	15	20
2	10	10	15
3	5	5	5
4	5	5	5
5	5	5	5

It is explained that the nominated percentage reduction would apply each time to the then-applicable CDQ level. Applicant notes that the above percentage limitations and terms would be in place of the options contemplated by § 284.10 (c) and (d) of the Commission's Regulations. Applicant further states that at the time of the customer's election to reduce its CDQ, a proposed "exit fee" would be calculated and assessed as the product of the applicable unit demand charge and the customer's desired CDQ reduction multiplied by twelve. As proposed, a

customer exercising a conversion option to firm transportation service would not be charged an "exit fee." Instead, Applicant proposes payment of a monthly reservation charge representing the capacity reserved.

Applicant also proposes to provide to each firm sales customer an opportunity to have Applicant transport volumes representing released natural gas from Applicant's producer/supplier's in daily quantities of up to 40 percent of the customer's CDQ level. Applicant states that it has filed companion Docket Nos. CI86-447-000 and CI86-450-000 on May 30, 1986, on behalf of its producer suppliers for the requisite producer authority. Applicant states that such transportation service would be offered on a firm basis under the new Rate Schedule FTS at the applicable commodity rate as proposed.

Applicant asserts that in addition to establishing CDQ levels, an element of its open access transportation program would, as proposed, establish and define Applicant's monthly and annual service level obligations based on each customer's nominations designated as current entitlement quantities (CEQ). Applicant states that the CEQ would represent each customer's anticipated montly purchases during a twelve month "Entitlement Year." Applicant explains that a customer would not be permitted to nominate takes of gas on any day in excess of the CDQ level. Applicant further states that any subsequent request for service in excess of the CDQ or CEQ levels would be offered as Authorized Overrun Transportation (AOT) service on an as available basis.

Applicant further proposes "open access" transportation service on both an interruptible and firm basis to any person in accordance with the proposed rates and terms as submitted in pro forma Rate Schedules ITS and FTS, respectively. Applicant states that as a general policy it would afford first-priority transportation capacity for the movement of natural gas released by Applicant's producer suppliers and second-priority transportation capacity for the movement of natural gas for its existing sales customers. Under the terms stated on the pro forma sheets submitted for Rate Schedules ITS and FTS, Applicant proposes to (1) reserve the right to refuse requests for transportation services under specified operational and economical conditions; (2) perform such services under Subparts B, G, or H or Part 284 of the Commission's Regulations; (3) permit customers to add or delete receipt/delivery points without affecting the customers priority of service, so long as such modification remains within established quantities; (4) stipulate the data to be included by customers when submitting requests for service; and, (5) assess the charges as shown in the attached Appendix and as stated on pro forma revised sheet No. 4-D for Rate Schedule ITS and pro forma Revised Sheets Nos. 4-E and 4E-1 for Rate Schedule FTS.

Applicant further proposes to assess a "gas supply availability charge" (GSAC) to customers purchasing under Applicant's Rate Schedules G, DG, or PL who do not purchase the volumes of natural gas which are nominated by them. Applicant states that the GSAC would be assessed on the basis of a customer's shortfalls in takes of "qualified throughput" during a month to satisfy its CEQ. Applicant explains that the phrase "qualified throughput" would include a customer's purchases from Applicant as well as the volumes transported by Applicant on behalf of the customer which provide Applicant with take or pay relief. Applicant proposes to bill the GSAC to each applicable customer by multiplying the proposed GSAC commodity rate of 27.5 cents per Mcf by the positive difference in volume obtained by subtracting a customer's "qualified throughput" for the month from 85 percent of a customer's CEQ for the month. Applicant indicates that the terms for the GSAC would be included in its General Terms and Conditions of Applicant's FERC Gas Tariff.

Comment date: July 7, 1986, in accordance with Standard Paragraph F at the end of this notice.

Appendix

RATE SCHEDULE ITS

Onshore transportation	Proposed commodity rates per MCF					
	Type*					
	I		II		III	
	Max.	Min.	Max.	Min.	Max.	Min.
Including Cost of Company-Used Gas	13.45¢	4.84¢	26.89¢	9.67¢	40.34¢	14.52¢
Including Cost of Company-Used Gas and Including GRI	14.80¢	6.19¢	28.24¢	11.02¢	41.69¢	15.87¢
Excluding Cost of Company-Used Gas	11.72¢	3.11¢	23.44¢	6.22¢	35.16¢	9.34¢
Excluding Cost of Company-Used Gas and Including GRI	13.07¢	4.46¢	24.79¢	7.57¢	36.51¢	10.69¢

*Type I: a haul equal to or less than 75 miles; TYPE II: a haul in excess of 75 miles and equal to or less than 300 miles; TYPE III: a haul in excess of 300 miles

AOT charges would be assessed the above maximum/minimum rates as applicable.

Offshore Transportation

Rates, as proposed, would be based on the incremental cost of the facilities required to provide such service but not less than 5¢ per Mcf of natural gas received by Applicant for transportation. The proposed onshore rates and GRI surcharge would also be applied, if applicable.

Proposed Imbalance Charge Under Rate Schedule ITS: 11.09¢ per Mcf.

RATE SCHEDULE FTS ONSHORE TRANSPORTATION

Rate schedule FTS-1	Proposed maximum commodity rates for customers transporting within CDQ under rate schedule					Proposed minimum commodity rates
	P1-N	DG-N	G-N	DG-S	G-S	
Including Cost of Company-Used Gas*	23.44¢	46.83¢	111.24¢	39.88¢	92.94¢	12.77¢
Excluding Cost of Company-Used Gas*	19.40¢	42.79¢	107.20¢	35.84¢	88.90¢	8.73¢

* Rates include a 1.35¢ GRI surcharge as applicable pursuant to FERC Opinion No. 243.

The Maximum AOT Rate is proposed to be: (1) a component reflecting 100% load factor of the applicable PL–N, DG–N or DG–S Demand Rate, plus (2) the applicable commodity rate. The Minimum AOT Rate would be the proposed applicable Minimum Commodity Rate.

Rate schedule FTS-2	Proposed for customer conversion from rate schedules			
	PL-N	DG-N/G-N	DG-S/G-S	
	Maximum	Maximum	Maximum	Maximum
Monthly reservation rates	$10.91	$8.09	$6.51	
Commodity Rates:				
Including Cost of Company-Used Gas*	21.12¢	26.72¢	24.24¢	12.77¢
Excluding Cost of Company-Used Gas*	17.08¢	22.68¢	20.20¢	8.73¢

* Rates include a 1.35¢ GRI surcharge as applicable pursuant to FERC Opinion No. 243.

The Maximum AOT Rate is proposed to be: (1) a component reflecting 100% load factor of the Reservation Rate, plus (2) the applicable commodity rate. The Minimum AOT Rate would be the proposed applicable Minimum Commodity Rate.

Rate schedule FTS-3	Proposed for all firm transportation customers	
	Maximum	Minimum
Reservation Rate: $9.46		
Commodity Rate:		
Including Cost of Company-Used Gas	21.81¢	11.42¢
Including Cost of Company-Used Gas and Including GRI*	23.16¢	12.77¢
Excluding Cost of Company-Used Gas	17.77¢	7.38¢
Excluding Cost of Company-Used Gas and Including GRI*	19.12¢	8.73¢

* Rates include a 1.35¢ GRI surcharge as applicable pursuant to FERC Opinion No. 243.

The Maximum AOT Rate is proposed to be: (1) a component reflecting 100% load factor of the Reservation Rate, plus (2) the applicable commodity rate. The Minimum AOT Rate would be the proposed applicable Minimum Commodity Rate.

Proposed Firm Offshore Transportation Rates

Rates, as proposed, would be based on the incremental cost of the facilities required to provide such service but not less than 5¢ times the customers maximum daily quantity times the number of days in the month. The proposed onshore rates and GRI surcharge would also be applied, if applicable.

2. Texas Gas Transmission Corporation

June 19, 1986.

[Docket No. CP86–521–000]

Take notice that on May 30, 1986, Texas Gas Transmission Corporation (Texas Gas), P.O. Box 1160, Owensboro, Kentucky 42302, filed in Docket No. CP86–521–000 an application pursuant to section 7(c) of the Natural Gas Act and § 284.221 of the Commission's Regulations for a blanket certificate of public convenience and necessity authorizing Texas Gas to transport gas for others, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Texas Gas states that in addition to the blanket certificate, it requests the Commission to authorize (1) the permanent incorporation of its TSC Rate Schedule into its FERC Gas Tariff, Original Volume No. 1 for availability to jurisdictional sales customers electing to execute new service agreements; (2) Texas Gas to provide firm sales service to its customers under a new form of service agreement to be entered into after Texas Gas accepts the Order 436 blanket certificate; (3) the interim contract demand, D–2 quantities and annual quantity level adjustments provided for herein, in the event of by-pass to Texas Gas; and (4) the incorporation into Texas Gas' tariff of the FT (Firm Transportation) and IT (Interruptible Transportation) Rate Schedules.

Texas Gas states that the new service agreements would be substantially the same as presently existing service agreements except for conditions relating to the term of the agreements, quantity adjustments, take-or-pay funding and curtailment liability. Texas Gas further states that customers would have a reimbursement obligation for actual payments made by Texas Gas as a result of gas prepayment claims asserted against Texas Gas pursuant to gas purchase contracts with producers, pipelines or other entities. Texas Gas states that Commission approval of this application would authorize interstate pipeline customers of Texas Gas to include and flow through the take-or-pay funding amounts paid pursuant to the CD or CDL Service Agreements in their Purchased Gas Adjustment filings.

Texas Gas states that except to the extent expressly provided for in its application, it would comply with the terms, conditions and procedures specified in § 284.221(c) of the Commission's Regulations.

Comment date: July 10, 1986, in accordance with Standard Paragraph F at the end of this notice.

3. Arkla Energy Resources, a division of Arkla, Inc.

June 19, 1986.

[Docket No. CP86–532–000]

Take notice that on June 3, 1986, Arkla Energy Resources (AER), a division of Arkla, Inc., P.O. Box 21734, Shreveport, Louisiana 71151 filed in Docket No. CP86–532–000 a request pursuant to §§ 157.205, 157.211 and 157.212 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205, 157.211 and 157.212 for authorization to construct and operate taps and related jurisdictional facilities necessary to enable Arkla to deliver gas from several of its jurisdictional pipelines to consumers served by Arkansas Louisana Gas Company (ALG), a division of Arkla, Inc., under the certificate issued in Docket Nos. CP82–384–000 and CP82–384–001 pursuant to section 7 of the Natural Gas Act, all as more fully set forth in the request which is on file with the Commission and open to public inspection.

It is stated that AER proposes to construct and operate: (1) A tap on its Line S to establish an additional town border delivery point as a needed supplemental feed into ALG's Shreveport, Louisiana, distribution system, AER states that approximately 4,000,000 Mcf per year would be delivered through the proposed facilities; (2) a sales tap on its Line JM-24 in Crittenden County, Arkansas, to deliver gas to ALG for service to a residential customer, Mr. Mike Forbis, who would use approximately 100 Mcf per year for residential purposes; (3) a sales tap on its Line 638 in Pontotoc County, Oklahoma, to deliver gas to ALG for service to a residential customer, Mr. Earl E. McKendree Jr., who would use approximately 320 Mcf per year for residential purposes; and (4) a sales tap on its Line E, in Union County, Arkansas, to deliver gas to ALG's Rural Extension No. 1187 for distribution to an anticipated 90 residential customers and 26 commercial customers, who would use an aggregate volume estimated at about 20,650 Mcf per year. It is estimated that the total cost of these facilities is $181,736.

AER states that the gas would be delivered from its general system supply, which AER indicates is adequate to provide the service.

Comment date: August 4, 1986, in accordance with Standard Paragraph G at the end of this notice.

4. Tennessee Gas Pipeline Company, a division of Tenneco, Inc.

June 19, 1986.

[Docket No. CP86-534-000

Take notice that on June 3, 1986, Tennessee Gas Pipeline Company, a Division of Tenneco; Inc. (Applicant), P.O. Box 2511, Houston, Texas 77001, filed in Docket No. CP86-534-000 an application pursuant to section 7(c) of the Natural Gas Act and § 284.221 of the Commission's Regulations for a blanket certificate of public convenience and necessity authorizing transportation of natural gas on behalf of the others, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Applicant indicates that it intends to transport natural gas on behalf of all shippers and elects to become a transporter under the terms and conditions of the Commission's Order No. 436, issued October 9, 1985, in Docket No. RM85-1-000. Applicant also requests pre-granted authorization to abandon transportation services as provided in Subpart G of Part 284 of the Commission's Regulations. Applicant states that it accepts and would comply with the conditions in paragraph (c) of § 284.221 of the Commission's Regulations which paragraph refers to Subpart A of Part 284 of the Commission's Regulations.

Further, Applicant states that it will accept the blanket certificate requested provided the Commission accepts, subject to refund, the concurrently, filed Second Revised Volume No. 1 to Applicant's FERC Gas Tariff and the Commission excludes Applicant's storage facilities and service from the open access conditions of Order Nos. 436, *et al.* Applicant further indicates that copies of this filing have been mailed to all of its customers and affected state regulatory commissions.

Comment date: July 10, 1986, in accordance with Standard Paragraph F at the end of this notice.

5. Panhandle Eastern Pipe Line Company

June 19, 1986.

[Docket No. CP86-530-000]

Take notice that on June 2, 1986, Panhandle Eastern Pipe Line Company (Panhandle), P.O. Box 1642, Houston, Texas 77251-1642, filed in Docket No. CP86-530-000 application pursuant to section 7(b) of the Natural Gas Act for permission and approval to abandon by sale to Phillips 66 Natural Gas Company (Phillips) certain wellhead compression facilities located in Converse County, Wyoming, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Panhandle proposes to retire from service by sale to Phillips its Compression Unit U-379 which is described as one White/Joy 580 horsepower gas compressor, and one-third of the building presently housing the three compressor units located at the Hogs Draw Compressor Station, Converse County, Wyoming. It is stated that the sales price is approximately $63,000. Panhandle explains that production rates from the related gas reservoirs have stabilized and its does not expect to add any new gas reserves from those reservoirs because they are old and well developed. Therefore, Panhandle states the unit would not be needed for any foreseeable compression requirements. It is stated that the subject unit was installed pursuant to authorization issued in Docket No. CP75-54.

Comment date: July 10, 1986, in accordance with Standard Paragraph F at the end of this notice.

6. Northwest Central Pipeline Corporation

June 19, 1986.

[Docket No. CP86-535-000]

Take notice that on June 4, 1986, Northwest Central Pipeline Corporation (Northwest Central), P.O. Box 3288, Tulsa, Oklahoma 74101, filed in Docket No. CP86-535-000 a request pursuant to §§ 157.205, 157.208, 157.212 and 157.216 of the Regulations under the Natural Gas Act (18 CFR 157.205, 157.208, 157.212 and 157.216) for authorization to replace existing measuring, regulating and appurtenant facilities for The Kansas Power and Light Company (KPL Gas Service) at the Driftwood town border in Johnson County, Kansas, the Foster Park town border in Washington County, Oklahoma; and the Republic town border in Greene County, Missouri, under its authorization issued in Docket No. CP82-479-000 pursuant to section 7 of the Natural Gas Act, all as more fully set forth in the request on file with the Commission and open to public inspection.

Northwest Centeral states the existing facilities are no longer adequate to serve existing and anticipated volumes. However, Northwest Central does not anticipate any significant increased deliveries through the proposed facilities at this time. It is stated that the Driftwood facilities would also be relocated to accommodate the construction of a planned highway. Northwest Central states that current volumes of delivery are 32,850 Mcf annually and 374 Mcf on a peak day to Driftwood; 53,655 Mcf annually and 364 Mcf on a peak day to Foster Park; and 237,615 Mcf annually and 2,212 Mcf on a peak day to Republic. The total cost to reclaim the facilities is estimated to be $12,000 and salvage value is estimated to be $8,480. Northwest Central estimates the total cost of construction to be $209,850, which would be paid from treasury cash. Finally, Northwest Central states that this change is not prohibited by an existing tariff and it has sufficient capacity to accomplish the deliveries specified without detriment or disadvantage to its other customers.

Comment date: August 4, 1986, in accordance with Standard Paragraph G at the end of this notice.

7. Northwest Central Pipeline Corporation

June 19, 1986.

[Docket No. CP86-533-000]

Take notice that on June 3, 1986, Nothwest Central Pipeline Corporation (Northwest Central), P.O. Box 3288, Tulsa, Oklahoma 74101, filed in Docket

No. CP86-533-000 a request pursuant to §§ 157.205 and 157.212 of the Regulations under the Natural Gas Act (18 CFR 157.205 and 157.212) for authorization to install and operate two additional delivery points on its system in Sumner and Johnson Counties, Kansas, under the certificate issued in Docket No. CP82-479-000, all as more fully set forth in the request which is on file with the Commission and open to public inspection.

Northwest Central states that the delivery points would serve Kansas Power and Light Comapny (KPL), an existing distribution customer, for resale to the City of Wellington, Kansas (Sumner County), for use in a gas-fired steam turbine, and to Overland Park, Kansas (Johnson County) for service to two town borders and to reinforce KPL's southern distribution system. Northwest Central estimates annual deliveries at the Wellington delivery point at 55,000 Mcf with a maximum peak day delivery of 2,160 Mcf. It is estimated that these deliveries would increase by the fifth year of service to 188,500 Mcf annually and 5,760 Mcf on a peak day. The cost of installing the facilities is estimated at $73,800. Northwest Central estimates annual deliveries at the Overland Park, delivery point at 490,100 Mcf with a maximum peak day delivery of 6,930 Mcf. It is estimated that these deliveries would increase by the fifth year to 941,000 Mcf per year and 16,560 on a peak day. The cost of installing the facilities is estimated at $2,090.

It is stated that the deliveries made at the new delivery points would be within KPL's authorized contract demand and that Northwest Central's sales to KPL would be made under Northwest Central's Rate Schedules F, C, and I.

Comment date: August 4, 1986, in accordance with Standard Paragraph G at the end of this notice.

8. Natural Gas Pipeline Company of America

June 19, 1986.

[Docket No. CP86-540-000]

Take notice that on June 5, 1986, Natural Gas Pipeline Company of America (Applicant), 701 East 22nd Street, Lombard, Illinois 60148, filed in Docket CP86-540-000 and application pursuant to section 7 of the Natural Gas Act for a certificate of public convenience and necessity authorizing it to increase its daily contract quantity to City of Perryville, Missouri (Perryville) and City of Nashville, Illinois (Nashville), and to modify existing regulator facilities at Perryville, all as more fully set forth in the application which is on file with the Commission and open for public inspection.

Applicant states that its existing customers, Perryville and Nashville, have requested increases in their daily contract quantities of 700 Mcf and 1,663 Mcf, respectively. In order to render the additional service to Perryville, Applicant proposes to modify the existing measuring facility at Perryville by removing the 1-inch regulators and appurtenant piping and replacing the same with 2-inch equipment at an estimated cost of $4,000. It is explained that such costs would be reimbursed to Applicant by Perryville. Applicant states that no additional facilities would be required to deliver the increased volumes to Nashville.

Comment date: July 10, 1986, in accordance with Standard Paragraph F at the end of this notice.

9. Iroquois Gas Transmission System

June 19, 1986.

[Docket No. CP86-524-000]

Take notice that on May 30, 1986, Iroquois Gas Transmission System (Iroquois), 598 Madison Avenue, 6th Floor, New York, New York 10022, filed an application pursuant to § 153.11 of the Commission's Regulations for a presidential permit for the construction, operation, maintenance, and connection at the international boundary between the United States and Canada of facilities for the importation of natural gas, all as more fully set forth in the application which is on file with the Commission and open for public inspection.

Iroquois states that it has filed concurrently, in Docket No. CP86-523-000, an application pursuant to section 7 of the Natural Gas Act and the optional expedited procedures of Subpart E of Part 157 of the Commission's Regulations (1) to construct and operate a new pipeline system with a capacity of 353,000 Mcf of natural gas per day from a point on the international border near Iroquois, Ontario, through the states of New York and Connecticut, along Long Island Sound to a point near South Commack, Long Island, New York; and, (2) to transport natural gas through the new pipeline system for local distribution companies in New Jersey, New York, and New England. Iroquois proposes that the 24-inch diameter pipeline to be owned by Iroquois interconnect at the border with the 24-inch diameter pipeline to be owned by TransCanada PipeLines Limited (TransCanada).

It is stated that the Iroquois Gas Transmission System would be established as a general partnership under the laws of New York and that the partners in Iroquois would be affiliates of TransCanada, The Brooklyn Union Gas Company, the Northeast Utilities system, Connecticut Natural Gas Corporation, New Jersey Natural Resources Company, Southern Connecticut Gas Company, and J. Makowski Associates, Inc.

Iroquois states that all of the affiliates which become partners in Iroquois would be United States corporations. It is stated that Iroquois would be managed by a management committee which would be comprised of a representative and an alternate representative of each partner to be designated after the general partnership agreement has been executed. Iroquois further states that, at that time, this application would be supplemented with a list of the members of the membership committee and their nationalities.

It is further stated that (1) neither Iroquois nor its pipeline would be owned in any part by any foreign government or directly or indirectly subventioned by any foreign government; (2) Iroquois has no existing contracts with any foreign government or private concern which relate to the control or fixing of rates for the purchase, sale or transportation of natural gas and which may serve in any way to restrict or prevent competing American companies from extending their own activities; and, (3) no foreign government or agency has granted Iroquois any landing license or permit in connection with the exportation or importation of natural gas.

Comment date: July 10, 1986, in accordance with Standard Paragraph F at the end of this notice.

10. K N Energy, INc.

June 20, 1986.

[Docket No. CP86-520-000]

Take notice that on May 30, 1986, K N Energy, Inc. (K N), P.O. Box 15265, Lakewood, Colorado, 80215, filed in Docket No. CP86-520-000 a request pursuant to §§ 157.205 and 157.211 of the Regulations under the Natural Gas Act (18 CFR 157.205 and 157.211) for authorization to construct and operate several sales taps for the delivery of gas to various end users in Kansas and Nebraska, under the certificates issued in Docket Nos. CP83-140-000, CP83-140-001, and CP83-140-002 pursuant to section 7 of the Natural Gas Act, all as more fully set forth in the request on file with the Commission and open to public inspection.

It is stated that the additional taps would have no significant impact on K

N's peak day and annual deliveries and would provide total annual volumes of 11,760 Mcf for commercial, irrigation, domestic and grain drying purposes.

Cost to install the facilities is estimated to be $16,350, of which each Kansas customer would reimburse K N $250 and each Nebraska customer would contribute $400 to K N.

Comment date: August 4, 1986, in accordance with Standard Paragraph G at the end of this notice.

11. Granite State Gas Transmission, Inc.

June 20, 1986.

[Docket No. CP86-538-000]

Take notice that on June 4, 1986, Granite State Gas Transmission, Inc. (Applicant), 120 Royall Street, Canton, Massachusetts 02021, filed in Docket No. CP86-538-000 an application pursuant to section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing increases in firm daily contract demand deliveries to Bay State Gas Company (Bay State) and Northern Utilities, Inc. (Northern Utilities) beginning November 1, 1986, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Applicant states that it is currently authorized to provide firm daily contract demand services of 83,640 Mcf of natural gas per day for Bay State under certificate authorization issued in Phase I of the proceeding in Boundary Gas, Inc., *et al.*, 24 FERC ¶ 61,114 (1984). Applicant states further that firm daily service to Bay State would be reduced to 80,566 Mcf per day on November 1, 1986, pursuant to the Commission's order in Phase 1-A of the Boundary Gas proceedings on which date Applicant's purchase of 9,814 dt equivalent of natural gas per day for system supply from Consolidated Gas Transmission Corporation (Consolidated) would be replaced by a total of 6,740 MMBtu of natural gas per day supplied by Algonguin Gas Transmission Company (Algonguin). Applicant avers that it has longstanding authorization to provide a firm daily contract demand service of 18,226 Mcf per day for Northern Utilities.

Applicant states that Tennessee Gas Pipeline Company, a Division of Tenneco, Inc. (Tennessee), proposes in an application in Docket No. CP86-251-000 to construct and operate new facilities to deliver to Applicant an additional 2,686 Mcf per day under Tennessee's firm Rate Schedule CD-6 for Applicant's system supply. It is explained that the Tennessee deliveries would provide an interim firm supply until the full volumes of Canadian gas in Phase 2 of the Boundary Gas project are available to Boundary Gas, Inc. Applicant states that the delivery of the Boundary Gas Phase 2 volumes has been delayed and the Tennessee interim supply is equal to Applicant's remaining share of the full Phase 2 volumes. Applicant states that when the Phase 2 volumes are available, the interim firm sales service from Tennessee would be converted to a firm transportation service for the Phase 2 volumes for Applicant's account. Applicant states that Tennessee proposes to have the new facilities applied for in Docket No. CP86-251-000 in place to commence the additional service by November 1, 1986.

Applicant explains that it would allocate the 2,686 Mcf per day of the interim firm supplies from Tennessee in the following manner: (1) 1,814 Mcf per day to Bay State; (2) 857 Mcf per day to Northern Utilities; and (3) 15 Mcf per day to company end use and unaccounted-for. Applicant requests authority herein to provide a total firm contract demand service to Bay State of 82,380 Mcf per day and a firm contract service for Northern Utilities of 19,083 Mcf per day, commencing on November 1, 1986. Applicant states that no additional facilities are required for the proposed increase in contract demand services for Bay State and Northern Utilities.

Applicant further requests authority to include in its future purchased gas cost adjustment filings the cost of the purchases from Algonquin Gas that would replace the cost of purchases from Consolidated and the cost of the additional interim purchases from Tennessee.

Comment date: July 11, 1986, in accordance with Standard Paragraph F at the end of this notice.

12. Iroquois Gas Transmission System

June 20, 1986.

[Docket No. CP86-523-000]

Take notice that on May 30, 1986, Iroquois Gas Transmission System (Iroquois), 598 Madison Avenue, 6th floor, New York, New York 10022, filed in Docket No. CP86-523-000 an application pursuant to section 7 of the Natural Gas Act and Subpart E of Part 157 of the Commission's Regulations for an optional expedited certificate of public convenience and necessity to construct and operate a new pipeline system, to transport natural gas through that pipeline system, and pre-granted authority to abandon the proposed services. Iroquois also requests a blanket transportation certificate of public convenience and necessity under Subpart G of Part 284 of the Commission's Regulations and a blanket facilities certificate of public convenience and necessity under Subpart F of Part 157 of the Commission's Regulations, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

The application states that Iroquois would be established as a general partnership under the laws of New York. It is stated that the partners would be affiliates of TransCanada PipeLines Limited (TransCanada), The Brooklyn Union Gas Company (Brooklyn Union), the Northeast Utilities system, Connecticut Natural Gas Corporation (Connecticute Natural), New Jersey Natural Resources Company, Southern Connecticut Gas Company (Southern Connecticut), and J. Makowski Associates.

Iroquois proposes to construct and operate a new pipeline system with a capacity of 353,000 Mcf of natural gas per day from a point on the international border near Iroquois, Ontario, through eastern New York and western Connecticut, and across Long Island Sound to a point near South Commack, Long Island, New York. Iroquois states that the pipeline system would consist of a mainline of (a) 293.5 miles of buried 24-inch diameter pipe and 3.0 miles of buried 20-inch diameter pipe from a point of interconnection with the facilities of TransCanada on the international border near Iroquois, Ontario, through eastern New York and western Connecticut, (b) 25.0 miles of underwater 20-inch diameter pipe from the Connecticut shoreline across Long Island Sound to a point near Northport, Long Island, New York, and (c) 8.3 miles of buried 20-inch diameter pipe from Northport to a terminus point near South Commack, Long Island, New York, and a lateral of 26.0 miles of buried 12-inch diameter pipe from a point near Washington, Connecticut to a point near Farmington, Connecticut. Iroquois states that at South Commack, the Iroquois pipeline would interconnect with the existing gas distribution system of Long Island Lighting Company (LILCO). Iroquois explains that by that interconnection, Iroquois would backfeed the New York Facilities Gas Distribution System, from which New Jersey gas distribution systems could in turn be backfed. Iroquois further states that no compressor stations would be required.

The proposed pipeline would traverse eleven New York counties (St. Lawrence, Lewis, Oneida, Herkimer, Montgomery, Schoharie, Albany, Greene, Columbia, Dutchess, and

Suffolk) and four Connecticut counties (Litchfield, New Haven, Fairfield, and Hartford). Iroquois requests authority to establish delivery points to the following companies at the respective points of interconnection:

Company	Point of interconnection
Consolidated Gas Supply Corporation.	MP 172 Canajoharie, NY
Tennessee Gas Pipeline Company.	MP 184 Wright, NY MP 291 Stratford, CT
Algonquin Gas Transmission Co., Inc..	MP 275 Southburg, CT
The Connecticut Light and Power Company.	MP 260 + 26 mi Farmington, CT
(Connecticut Light and Power).	MP 265 Roxbury, CT MP 287 Huntington, CT
Connecticut Natural	MP 260 + 26 mi Farmington, CT
Southern Connecticut	MP 292 Chapel St., Milford, CT MP 293.5 Milford, CT
LILCO	MP 329.8 South Commack, NY

Iroquois states that at the present time it proposes to construct interconnect facilities for the delivery points at Farmington, Roxbury, Huntington, Chapel St. and Milford in Connecticut and at South Commack in New York. Iroquois states that it would request appropriate authority to construct and operate interconnect facilities for the remaining delivery points as required.

Iroquois states that the preliminary environmental report included in the application concludes that the construction and operation of the proposed pipeline would have no significant impact on the human environment. Iroquois states that a final environmental report will be filed on or about August 1, 1986.

It is stated that the projected in-service date is November 1, 1988, but that an earlier in-service date is under consideration and could be implemented if timely regulatory and permit approvals were assured. Iroquois estimates that the cost of the completed facilities would be $357.2 million. Iroquois states that the rate design is based on the expectation that twenty-five percent of the construction costs would be financed by equity contributions and seventy-five percent by non-recourse debt financing. It is stated that the Iroquois pipeline would be constructed and operated by TCPL Iroquois Ltd., an indirectly, wholly-owned subsidiary of TransCanada which will be a partner in Iroquois.

Iroquois proposes to provide firm and interruptible transportation service on an open access, non-discriminatory basis. Iroquois requests authorization to provide firm reserved transportation services on behalf of the following shippers for up to the daily volume of gas nominated by each shipper:

Shipper	Nomination (Mcf per day)
Brooklyn Union	85,000
Connecticut Light and Power	50,000
Connecticut Natural	50,000
New Jersey Natural Gas Company*	35,000
Southern Connecticut	35,000
LILCO	25,000
South Jersey Gas Company*	25,000
Public Service Electric and Gas Company	20,000
Consolidated Edison Company of New York, Inc.	5,000
Elizabethtown Gas Company*	5,000
Total	335,000

*Iroquois states that the volumes nominated by the New Jersey shippers would be delivered by Iroquois to the New Jersey shippers at the terminus of the Iroquois pipeline at South Commack, New York. Iroquois further states that each New Jersey shipper would be responsible for making its own arrangements for transporation of its volumes from South Commack to its distribution system.

Iroquois states that it would act solely as the transporter of the nominated volumes. Iroquois contends that supply arrangements are the responsibility of the individual shippers. Iroquois asserts that it is its understanding that the shippers have arranged to transport on the Iroquois pipeline Canadian volumes to be exported by TransCanada under License Nos. GL-86 and GL-87. Iroquois states that it is also its understanding that the shippers have made arrangements to transport additional volumes purchased from TransCanada and one or more other Canadian suppliers. The Commission has jurisdiction over the proposed facilities and transportation whereas the Economic Regulatory Administration of the Department of Energy has jurisdiction over the importation of Canadian volumes by the shippers. Iroquois has filed concurrently with the Commission in Docket No. CP86-524-000, an application for a presidential permit for the construction, operation, maintenance and connection at the international boundary of facilities for the importation of natural gas.

Iroquois proposes maximum and minimum rates for each of Iroquois' three transportation services: Firm reserved, firm unreserved, and interruptible.[1]

[1] Iroquois states that the rates set forth in its application are predicated on the assumption that Iroquois will qualify for investment tax credits (ITC's) and the accelerated cost recovery sysem (ACRS) as provided in the Internal Revenue Code of 1954, as amended (the 1954 Code). In the event that the 1954 Code is further amended so that Iroquois does not qualify for ITC's or ACRS at the time that its facilities are placed in service, Iroquois requests advance authorization to file, without being subject to suspension or refunds, revised rates that reflect the nominal tax liability of Iroquois as a result of such further amendments tot he 1954 Code, but which are otherwise in the same form as set forth in Exhibit P of this application.

Iroquois states that the firm reserved service would be an annual service sold under a two-part rate consisting of a reservation fee to recover approximately 98 percent of all fixed costs, except return on equity and income taxes, and a commodity charge. Iroquois system would be the firm unreserved rate, which would be a volumetric rate designed to recover the fixed and variable costs associated with providing that service. Iroquois further states that the off-peak rate would be the interruptible rate which is designed to recover only costs includable in the commodity charge for firm reserved service and thus to maximize throughput on the pipeline. Iroquois asserts that the rates for each of the three services are based on projected untis of service to recover all of the pipeline's costs. Iroquois proposes a rate of return of 16.7 percent. The proposed rates are shown below.

Statement of Illustrative Rates All Delivery Points

Firm Reserved Service.

Maximum Monthly Reservation Rates:

For 20 yr. reservations, $13.4527, per month per Mcf of reservation.

For reservations of 15-20 yrs., $14.6580, per month per Mcf of reservation.

For reservations of 10-15 yrs., $17.0688, per month per Mcf of reservation.

For reservations of 1-10 yrs., $24,3010, per month per Mcf of reservation.

Minimum Monthly Reservations Rates, $0.3042, per month per Mcf of reservation.

Maximum Commodity Charge, 26.0523, cents per Mcf of gas transported.

Minimum Commodity Charge, 1.0000, cent per Mcf of gas transported.

Firm Unreserved Service

Maximum Charge, 132.9619, cents per Mcf of gas transported.

Minimum Charge, 1.0000, cent per Mcf of gas transported.

Interruptible Service

Maximum Charge, 26.0532, cents per Mcf of gas transported.

Minimum Charge, 1.0000, cent per Mcf of gas transported.

Comment date: July 11, 1986, in accordance with Standard Paragraph F at the end of this notice.

13. Mountaineer Gas Company

June 20, 1986.

[Docket No. CP86-510-000]

Take notice that on May 21, 1986, Mountaineer Gas Company (Mountaineer), 414 Summers Street, Charleston, West Virginia 25301, filed in Docket No. CP86-510-000 a complaint and motion to institute an investigation pursuant to § 385.206 of the Commission's Rules of Practice and

Procedure (18 CFR 385.206) to prohibit Columbia Gas Transmission Corporation (Columbia) and Weirton Service Pipeline Company (Weirton Service) from transporting natural gas to Weirton Steel Corporation (Weirton Steel), all as more fully set forth in the complaint and motion which is on file with the Commission and open to public inspection.

Mountaineer, a local distribution company (LDC), states that Weirton Steel is an industrial user of natural gas whose total gas requirements historically have been delivered by Mountaineer. Mountaineer further states that it was notified by letters both dated May 15, 1986, that Columbia and Weirton Service would commence transportation of natural gas to Weirton Steel on May 16, 1986. Mountaineer alleges that because it knows that such deliveries are not being made pursuant to section 7 certificate authority, it assumes that Columbia is performing a transportation on behalf of Weirton Service under section 311(a)(1) of the Natural Gas Policy Act of 1978 (NGPA), and that Weirton Service is performing a transportation on behalf of Columbia under section 311(a)(2) of the NGPA. It is asserted that Weirton Service is a new entity with limited capitalization and delivers these volumes from Columbia to Weirton Steel through 24 feet of recently constructed pipeline which interconnects Columbia and Weirton Steel's facilities.

Mountaineer alleges that Weirton Service was formed to permit Columbia's by-pass of the Mountaineer system under the guise of NGPA section 311(a) and that section 7 affords an LDC certain procedural protections before an interstate pipeline is allowed to by-pass such LDC and make direct deliveries of gas to an end-user in its service area. Mountaineer also alleges that Weirton Service is strictly a shell corporation which cannot meet the standards applied by the Commission in determining whether a new entity may be considered an intrastate pipeline for purposes of engaging in section 311(a)(2) transportation. Mountaineer further alleges that the transportation of natural gas to Weirton Steel by Columbia and Weirton Service was not contemplated by NGPA section 311(a) and constitutes a clear attempt to circumvent the Commission's jurisdiction under NGA section 7 and the Commission's regulations under Order No. 436. Mountaineer moves that the Commission order Columbia and Weirton Service to cease and desist from their alleged unlawful activity and that a formal investigative hearing be instituted regarding the issues raised.

Comment date: July 21, 1986, in accordance with the first subparagraph of Standard Paragraph F at the end of this notice.

14. Natural Gas Pipeline Company of America

June 20, 1986.

[Docket No. CP86-542-000]

Take notice that on June 6, 1986, Natural Gas Pipeline Company of America (Natural), 701 East 22nd Street, Lombard, Illinois 60148, filed in Docket No. CP86-542-000 an application pursuant to Section 7 of the Natural Gas Act for a certificate of public convenience and necessity authorizing Natural to transport on an interruptible basis gas under a Gas Exchange Agreement and a Gas Transportation Agreement for Delhi Gas Pipeline Corporation (Delhi), and it assigns, Louisiana Industrial Gas Supply Systems (LIGS), Pontchartrain Natural Gas System (Pontchartrain), and Spindeltop Gas Distribution System (Spindeltop), all as more fully set forth in the application which is on file with the Commission and open for public inspection.

Natural has executed a group of agreements with Delhi and TXO Production Corporation (TXO), an affiliate of Delhi, which provide for the commitment of long term firm reserves and best efforts section 311(b) gas sales and transportation to Natural in return for two separate transportation services to be provided by Natural. The purchase agreements provide for Natural to purchase gas only when the demand on Natural's system is its highest—October through May of each year. Further, Delhi or its nominees, LIGS, Spindeltop and Pontchartrain, have the option to purchase gas available during the time period which Natural does not need, and any such purchases are credited toward Natural's take or pay obligation. Natural has the ability, but not the obligation, to purchase gas during the summer months that is in excess of the gas that Delhi or its nominee has purchased. Natural also has the option to purchase up to 50,000 MMBtu/day of volumes transported under the Transportation Agreement described below. In exchange for the favorable treatment, Natural proposes to provide two transportation services on an interruptible basis for Delhi and its assigns:

(1) Under the Gas Exchange Agreement, Natural will transport volumes that Delhi and its assigns purchase that are attributable to the working interests dedicated to Natural under the purchase agreements described above. Natural will not charge any fee for this transportation service under the Gas Exchange Agreement commenced on June 7, 1984 under Docket No. ST84-1000 and is scheduled to terminate June 6, 1986.

(2) Under the Gas Transportation Agreement, Natural proposes to transport additional gas that Delhi or its designees purchase, up to 100,000 MMBtu/day, less volumes that Natural purchases under the section 311(b) sales agreement with Delhi referred to above (up to 50,000 MMBtu/day). Service under this transportation agreement commenced on January 13, 1984 pursuant to Subpart B of Part 284 of the Commission's Regulations and Docket No. ST84-315. Service was halted on January 12, 1986 as required by the provisions of Order 436. Natural proposes to charge a transportation fee of 10.1¢ per MMBtu of gas delivered to it, the applicable GRI fee and to deduct 2.9% of such gas for fuel and gas lost and unaccounted for.

Natural list 8 existing receipt points in Beckham, Custer, Dewey, Grady, Stephens and Woodward Counties, Oklahoma and 13 existing delivery points in Cameron, Vermilion and Pointe Coupee Parishes, Louisiana and in Jefferson and Montgomery Counties, Texas. Natural does not propose the construction of any new facilties.

Comment date: July 11, 1986, in accordance with Standard Paragraph F at the end of this notice.

15. Shell Gas Pipeline Company

[Docket No. CP86-528-000]

June 20, 1986.

Take notice that on May 21, 1986, Shell Gas Pipeline Company (SGPC), P.O. Box 2463, Houston, Texas 77001, filed in Docket No. CP86-528-000, pursuant to Rule 207 of the Commission's Rules of Practice and Procedure, a petition for an order declaring certain pipeline facilities proposed to be constructed and operated in federal Outer Continental Shelf (OCS) waters exempt under section 1(b) of the Natural Gas Act (NGA). Alternatively, in the event that the Commission denies its petition for declaratory order, SGPC requests (1) an optional expedited certificate of public convenience and necessity filed pursuant to section 7 of the NGA and Subpart E of Part 157 of the Commission's Regulations authorizing the construction and operation of certain pipeline facilities, the

transportation of natural gas through such facilities, and the abandonment of such transportation services; and (2) a blanket certificate of public convenience and necessity for transportation authority pursuant to § 284.221 of the Commission's Regulations, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

SGPC states that natural gas has been found by its affiliate, Shell Offshore Inc. (SOI) and other working interest owners in federal OCS waters, Matagorda Island Block No. 681 (MI 681), offshore Texas. It is stated that no gathering facilities or other means of transportation by which the gas can reach the market are available in the production area. SGPC purposes to construct and oeprate 16 miles of 14-inch pipeline and related facilties from SOI's production platform in MI 681 to transport the gas to a point of interconnection with the Matagorda Offshore Pipeline System (MOPS), a 24-inch interstate natural gas transmission line operated by Northern Natural Gas Company, a Division of Enron Corp. (Northern). The point of interconnection, it is stated, would be upstream of the MOPS compressor platform located in federal OCS waters in MI 686, offshore Texas. It is further stated that Northern would then transport the gas through MOPS to an onshore separation and dehydration facility owned by Northern at Tivoli, Texas, where water and condensate would be removed.

It is indicated that the proposed facilities would have sufficient capacity to transport 100 percent of the natural gas expected to be produced from SOI's production platform in MI 681. SGPC states that it would offer to transport the gas owned by the working interest owner in MI 681 for the same transportation charges as in its proposed Optional Expedited Certificate application if found to be gathering facilities. In addition, transportation services would be offered on the same terms to any other shippers who may purchase the gas from the working interest owners.

It is stated that the estimated cost of the proposed facilities is approximately $9.9 million which would be financed through the sales of equity securities. First movement of gas from the producing area through the proposed facilities is planned for late 1986 or early 1987.

Comment date: July 11, 1986, in accordance with Standard Paragraph F at the end of this notice.

16. Transcontinental Gas Pipe Line Company

June 20, 1986.

[Docket No. CP86-539-000]

Take notice that on June 4, 1986, Transcontinental Gas Pipe Line Corporation (Transco), P.O. Box 1396, Houston, Texas 77251, filed in Docket No. CP86-539-000 an application pursuant to section 7(b) of the Natural Gas Act for permission and approval to abandon certain facilities, all as more fully set forth in the application which is on file with the Commission and open for public inspection.

Specifically, Transco proposes to abandon by removal one skid-mounted 1,080 HP Solar Saturn gas turbine compressor unit and one skid-mounted 3,480 HP Solar Centaur gas turbine compressor unit, and appurtenances, located on the South Marsh Block 66 "C" platform, offshore Louisiana. Transco states that these facilities, originally designated as Section No. 67 but now known as Station 0001, were originally installed to permit its system upstream to accommodate 85,700 Mcf of additional natural gas volumes attributable to existing firm transportation and exchange arrangements and additional purchase volumes from existing sources of gas supply in the area. However, Transco states that purchase volumes from such sources have now declined by a total of 82,900 Mcf per day, and that this decline, although offset by a small increase of 14,800 Mcf per day in firm transportation and exchange volumes, has eliminated the need for the subject compressor units. Transco states that the compressor units would be salvaged for possible use at other locations.

Comment date: July 11, 1986, in accordance with Standard Paragraph F at the end of this notice.

Standard Paragraphs

F. Any person desiring to be heard or make any protest with reference to said filing should on or before the comment date file with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to jurisdiction conferred upon the Federal Energy Regulatory Commission by sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this filing if no motion to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a motion for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for the applicant to appear or be represented at the hearing.

G. Any person or the Commission's staff may, within 45 days after the issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to § 157.205 of the Regulations under the Natural Gas Act (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefor, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to section 7 of the Natural Gas Act.

Kenneth F. Plumb,

Secretary.

[FR Doc. 86-14425 Filed 6-25-86; 8:45 am]

BILLING CODE 6717-01-M

ENVIRONMENTAL PROTECTION AGENCY

[OPTS-140075; FRL-3026-4]

Access to Confidential Business Information by Versar, Inc.

Correction

In FR Doc. 86-12722 beginning on page 20703 in the issue of Friday, June 6, 1986, make the following correction:

On page 20704, first column, first paragraph, third line from the bottom, insert "water," after "Soil,".

BILLING CODE 1505-01-M

FEDERAL HOME LOAN BANK BOARD

Audubon Federal Savings and Loan Association, New Orleans, LA; Appointment of Receiver

Notice is hereby given that pursuant to the authority contained in Section 5(d)(6)(A) of the Home Owners' Loan Act of 1933, as amended, 12 U.S.C. 1464(d)(6)(A) (1982), the Federal Home Loan Bank Board duly appointed the Federal Savings and Loan Insurance Coporation as sole receiver from Audubon Federal Savings and Loan Association, New Orleans, Louisiana, on June 20, 1986.

Dated: June 23, 1986.

Jeff Sconyers,

Secretary.

[FR Doc. 86-14491 Filed 6-25-86; 8:45 am]

BILLING CODE 6720-01-M

Crescent Federal Savings Bank, New Orleans, LA; Appointment of Receiver

Notice is hereby given that, pursuant to the authority contained in Section 5(d)(6)(A) of the Home Owners' Loan Act of 1933, as amended, 12 U.S.C. 1464(d)(6)(A) (1982), the Federal Home Loan Bank Board duly appointed the Federal Savings and Loan Insurance Coporation as sole receiver for Crescent Federal Savings Bank, New Orleans, Louisiana, on June 20, 1986.

Dated: June 23, 1986.

Jeff Sconyers,

Secretary.

[FR Doc. 86-14492 Filed 6-25-86; 8:45 am]

BILLING CODE 6720-01-M

Community Savings and Loan Association, Baton Rouge, LA; Appointment of Receiver

Notice is hereby given that, pursuant to the authority contained in section 406(c)(1)(B)(i)(I) of the National Housing Act, as amended, 12 U.S.C. 1729(c)(1)(B)(i)(I) (1982), the Federal Home Loan Bank Board duly appointed the Federal Savings and Loan Insurance Corporation's as sole receiver for Community Savings and Loan Association, Baton Rouge, Louisiana, on June 20, 1986.

Dated: June 23, 1986.

Jeff Sconyers,

Secretary.

[FR Doc. 86-14493 Filed 6-25-86; 8:45 am]

BILLING CODE 6720-01-M

New Orleans Federal Savings and Loan Association, New Orleans, LA; Appointment of Receiver

Notice is hereby given that pursuant to the authority contained in section 5(d)(6)(A) of the Home Owners' Loan Act of 1933, as amended, 12 U.S.C. 1464(d)(6)(A) (1982), the Federal Home Loan Bank Board duly appointed the Federal Savings and Loan Insurance Corporation as sole receiver for New Orleans Federal Savings and Loan Association, New Orleans, Louisiana, on June 20, 1986.

Dated: June 23, 1986.

Jeff Sconyers,

Secretary.

[FR Doc. 86-14494 Filed 6-25-86; 8:45 am]

BILLING CODE 6720-01-M

Northlake Federal Savings and Loan Association, Covington, LA; Replacement of Conservator With Receiver

Notice is hereby given that pursuant to the authority contained in section 5(d)(6)(D) of the Home Owners' Loan Act of 1933, as amended, 12 U.S.C. 1464(d)(6)(D) (1982), the Federal Home Loan Bank Board on June 20, 1986, replaced James S. Hinman as conservator for Northlake Federal Savings and Loan Association, Covington, Louisiana ("Association"), with the Federal Savings and Loan Insurance Corporation as sole receiver for the Association.

Dated: June 23, 1986.

Jeff Sconyers,

Secretary.

[FR Doc. 86-14488 Filed 6-25-86; 8:45 am]

BILLING CODE 6720-01-M

[No. 86-624]

Application for Unlisted Trading Privileges and Opportunity for Hearing; Cincinnati Stock Exchange

Date: June 19, 1986.

AGENCY: Federal Home Loan Bank Board.

ACTION: Notice.

SUMMARY: The Cincinnati Stock Exchange has filed on May 9, 1986, pursuant to section 12(f)(1)(B) of the Securities Exchange Act of 1934 and Rule 12f-1, an application ("Application") with the Federal Home Loan Bank Board ("Board") for unlisted trading privileges in the following securities:

Columbia Savings and Loan Association (FHLBB No. 6325) Common Stock, $1.00 Par Value.

These securities are listed and registered on one or more other national securities exchanges and are reported in the consolidated transactions reporting system.

Comments: Any interested person may inspect the Application at the Board and, within 15 days of publication of this notice in the **Federal Register**, submit to the Corporate and Securities Division, Office of General Counsel, Federal Home Loan Bank Board, 1700 G Street, NW., Washington, DC 20552, written data, views and arguments bearing upon whether the extension of unlisted trading privileges pursuant to the Application is consistent with the maintenance of fair and orderly markets and the protection of investors. Following this opportunity for hearing, the Board will grant an approval of the Application after the date mentioned above if it finds, based upon all the information available to it, that the extension of unlisted trading privileges pursuant to the Application is consistent with the maintenance of fair and orderly markets and the protection of investors.

FOR FURTHER INFORMATION CONTACT: John P. Harootunian, Assistant General Counsel for Securities Policy, Corporate and Securities Division, Office of General Counsel, at (202) 377-6415 or at the above address.

By the Federal Home Loan Bank Board.

Jeff Sconyers,

Secretary.

[FR Doc. 14488 Filed 6-25-86; 8:45 am]

BILLING CODE 6720-01-M

[No. 86-627]

Approval of Application for Unlisted Trading Privileges; Philadelphia Stock Exchange, Inc.

Date: June 20, 1986.

AGENCY: Federal Home Loan Bank Board.

ACTION: Notice.

SUMMARY: On February 19, 1986, The Philadelphia Stock Exchange, Inc. ("PHLX") filed with the Federal Home Loan Bank Board ("Board") an application ("Application"), pursuant to section 12(f)(1)(B) of the Securities Exchange Act of 1934 ("Act") and Rule

12f-1 [17 CFR 240.12f-1] thereunder, for unlisted trading privileges in the following securities which are listed on one or more national securities exchange:

MeraBank, a Federal Savings Bank (FHLBB No. 6877), Common Stock, $1.01 Par Value.

Western Savings and Loan Association (FHLBB No. 1920), Permanent Reserve Guarantee Stock.

Notice of the Application and opportunity for hearing was published in the **Federal Register** on May 12, 1986, and interested persons were invited to submit written data, views and arguments by May 27, 1986. See Board Resolution No. 86-468, dated May 5, 1986. (51 FR 17407, May 12, 1986). The Board received no comments with respect to the Application. Notice is hereby given that the Board approved the Application for unlisted trading privileges in these securities on June 5, 1986.

SUPPLEMENTARY INFORMATION: The Board finds that the approval of the Application for unlisted trading privileges in these securities is consistent with the maintenance of fair and orderly markets and the protection of investors. As a national securities exchange registered with the Securities and Exchange Commission ("Commission") pursuant to section 6 of the Act, the PHLX is subject to the provisions of paragraph (b) of that section, and to the Commission's inspection authority and oversight responsibility under sections 17 and 19 of the Act and the rules and regulations thereunder. Transactions in the subject securities, regardless of the market in which they occur, are reported in the consolidated transaction reporting system contemplated by Rule 11Aa3-1 under the Act [17 CFR 240.11Aa3-1]. The availability of last sale information for the subject securities should contribute to pricing efficiency and to ensuring that transactions on the PHLX are executed at prices which are reasonably related to those occurring in other markets.

Further, the approval of the Application will provide increased opportunities for competition among brokers and dealers and among exchange markets consistent with the purposes of the Act and the objectives of the national market system. Finally, the Board received no comments indicating that the granting of the Application would not be consistent with the maintenance of fair and orderly markets and the protection of investors.

Accordingly, pursuant to section 12(f)(1)(B) of the Act, the Application for unlisted trading privileges in the above named securities was approved on June 5, 1986.

By the Federal Home Loan Bank Board.

Jeff Sconyers,

Secretary.

[FR Doc. 86-14489 Filed 6-25-86; 8:45 am]

BILLING CODE 6720-01-M

FEDERAL MARITIME COMMISSION

Agreement(s) Filed

The Federal Martime Commission hereby gives notice of the filing of the following agreement(s) pursuant to section 5 of the Shipping Act of 1984.

Interested parties may inspect and obtain a copy of each agreement at the Washington, DC Office of the Federal Maritime Commission, 1100 L Street, NW., Room 10325. Interested parties may submit comments on each agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within 10 days after the date of the **Federal Register** in which this notice appears. The requirements for comments are found in § 572.603 of Title 46 of the Code of Federal Regulations. Interested persons should consult this section before communicating with the Commission regarding a pending agreement.

Agreement No: 202-010748-002.

Title: West Coast/Middle East and West Asia Rate Agreement.

Parties:

American President Lines, Ltd.
Hoegh Lines
AP Moller Maersk Line

Synopsis: The proposed amendment modifies the geographic scope of the agreement by including ports and points in Bangladesh, Burma and the East Coast of India.

Agreement No.: 224-010962.

Title: Board of Harbor Commissioners and Sea-Land Service, Inc. Revocable Permit Agreement.

Parties:

Board of Harbor Commissioners of the City of Long Beach (Board)
Sea-Land Service, Inc. (Permittee)

Synopsis: The proposed agreement would permit the Board to grant permission to Permittee to use and occupy approximately 2.5 acres of land on Pier G for marine container terminal operations. Permittee shall pay to the Board as rental the sum of Nine Thousand Five Hundred Eighty-three Dollars ($9,583.00) per month payable in advance on the first day of each month. The permit is revocable by either party upon thirty (30) days' written notice to the other party. The parties have requested a shortened review period.

Agreement No.: 224-010963.

Title: Port of Galveston Wharves Terminal Agreement.

Parties:

Board of Trustees of the Galveston Wharves (Wharves)
Interoceanic Agency, Inc. (Interoceanic)

Synopsis: The proposed agreement provides for the preferential assignment of berth, shed space and upland marshalling area by the Wharves to interoceanic. Interoceanic agrees to provide continuous weekly service of its vessels to Wharves facilities. The term of the agreement is for three years with renewal provisions. The parties have requested a shortened review period.

Agreement No.: 224-010964.

Title: Port of Indiana Lease Agreement.

Parties:

Indiana Port Commission
Mid-Continent Coal & Coke Company (Lessee)

Synopsis: The proposed agreement would permit the Lessee to occupy the demised premises for the sole and only purpose of the installation and operation of a screening, storage, processing and distribution facility for coke, and the transportation of the material necessary and incidental to such activity. The initial term of this lease shall begin on the 1st day of August, 1985, and continue through the 31st of July, 1990, with renewal provisions.

By Order of the Federal Maritime Commission.

Dated: June 23, 1986.

John Robert Ewers,

Secretary.

[FR Doc. 86-14475 Filed 6-25-86; 8:45 am]

BILLING CODE 6730-01-M

Ocean Freight Forwarder License Applicants; J.P.H. International, Inc., et al.

Notice is hereby given that the following persons have filed applications for licenses as ocean freight forwarders with the Federal Maritime Commission pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. app. 1718) and 46 CFR Part 510.

Persons knowing of any reason why any of the following persons should not receive a license are requested to contact the Office of Freight Forwarders, Federal Maritime Commission, Washingon, DC 20573.

J.P.H. International, Inc., 5489 N.E. 72nd Avenue, Miami, FL 33166, Officers: Joseph A. Jacquemin, President, Karl H. Schneider, Assistant Vice President

Servco Intercontinental Corp., 1122 B Street, Suite 306, Hayward, CA 94544, Officers: Thomas I. Fukunaga, President/Director; Matt N. Masuoka, Executive Vice President/Director; George G. Sakurai, Vice President/Director; Gerald K. Harbottle, Vice President/Treasurer; Jean Nakagawa, Vice President; Michael R. Hirokawa, Assistant Vice President/Secretary; Allen Ishida, Assistant Vice President; Shirley S. Minami, Assistant Treasurer; Edith Endo, Assistant Secretary; Shirley Okubo, Assistant Secretary; George J. Fukunaga, Director

Betsy Elie dba B.A.J. International, 4686 West 137 Place, #A, Hawthorne, CA 90250

Clover Systems, Inc., 1342 N.W. 78th Avenue, Miami, FL 33126, Officers: Luis A. Rincon, Director; Jose A. Rodriquez, Vice President; Holly Susan de Rincon, Secretary.

Dated: June 23, 1986.

John Robert Ewers,

Secretary.

[FR Doc. 86-14474 Filed 6-25-86; 8:45 am]

BILLING CODE 6730-01-M

FEDERAL RESERVE SYSTEM

AmeriTrust Corp., et al.; Formations of; Acquisitions by; and Mergers of Bank Holding Companies

The companies listed in this notice have applied for the Board's approval under section 3 of the Bank Holding Company Act (12 USC 1842) and § 225.14 of the Board's Regulation Y (12 CFR 225.14) to become a bank holding company or to acquire a bank or bank holding company. The factors that are considered in acting on the applications are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank or to the offices of the Board of Governors. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Unless otherwise noted, comments regarding each of these applications must be received not later than July 17, 1986.

A. **Federal Reserve Bank of Cleveland** (Lee S. Adams, Vice President) 1455 East Sixth Street, Cleveland, Ohio 44101:

1. *AmeriTrust Corporation,* Cleveland, Ohio; to acquire 100 percent of the voting shares of Amerian National Bancshares, Inc., Noblesville, Indiana, thereby indirectly acquiring American National Bank of Noblesville, Noblesville, Indiana.

2. *AmeriTrust Corporation,* Cleveland, Ohio; to acquire 100 percent of the voting shares of Indcorp, Martinsville, Indiana, and thereby indirectly acquire Indiana Bank and Trust Company, Martinsville, Indiana.

B. **Federal Reserve Bank of Atlanta** (Robert E. Heck, Vice President) 104 Marietta Street, NW., Atlanta, Georgia 30303:

1. *Peoples Exchange Bancshares, Inc.,* Beatrice, Alabama; to become a bank holding company by acquiring 91.5 percent of the voting shares of People Exchange Bank of Monroe County, Beatrice, Alabama.

C. **Federal Reserve Bank of Chicago** (Franklin D. Dreyer, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. *St. Joseph Bancorp, Inc.,* St. Joseph, Illinois; to become a bank holding company by acquiring 100 percent of the voting shares of The State Bank of Saint Joseph, Saint Joseph, Illinois.

2. *West Suburban Bancorp, Inc.,* Lombard, Illinois, to become a bank holding company by acquiring 80 percent each of the following—West Suburban Bank, Lombard, Illinois; West Suburban Bank of Downers Grove/Lombard, Downers Grove, Illinois; West Suburban Bank of Darien, Darien, Illinois; and West Suburban Bank of Carol Stream/Straford Square, Carol Stream, Illinois. The comment period on this application ends July 14, 1986.

D. **Federal Reserve Bank of St. Louis** (Delmer P. Weisz, Vice President) 411 Locust Street, St. Louis, Missouri 63166:

1. *Martinco Financial Corp.,* Shoals, Indiana; to become a bank holding company by acquiring 100 percent of the voting shares of The Martin County Bank, Shoals, Indiana.

E. **Federal Reserve Bank of Kansas City** (Thomas M. Hoenig, Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. *Capital National Bancshares, Inc.,* Oklahoma City, Oklahoma; to become a bank holding company by acquiring 100 percent of the voting shares of Capital National Bank Oklahoma City, Oklahoma.

F. **Federal Reserve Bank of Dallas** (Anthony J. Montelaro, Vice President) 400 South Akard Street, Dallas, Texas 75222:

1. *Goliad Bancshares, Inc.,* Goliad, Texas; to become a bank holding company by acquiring 100 percent of the voting shares of First National Bank of Goliad, Goliad, Texas.

G. *Federal Reserve Bank of San Francisco* (Harry W. Green, Vice President) 101 Market Street, San Francisco, California 94105:

1. *Verde Valley Bancorp, Inc.,* Cottonwood, Arizona; to become a bank holding company by acquiring 100 percent of the voting shares of The Bank of Verde Valley, Cottonwood, Arizona, a *de novo* bank.

H. **Federal Reserve Bank of Dallas** (Anthony J. Montelaro, Vice President) 400 South Akard Street, Dallas, Texas 75222:

1. *Texas Commerce Bancshares, Inc.,* Houston, Texas; to acquire 100 percent of the voting shares of Texas Commerce Bank-Richardson, N.A., Richardson, Texas, a *de novo* bank.

Board of Governors of the Federal Reserve System, June 20, 1986.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 86-14400 Filed 6-25-86; 8:45 am]

BILLING CODE 6210-01-M

Commercial Landmark Corp.; Application To Engage de Novo in Permissible Nonbanking Activities

The company listed in this notice has filed an application under § 225.23(a)(1) of the Board's Regulation Y (12 CFR 225.23(a)(1)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to commerce or to engage *de novo,* either directly or through a subsidiary, in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

The application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition,

conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Unless otherwise noted, comments regarding the application must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than July 16, 1986.

A. **Federal Reserve Bank of Kansas City** (Thomas M. Hoenig, Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. *Commercial Landmark Corporation*, Muskogee, Oklahoma; to engage *de novo* through its subsidiary, Landmark Service Company, Muskogee, Oklahoma, in providing to others data processing and transmission services and facilities pursuant to § 225.25(b)(7) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, June 20, 1986.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 86-14401 Filed 6-25-86; 8:45 am]

BILLING CODE 6210-01-M

First National Cincinnati Corp., et al.; Formations of; Acquistions by; and Mergers of Bank Holding Companies

The companies listed in this notice have applied for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) and § 225.14 of the Board's Regulation Y (12 CFR 225.14) to become a bank holding company or to acquire a bank or bank holding company. The factors that are considered in acting on the applications are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank or to the offices of the Board of Governors. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Unless otherwise noted, comments regarding each of these applications must be received not later than July 18, 1986.

A. **Federal Reserve Bank of Cleveland** (Lee S. Adams, Vice President) 1455 Sixth Street, Cleveland, Ohio 44101:

1. *First National Cincinnati Corporation*, Cincinnati, Ohio; to acquire 100 percent of the voting shares of Second National Corporation, Richmond, Indiana, and thereby indirectly acquire The Second National Bank of Richmond, Richmond, Indiana, and Bentonville State Bank, Bentonville, Indiana.

2. *James Madison Limited*, Washington, DC; to merge with UNB Bancshares, Incorporated, Washington, DC, and thereby indirectly acquire United National Bank of Washington, Washington, DC.

B. **Federal Reserve Bank of St. Louis** (Delmer P. Weisz, Vice President) 411 Locust Street, St. Louis, Missouri 63166:

1. *SBT Bancshares, Inc.*, Selmer, Tennessee; to become a bank holding company by acquiring 100 percent of the voting shares of Selmer Bank and Trust Company, Selmer, Tennessee.

2. *Valley Bancshares, Inc.*, Valley Part, Missouri; to acquire at least 84 percent of the voting shares of Meramec State Bank, Sullivan, Missouri.

Board of Governors of the Federal Reserve System, June 20, 1986.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 86-14402 Filed 6-25-86; 8:45 am]

BILLING CODE 6210-01-M

Hospers Agency Co., et al.; Acquisitions of Companies Engaged in Permissible Nonbanking Activities

The organizations listed in this notice have applied under § 225.23(a)(2) or (f) of the Board's Regulation Y (12 CFR 225.23(a)(2) or (f)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 USC 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to acquire or control voting securities or assets of a company engaged in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated for the application or the offices of the Board of Governors not later than July 17, 1986.

A. **Federal Reserve Bank of Chicago** (Franklin D. Dreyer, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. *Hospers Agency Company*, Sioux Center, Iowa; to acquire Van Bruggen Insurance, Inc., Sioux Center, Iowa, and thereby engage in general insurance activities in a town of less than 5,000 in population, pursuant to § 225.25(b)(8)(iii) of Regulation Y.

B. **Federal Reserve Bank of St. Louis** (Delmer P. Weisz, Vice President) 411 Locust Street, St. Louis, Missouri 63166:

1. *Mid South Bancshares, Inc.*, Paragould, Arkansas; to acquire Profit Consultants, Inc., Jonesboro, Arkansas, and thereby engage in providing management consulting advice to nonaffiliated banks and financial institutions, pursuant to § 225.5(b)(11) of the Board's Regulation Y. Comments on this application must be received no later than July 10.

Board of Governors of the Federal Reserve System, June 20, 1986.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 86-14403 Filed 6-25-86; 8:45 am]

BILLING CODE 6210-01-M

Midland Bank, plc, et al.; Applications To Engage de Novo in Permissible Nonbanking Activities

The companies listed in this notice have filed an application under § 225.23(a)(1) of the Board's Regulation Y (12 CFR 225.23(a)(1)) for the Board's approval under section 4(c)(8) of the

Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to commence or to engage *de novo*, either directly or through a subsidiary, in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than July 15, 1986.

A. **Federal Reserve Bank of New York** (William L. Rutledge, Vice President) 33 Liberty Street, New York, New York 10045:

1. *Midland Bank, plc*, London, England; to engage *de novo* through its subsidiary, Midland-Montagu Municipal Securities, Inc., San Francisco, California, in providing securities brokerage activities, related securities credit activities and incidental activities such as offering custodial services, pursuant to § 225.25(b)(15) of the Board's Regulation Y.

B. **Federal Reserve Bank of Philadelphia** (Thomas K. Desch, Vice President) 100 North 6th Street, Philadelphia, Pennsylvania 19105:

1. *Southern Jersey Bancorp*, Bridgeton, New Jersey; to engage *de novo* in data processing, by providing to others data processing and/or data transmission services, facilities (including data processing and data transmission services, hardware, software, documentation or operating personnel), data bases or access to such services, facilities or data bases by any technological means, pursuant to § 225.25(b)(7) of the Board's Regulation Y. These activities will be performed in New Jersey and contiguous states.

C. **Federal Reserve Bank of Kansas City** (Thomas M. Hoeing, Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. *Greater Metro Bank Holding Company*, Aurora, Colorado; to engage *de novo* through its subsidiary Aurora National Mortgage Company, Aurora, Colorado, in making and servicing loans and other extensions of credit as would be conducted by a mortgage company, and in performing real estate appraisals, pursuant to §§ 225.25(b)(1) and (13) of the Board's Regulation Y.

2. *First State Bancshares, Inc.*, Scottabluff, Nebraska; to engage *de novo* through its subsidiary First State Insurance, Inc., Scottsbluff, Nebraska, in the sale of general insurance, except life insurance and annuities, pursuant to section 4(c)(8)(F) of the Bank Holding Company Act.

Board of Governors of the Federal Reserve System, June 20, 1986.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 86-14404 Filed 6-25-86; 8:45 am]

BILLING CODE 6210-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Institutes of Health; Statement of Organization, Functions, and Delegations of Authority

Correction

In FR Doc. 86-8487 beginning on page 12928 in the issue of Wednesday, April 16, 1986, make the following corrections:

1. On page 12929, first column, insert the following before the first line: "and (5) coordinates with the other research institutes and with all Federal"

2. On page 12930, first column, the first two lines should be removed.

BILLING CODE 1505-01-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

Arizona Strip District Grazing Advisory Board Meeting

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of meeting.

SUMMARY: The first meeting of the newly re-created Arizona Strip District Grazing Advisory Board meeting will be held Tuesday, July 22, 1986 at 9:00 a.m. Primary topic will be range improvement projects.

ADDRESS: Sugar Loaf Restaurant, 290 East St. George Blvd., St. George, Utah 84770.

FOR FURTHER INFORMATION CONTACT: G. William Lamb, District Manager, 196 E. Tabernacle, St. George, Utah 84770.

SUPPLEMENTARY INFORMATION: Election of officers will precede discussion of range projects in wilderness areas and land exchanges affecting permittees. The Board will also hear an update on planned and completed range projects. Comments from the public may be given at 3:00 p.m.

G. William Lamb,

Arizona Strip District Manager.

[FR Doc. 86-14410 Filed 6-25-86; 8:45 am]

BILLING CODE 4310-32-M

Proposed Reinstatement of a Terminated Oil and Gas Lease; Alaska

In accordance with Title IV of the Federal Oil and Gas Royalty Management Act (Pub. L. 97-451), a petition for reinstatement of oil and gas lease AA-48224-AF has been received covering the following lands:

Fairbanks Meridian, Alaska

T. 18 S., R. 2 W.,
Sec. 12, N½NW¼;
Sec. 22, S½NE¼.
(160 acres)

The proposed reinstatement of the lease would be under the same terms and conditions of the original lease, except the rental will be increased to $5 per acre per year, and royalty increased to 16⅔ percent. The $500 administrative fee and the cost of publishing this Notice have been paid. The required rentals and royalties accruing from December 1, 1985, the date of termination, have been paid.

Having met all the requirements for reinstatement of lease AA-48224-AF as set out in section 31 (d) and (e) of the Mineral Leasing Act of 1920 (30 U.S.C. 188), the Bureau of Land Management is proposing to reinstate the lease, effective December 1, 1985, subject to the terms and conditions cited above.

Dated: June 19, 1986.

Sue A. Faught,

Acting Chief, Branch of Mineral Adjudication.

[FR Doc. 86-14411 Filed 6-25-86; 8:45 am]

BILLING CODE 4310-JA-M

[W-64779]

Wyoming; Proposed Reinstatement of Terminated Oil and Gas Lease

June 18, 1986.

Pursuant to the provisions of Pub. L. 97-451, 96 Stat. 2462-2466, and Regulation 43 CFR 3108.2.3 (a) and (b)(1), a petition for reinstatement of oil and gas lease W-64779 for lands in Campbell County, Wyoming was timely filed and was accompanied by all the required rentals accruing from the date of termination.

The lessee has agreed to the amended lease terms for rentals and royalties at rates of $5.00 per acre, or fraction thereof, per year and 16⅔ percent, respectively.

The lessee has paid the required $500.00 administrative fee and $106.25 to reimburse the Department for the cost of this **Federal Register** notice. The lessee has met all the requirements for reinstatement of the lease as set out in section 31 (d) and (e) of the Mineral Lands Leasing Act of 1920 (30 U.S.C. 188), and the Bureau of Land Management is proposing to reinstate lease W-64779 effective October 1, 1985, subject to the original terms and conditions of the lease and the increased rental and royalty rates cited above.

Patricia J. Wattles,

Acting Chief, Leasing Section.

[FR Doc. 86-14412 Filed 6-25-86; 8:45 am]

BILLING CODE 4310-22-M

Colorado; Filing of Plats of Survey

June 20, 1986.

The plats of survey of the following described land will be officially filed in the Colorado State Office, Bureau of Land Management, Denver, Colorado, effective 10:00 a.m., June 20, 1986.

The plat, in three sheets, representing the dependent resurvey of a portion of the north boundary, a portion of the subdivisional lines, the Georgetown Townsite, a portion of certain mineral surveys; the metes-and-bounds surveys of certain irregular lot lines, a portion of the east right-of-way of Interstate 70, and the survey of the subdivision of section 5, T. 4 S., R. 74 W., Sixth Principal Meridian, Colorado, Group No's. 517 and 696, was accepted June 9, 1986.

This survey was executed to meet certain administrative needs of this Bureau.

The plat, representing the dependent resurvey of a portion of the east boundary, a portion of the subdivisional lines, and the subdivision of sec. 1, T. 1N., R. 3W., Ute Meridian, Colorado, Group No. 808, was accepted June 12, 1986.

The plat, representing the dependent resurvey of a portion of the south and east boundaries, a portion of the subdivisional lines, and the subdivision of sec. 36, T. 2 N., R. 3 W., Ute Meridian Colorado, Group No. 808, was accepted June 12, 1986.

These surveys were executed to meet certain adminstrative needs of the Bureau of Reclamation.

All inquiries about this land should be sent to the Colorado State Office, Bureau of Land Management, 2020 Arapahoe Street, Denver, Colorado 80205.

Jack A. Eaves,

Chief Cadastral Surveyor for Colorado.

[FR Doc. 86-14415 Filed 6-25-86; 8:45 am]

BILLING CODE 4310-84-M

[NM-0555014]

Proposed Continuation of Withdrawal, New Mexico

AGENCY: Bureau of land Management, Interior.

ACTION: Notice.

SUMMARY: The Department of the Interior proposes that a 55.87-acre withdrawal for the Department of Agriculture, Forest Service continue for an additional 20 years. The lands will remain withdrawn from appropriation under the United States mining laws and will remain open to leasing under the mineral leasing laws.

DATE: Comments should be received by September 24, 1986.

FOR FURTHER INFORMATION CONTACT: Kay Thomas, BLM New Mexico State Office, P.O. Box 1449, Santa Fe, NM 87504-1449, (505) 988-6589.

The Department of the Interior proposes that the existing land withdrawal made by Public Land Order 3553 of February 23, 1965, be continued for a period of 20 years pursuant to section 204 of the Federal Land Policy and Management Act of 1976, 90 Stat. 2751, 43 U.S.C. 1714. The land is described as follows:

New Mexico Principal Meridian

Cibola National Forest

John F. Kennedy Campground (formerly Trigo Canyon Campground)

T. 5 N., R. 4 E., (unsurveyed),

Sec. 12, that area within the Cibola National Forest (which may be, when surveyed) in the SE¼NE¼ and E½SE¼, excluding that portion lying within the boundary of the Manzano Mountain Wilderness (Pub. L. 95-237).

T. 5 N., R. 5 E.,

Sec. 7, W½ of lots 3 and 4, excluding that portion lying within the boundary of Manzano Mountain Wilderness (Pub. L 95-237).

The areas described aggregated approximately 55.87 acres in Valencia and Torrance Counties.

The purpose of the withdrawal is for use in connection with the Cibola National Forest, Mountainair Ranger District. The area has been developed for public recreational use and is heavily utilized for this purpose.

The withdrawal segregates the land from location and entry under the mining laws, but not from leasing under the mineral leasing laws.

For a period of 90 days from the date of publication of this notice, all persons who wish to submit comments in connection with the proposed withdrawal continuation may present their views in writing to the Chief, Branch of lands and Minerals Operations, in the New Mexico State Office.

A report will be prepared for consideration by the Secretary of the Interior, the President, and Congress, who will determine whether or not the withdrawal will be continued and if so, for how long. The final determination on the continuation of the withdrawal will be published in the **Federal Register.** The existing withdrawal will continue until such final determination is made.

Dated: June 12, 1986.

Monte G. Jordan,

Associate State Director.

[FR Doc. 86-14418 Filed 6-25-86; 8:45 am]

BILLING CODE 4310-FB-M

[WASH-04293, OR-22054(WASH), OR-22057(WASH)]

Washington; Proposed Continuation of Withdrawals

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The Bureau of Reclamation proposes that three land withdrawals for the Yakima Project continue for an additional 100 years. The lands would remain closed to surface entry and mining but have been and would remain open to mineral leasing.

FOR FURTHER INFORMATION CONTACT: Champ Vaughan, BLM Oregon State Office P.O. Box 2965, Portland, Oregon 97208 (Telephone 503-231-6905).

SUPPLEMENTARY INFORMATION: The Bureau of Reclamation proposes that the existing land withdrawals made by the

Secretarial Orders of September 12, 1905, and August 4, 1910, and Public Land Order No. 2828 of December 3, 1962, be continued for a period of 100 years pursuant to section 204 of the Federal Land Policy and Management Act of 1976, 90 Stat. 2751, 43 U.S.C. 1714.

The lands involved include three parcels; the first containing 150 acres located 10 miles north of Yakima in sections 28 and 32, T. 15 N., R. 19 E., W.M., Kittitas County, Washington; the second containing 25 acres located 4 miles northeast of Prosser in section 20, T. 9 N., R. 25 E.,; and the third containing 7.50 acres located 11 miles northeast of Prosser in section 32, T. 10 N., R. 26 E., W.M., Benton County, Washington.

The purpose of the withdrawals is to protect the Yakima Project. The withdrawals segregate the lands from operation of the public land laws generally, including the mining laws, but not the mineral leasing laws. No change is proposed in the purpose or segregative effect of the withdrawals.

For a period of 90 days from the date of publication of this notice, all persons who wish to submit comments, suggestions, or objections in connection with the proposed withdrawal continuation may present their views in writing to the undersigned officer at the address specified above.

The authorized office of the Bureau of Land Management will undertake such investigations as are necessary to determine the existing and potential demand for the lands and its resources. A report will also be prepared for consideration by the Secretary of the Interior, the President and Congress, who will determine whether or not the withdrawals will be continued and if so, for how long. The final determination on the continuation of the withdrawals will be published in the **Federal Register.** The existing withdrawals will continue until such final determination is made.

Dated: June 19, 1986.

B. LaVelle Black,

Chief, Branch of Lands and Minerals Operations.

[FR Doc. 86-14419 Filed 6-25-86; 8:45 am]

BILLING CODE 4310-33-M

[AA-6687-A]

Alaska Native Claims Selection; Old Harbor Native Corp.

In accordance with Departmental regulation 43 CFR 2650.7(d), notice is hereby given that a decision to issue conveyance under the provisions of section 14(a) of the Alaska Native Claims Settlement Act of December 18, 1971 (ANCSA), 43 U.S.C. 1601, 1613(a), will be issued to Old Harbor Native Corporation for 1 acre. The lands involved are within Sec. 30, T. 34 S., R. 24 W., Seward Meridian, in the vicinity of Old Harbor, Alaska.

A notice of the decision will be published once a week for four (4) consecutive weeks, in the KODIAK DAILY MIRROR. Copies of the decision may be obtained by contacting the Bureau of Land Management, Alaska State Office, 701 C Street, Box 13, Anchorage, Alaska 99513. ((907) 271-5960.)

Any party claiming a property interest which is adversely affected by the decision shall have unitl July 28, 1986, to file an appeal. However, parties receiving service by certified mail shall have 30 days from the date of receipt to file an appeal. Appeals must be filed in the Bureau of Land Management, Division of Conveyance Management (960), address identified above, where the requirements for filing an appeal can be obtained. Parties who do not file an appeal in accordance with the requirements of 43 CFR Part 4, Subpart E shall be deemed to have waived their rights.

Ann Adams,

Section Chief, Branch of ANCSA Adjudication.

[FR Doc. 86-14167 Filed 6-25-86; 8:45 am]

BILLING CODE 4310-JA-M

[A 20346-B]

Amendment to Notice of Realty Action; Exchange of Public Lands; Arizona

This amends Notice of Realty Action A 20346-B, published May 7, 1986, by inserting the following, immediately preceding the last paragraph.

The Arizona State lands will be those portions of the following described sections that are determined by appraisal to be of equal value.

Gila and Salt River Meridian, Arizona

T. 15 N., R. 10 W.,
Sec. 2, all;
Sec. 16, all.
T. 16 N., R. 10 W.,
Sec. 2, all;
Sec. 4, all;
Sec. 6, all;
Sec. 8, all;
Sec. 16, all;
Sec. 18, all;
Sec. 32, all;
Sec. 36, all.
T. 16½ N., R. 10 W.,
Sec. 32, all.
T. 11 N., R. 11 W.,
Sec. 13, N½;
Sec. 14, N½.
T. 16 N., R. 11 W.,
Sec. 2, all;
Sec. 16, all;
Sec. 32, all;
Sec. 36, all.
T. 16½ N., R. 11 W.,
Sec. 32, all.
T. 17 N., R. 11 W.,
Sec. 16, all;
Sec. 18, all;
Sec. 20, all;
Sec. 28, all;
Sec. 30, all;
Sec. 32, all.
T. 14 N., R. 12 W.,
Sec. 2, all;
Sec. 16, all.
T. 16 N., R. 12 W.,
Sec. 2, all;
Sec. 16, all;
Sec. 32, all;
Sec. 36, all.
T. 16½ N., R. 12 W.,
Sec. 36, all.
T. 17 N., R. 12 W.,
Sec. 14, all;
Sec. 24, all;
Sec. 26, all;
Sec. 36, all.

Containing approximately 21,760 acres.

Dated: June 18, 1986.

Marlyn V. Jones,

District Manager.

[FR Doc. 86-14413 Filed 6-25-86; 8:45 am]

BILLING CODE 4310-32-M

Conveyance of Mineral Interests in California

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of realty action; conveyance of the reserved mineral interest.

SUMMARY: The private lands described in this notice have been examined and found suitable for conveyance of the reserved mineral interest pursuant to section 209 of the Federal Land Policy and Management Act of October 21, 1976.

The mineral interests will be conveyed in whole or in part upon favorable mineral examination.

Serial No.	Legal description	Acres	County	Mineral reservation, percent all minerals
CA-9506	T. 36 N., R. 9 E., MDMer., Sec. 1, NE¼SW¼ portion of; Sec. 2, Lots 1 thru 4, SE¼SW¼, S½NW¼, N½SW¼, SE¼SE¼; Sec. 11, SE½NE; Sec. 12 NE¼, E½NW¼, SW¼NW¼.	1044.81	Lassen	100
	T. 36 N., R. 10 E., MDMer., Sec. 6, Lot 7			.....
	T. 37 N., R. 9 E., MDMer., Sec. 36, NW¼NE¼, N½NW¼			.....
CA-13058	T. 9 N., R. 10 E., MDMer., Sec. 25, Lots 1 thru 5, 7 and SE¼SW¼	180.69	El Dorado	100
CA-13247	T. 7 N., R. 12 W., MDMer., Sec. 3, Lot 1; M&B	21.11	Amador	100
CA-14066	T. 4 S., R. 16 E., MDMer., Sec. 25, Lot 3, portion of; S½NE¼, SE¼NW¼, SW¼, N½SE¼, SE¼SE¼; Sec. 26, Lot 3, portion of.	411.32	Mariposa	100
CA-14509	T. 3 S., R. 16 E., MDMer., Sec. 8, Lot 1; Sec. 9, Lots 4, 9, 10, and 20	225.62	Mariposa	100
CA-16823	T. 13 N., R. 6 W., MDMer., Sec. 10, NW¼, N½SE¼, SE¼SE¼; Sec. 11, NW¼SW¼	320.0	Lake	100
CA-16830	T. 6 N., R. 9 W., MDMer., Sec. 3, Parcel 7 (FFMCo.)	5.0	Sonoma	50
CA-17027	T. 9 S., R. 21 E., MDMer., Sec. 7 Lot 4; Sec. 8, S½sW¼, SW½SE¼; Sec. 17, N½NW¼, W½SW¼; Sec. 18, SE¼NW¼, E½NE½, N½SE¼.	519.90	Madera	100
CA-17136	T. 12 N., R. 9 E., MDMer., Sec. 24, NE¼	160.0	El Dorado	100
CA-17432	T. 1 N., R. 14 E., MDMer., Sec. 27, Lot 6	1.610	Tuolumne	100
CA-17436	T. 4 S., R. 18 E., MDMer., Sec. 21, S½SE¼SW¼; Sec. 28, Lots 3 thru 7, W½NE¼, SE¼, N½SW¼, SE¼SW¼; Sec. 33, NE¼NW¼.	521.90	Mariposa	100
CA-17934	T. 5 N., R. 13 W., SBMer., Sec. 5, Lot 7, SW¼SE¼, E½SE¼. Sec. 8, NW¼NE¼, E½NW¼	320.00	Los Angeles	100
CA-18128	T. 4 S. R. 2 E., HBMer., Sec. 21, S½NW¼	80.00	Lassen	100
CA-18151	T. 16 S., R. 7 E., SBMer., Sec. 19, SE¼NE¼, NE¼SE¼; Sec. 20, SW¼NW¼, NE¼SW¼; Sec. 29, W½SW¼, SE¼SW¼; Sec. 30, W½SE¼, SW¼NE¼: Sec. 31, E½; Sec. 32, W½W½.	1048.23	San Diego	100
	T. 17 S., R. 7 E., SBMer., Sec. 5, Lot 4; Sec. 6, Lot 1			.....
CA-18210	T. 9 N., R. 12 E., MDMer., Sec. 12, N½NW¼ SE¼NW¼	120.00	El Dorado	100
CA-18786	T. 9 N., R. 12 E., MDMer., Sec. 11, N½NE¼	80.00	El Dorado	100
CA-18879	T. 10 N., R. 5 W., MDMer., Sec. 10, E½sE¼; Sec. 14, W½NW¼; Sec. 15, E½NE¼: Sec. 23, NW¼NW¼, NE¼NW¼, NW¼NE¼.	516.00	Napa	100
CA-18916	T. 6 S., R. 4 E., MDMer., Sec. 14, E½E½	160.00	Santa Clara	100
CA-18932	T. 3 N., R. 4 E., SBMer., Sec. 22, E½NE¼NE¼NW¼	5.00	San Bernardino	100
CA-18980	T. 16 N., R. 8 E., MDMer., Sec. 28, Lot 3, portion of	1.00	Nevada	100
CA-19052	T. 17 N., R. 9 E., MDMer., Sec. 32, Lot 6	1.40	Nevada	100
CA-19356	T. 8 S., R. 1 E., SBMer., Sec. 29, SE¼NW¼, NE¼SW¼	80.00	Riverside	100

The purpose is to allow consolidation of surface and subsurface of minerals ownership where there are no known mineral values or in those instances where the reservation interferes with or precludes appropriate non-mineral development and such development is a more beneficial use of the land than the mineral development.

Upon publication of this notice of realty action in the **Federal Register** as provided in 43 CFR 2720.1(b), the mineral interests owned by the United States in the private land covered by the application shall be segregated to the extent that they will not be subject to appropriation under the public land laws, including the mining laws. The segregative effect of the application shall terminate either upon issuance of a patent or other document of conveyance to such mineral interests, upon final rejection of the application or two years from the date of filing of the application, whichever occurs first.

FOR FURTHER INFORMATION CONTACT: Elizabeth Hoefler, Bureau of Land Management, California State Office, 2800 Cottage Way, Room E. 2841, Federal Office Building, Sacramento, California 95825, 916-978-4815.

Dated: June 19, 1986.

Nancy J. Alex,

Chief, Lands Section, Branch of Lands and Minerals Operations.

[FR Doc. 86-14414 Filed 6-25-86; 8:45 am]

BILLING CODE 4310-40-M

[NM-46833]

Proposed Continuation of Withdrawal; New Mexico

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The Department of the Interior proposes that a 40.00-acre withdrawal for the Department of Agriculture, Forest Service, continue for an additional 18 years. The lands will remain withdrawn from appropriation under the United States mining laws, and will remain open to leasing under the mineral leasing laws. The lands will be opened to operation under the public land laws.

DATES: Comments should be received by September 24, 1986.

FOR FURTHER INFORMATION CONTACT: Kay Thomas, BLM, New Mexico State Office, P.O. Box 1449, Santa Fe, NM 87504-1449, (505) 988-6589.

SUPPLEMENTARY INFORMATION: The Department of the Interior proposes that the existing land withdrawal made by Secretarial Order of November 19, 1907, be continued for a period of 18 years pursuant to section 204 of the Federal Land Policy and Management Act of 1976, 90 Stat. 2751, 43 U.S.C. 1714. The land is described as follows:

New Mexico Principal Meridian

Cibola National Forest

Canon Lobo Administrative Site

T. 11 N., R. 8 W.,
Sec. 6, SE¼SE¼.

The area described contains 40.00 acres in Cibola County.

The purpose of the withdrawal is for use in connection with the Cibola National Forest, Mount Taylor Ranger District. The area has been developed for public recreational use and is heavily utilized for this purpose.

The withdrawal segregates the land from location and entry under the mining laws. The lands will be open to operation under the public land laws; they have been, and will remain open to leasing under the mineral leasing laws.

For a period of 90 days from the date of publication of this notice, all persons who wish to submit comments in connection with the proposed withdrawal continuation may present their views in writing to the Chief, Branch of Lands and Minerals Operations, in the New Mexico State Office.

A report will be prepared for consideration by the Secretary of the Interior, the President, and Congress, who will determine whether or not the withdrawal will be continued and if so, for how long. The final determination on the continuation of the withdrawal will be published in the **Federal Register.**

The existing withdrawal will continue until such final determination is made.

Dennis R. Erhart,

Acting State Director.

[FR Doc. 86-14416 Filed 6-25-86; 8:45 am]

BILLING CODE 4310-FB-M

[NM-46836]

Proposed Continuation of Withdrawal; New Mexio

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The Department of the Interior proposes that a 279.58-acre withdrawal for the Department of Agriculture, Forest Service continue for an additional 20 years. The lands will remain withdrawn from appropriation under the United States mining laws and will remain open to leasing under the mineral leasing laws. The lands will be open to operation under the public land laws.

DATES: Comments should be received by September 24, 1986.

FOR FURTHER INFORMATION CONTACT: Kay Thomas, BLM, New Mexico State Office, P.O. Box 1449, Santa Fe, NM 87504-1449, (505) 988-6589.

SUPPLEMENTARY INFORMATION: The Department of the Interior proposes that the existing land withdrawal made by Public Land Order 1030 of November 15, 1954, be continued for a period of 20 years pursuant to section 204 of the Federal Land Policy and Management Act of 1976, 90 Stat.2751, 43 U..C. 1714. The land is described as follows:

New Mexico Principal Meridian

Cibola National Forest

Mountainair Administrative Site

T. 3 N., R. 6 E.,
Sec. 1, lots 1-4, SW¼NE¼, S½NW¼.

The area described contains 279.58 acres in Torrance County.

The purpose of the withdrawal is for use in connection with the Cibola National Forest, Mountainair Ranger District. The administrative site consists of extensive permanent facilities and improvements.

The withdrawal segregates the land from location and entry under the mining laws. The lands will be open to operation under the public land laws, and have been and will remain open to the mineral leasing laws.

For a period of 90 days from the date of publication of this notice, all persons who wish to submit comments in connection with the proposed withdrawal continuation may present their views in writing to the Chief, Branch of Lands and Minerals Operations, in the New Mexico State Office.

A report will be prepared for consideration by the Secretary of the Interior, the President, and Congress, who will determine whether or not the withdrawal will be continued and if so, for how long. The final determination on the continuation of the withdrawal will be published in the **Federal Register.** The existing withdrawal will continue until such final determination is made.

Dennis R. Erhart,

Acting State Director.

[FR Doc. 86-14417 Filed 6-25-86; 8:45 am]

BILLING CODE 4310-FB-M

[W-37737]

Wyoming; Proposed Reinstatement of Terminated Oil and Gas Lease

June 18, 1986.

Pursuant to the provisions of Pub. L. 97-451, 96 Stat. 2462-2466, and Regulation 43 CFR 3108.2-3 (a) and (b)(1), a petition for reinstatement of oil and gas lease W-37737 for lands in Lincoln County, Wyoming was timely filed and was accompanied by all the required rentals accruing from the date of termination.

The lessees have agreed to the amended lease terms for rentals and royalties at rates of $5.00 per acre, or fraction thereof, per year and 16⅔ percent, respectively.

The lessees have paid the required $500.00 administrative fee and $106.25 to reimburse the Department for the cost of this **Federal Register** notice. The lessees have met all the requirements for reinstatement of the lease as set out in section 31 (d) and (e) of the Mineral Lands Leasing Act of 1920 (30 U.S.C. 188), and the Bureau of Land Management is proposing to reinstate lease W-37737 effective November 1, 1985, subject to the original terms and conditions of the lease and the increased rental and royalty rates cited above.

Patricia J. Wattles,

Acting Chief, Leasing Section.

[FR Doc. 86-14461 Filed 6-25-86; 8:45 am]

BILLING CODE 4310-22-M

[A-22098]

Realty Action; Arizona

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Realty Action-Exchange, Federal MInerals in La Paz, Maricopa, Mohave, Pinal, and Yavapai Counties, Arizona.

SUMMARY: All or part of the following described federal mineral estate has been determined to be suitable for disposal by exchange under section 206 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1716: Gila and Salt River Meridian, Arizona.

T. 3 N., R. 2 E.,
Sec. 1.
T. 5 N., R. 2 E.,
Sec. 12, 13.
T. 6 N., R. 2 E.,
Sec. 1, 3, 9, 13, 14, 15, 22, 23, 24, 27, 33, 34.
T. 7 N., R. 2 E.,
Sec. 11, 18, 19, 23.
T. 5 N., R. 3 E.,
Sec. 22.
T. 6 N., R. 3 E.,
Sec. 6, 8, 11, 12, 13, 14, 15, 17, 18, 19, 20, 21, 22, 23, 24, 27, 28.
T. 6 N., R. 4 E.,
Sec. 7, 8, 9, 18, 19, 29.
T. 3 N., R. 5 E.,
Sec. 1, 2, 9, 11, 12, 15.
T. 7 N., R. 7 W.,
Sec. 25, 26, 27, 28, 34, 35.
T. 8 N., R. 7 W.,
Sec. 5, 6, 7, 8, 18, 30.
T. 7 N., R. 8 W.,
Sec. 3, 4, 5, 7, 8, 9, 10, 14, 22, 23.
T. 8 N., R. 8 W.,
Sec. 1, 6, 11, 12, 13, 14, 23, 24, 25, 26, 27, 33, 34.
T. 7 N., R. 9 W.,
Sec. 1.
T. 10 S., R. 9 E.,
Sec. 21, 22, 26, 29, 33.
Comprising 40,247.05 acres.

In exchange for the federal mineral estate described above, the United States will acquire all or part of the following state-owned mineral estates:

T. 3 N., R. 7 W.,
Sec. 2, 16, 32.
T. 4 N., R. 7 W.,
Sec. 2, 32.
T. 4 N., R. 8 W.,
Sec. 36.
T. 3 N., R. 9 W.,
Sec. 2, 16, 32, 36.
T. 6 N., R. 9 W.,
Sec. 32.
T. 2 N., R. 10 W.,
Sec. 2.
T. 9 N., R. 10 W.,
Sec. 2, 16, 32, 36.
T. 10 N., R. 10 W.,
Sec. 2, 16, 32.
T. 4 N., R. 11 W.,
Sec. 2, 16, 36.
T. 7 N., R. 11, W.,
Sec. 34.
T. 3 N., R. 12 W.,
Sec. 2.
T. 4 N., R. 12 W.,
Sec. 2, 16, 32, 36.
T. 5 N., R. 12 W.,
Sec. 2, 5.
T. 5 N., R. 13 W.,
Sec. 32.

T. 6 N., R. 13 W.,
Sec. 2, 16, 19, 20.
T. 11 N., R. 13 W.,
Sec. 2, 32.
T. 1 N., R. 14 W.,
Sec. 2, 16, 32, 36.
T. 2 N., R. 14 W.,
Sec. 2, 16, 32, 36.
T. 4 N., R. 14 W.,
Sec. 2.
T. 5 N., R. 14 W.,
Sec. 32, 36.
T. 7 N., R. 14 W.,
Sec. 32.
T. 11 N., R. 14 W.,
Sec. 16.
T. 12 N., R. 14 W.,
Sec. 36.
T. 6 N., R. 15 W.,
Sec. 16, 36.
T. 6 N., R. 16 W.,
Sec. 2.
T. 28 N., R. 16 W.,
Sec. 16, 32.
T. 7 N., R. 17 W.,
Sec. 2.
T. 28 N., R. 17 W.,
Sec. 2, 16, 36.
T. 13 N., R. 18 W.,
Sec. 16.
T. 1 S., R. 7 W.,
Sec. 16.
T. 1 S., R. 8 W.,
Sec. 36.
T. 1 S., R. 9 W.,
Sec. 32, 36.
T. 1 S., R. 10 W.,
Sec. 2, 16, 32, 36.
Comprising 40,202.32 Acres.

The purpose of this exchange is to unite State and Federal split estates, thereby eliminating surface management difficulties and providing for the consolidation of surface and mineral ownership.

The above described mineral estates are not encumbered by mining claim locations. They are, however, encumbered by several oil and gas leases.

Based on leasable and locatable mineral potential reports, it has been determined that the overall potential mineral value of the State and Federal mineral estates are approximately equal.

Mineral estates to be transferred from the United States to the State of Arizona will be subject to the following terms and conditions:

1. Oil and gas leases A-16954 and A-14546 and the right of the mineral lessee to occupy and use as much of the surface of the land as may be reasonably necessary for mineral leasing operations, in accordance with the Acts of February 25, 1920 and March 4, 1933 (30 U.S.C. 186, 124). The United States will continue to administer these leases until their expiration or cessation of operations, at which time the leasing function will transfer to the State of Arizona.

2. Subject to all valid existing rights and those applications on record as of the date of this notice.

Minerals to be acquired by the United States from the State of Arizona will be subjcet to the following terms and conditions:

1. Oil and gas leases 13-42340, 13-87339, 13-87342, 13-87340, 13-87209, and 13-87208 with the right to explore for and remove such deposits. The State of Arizona will continue to administer these leases until their expiration or cessation of operations, at which time the leasing function will transfer to the United States.

Publication of this notice shall segregate the federal minerals, as described in this notice, from appropriation under the mining laws with the exception of the mineral leasing laws. This segregative effect shall terminate upon the issuance of a patent or two years from the date of this notice, or upon publication of a Notice of Termination.

Detailed information concerning the exchange, including the environmental assessment, the locatable mineral potential, and the leasable mineral potential reports, can be obtained from the Phoenix Resource Area Manager, 2015 West Deer Valley Road, Phoenix, Arizona 85027. For a period of forty-five (45) days, from the date of this notice, interested parties may submit comments to the Phoenix District Manager, 2015 West Deer Valley Road, Phoenix, Arizona 85027. Any adverse comments will be evaluated by the State Director, who may sustain, vacate or modify this realty action. In the absence of any objections this realty action shall become the final determination of the Department of the Interior.

Dated: June 19, 1986.

Marlyn V. Jones,

District Manager.

[FR Doc. 86-14503 Filed 6-25-86; 8:45 am]

BILLING CODE 4310-32-M

Fish and Wildlife Service

Receipt of Applications for Permits

The following applicants have applied for permits to conduct certain activities with endangered species. This notice is provided pursuant to section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531, *et seq.*):

Applicant: San Diego Zoo, San Diego, CA, PRT 707793.

The applicant requests a permit to import three pairs of captive-born McNeill's deer (*Cervus elaphas macneilii*) from the Chengdu Zoo, Chendgu, People's Repuhlic of China for the purpose of enhancement of propagation.

Applicant: Toledo Zoological Gardens; Toledo, OH, PRT 707799.

The applicant requests a permit to import four female Cuban crocodiles (*Crocodylus rhombifer*) from the Skansen-Akvariet, Stockholm, Sweden for the purpose of enhancement of propagation.

Applicant: San Diego Zoo, San Diego, CA, PRT 707791.

The applicant requests a permit to import two female captive-born Sumatran tigers (*Panthera tigris sumatrae*) from the Taronga Zoo, Mosman, Australia for the purpose of enhancement of propagation.

Applicant: I&K Productions, Inc., Washington, DC, PRT 708550.

The applicant requests a permit to export and reimport one male and four female Asian elephants (*Elephas maximus*) for the purpose of enhancement of propagation.

Applicant: Jay D. Yeager, Sandy, OR, PRT 708405.

The applicant requests a permit to purchase one male and two female captive-hatched masked bobwhite (*Colinus viginianus ridgewayi*) from the NN Quail Farm, Lawrenceburg, IN, for the purpose of enhancement of propagation.

Documents and other information submitted with these applications are available to the public during normal business hours (7:45 am to 4:15 pm) Room 611, 1000 North Glebe Road, Arlington, Virginia 22201, or by writing to the Director, U.S. Fish and Wildlife Service of the above address.

Interested persons may comment on any of these applications within 30 days of the date of this publication by submitting written views, arguments, or data to the Director at the above address. Please refer to the appropriate PRT number when submitting comments.

Dated: June 19, 1986.

R.K. Robinson,

Acting Chief, Federal Wildlife Permit Office.

[FR Doc. 86-14497 Filed 6-25-86; 8:45 am]

BILLING CODE 4310-55-M

Receipt of Applications for Permits

The public is invited to comment on the following applications for permits to conduct certain activities with marine mammals. The applications were submitted to satisfy requirements of the Marine Mammal Protection Act of 1972, *as amended* (16 U.S.C. 1361 *et seq.*, and

the regulations governing marine mammals (50 CFR Part 18).

Applicant: Name: Shimoda Aquarium, 3-22.31, Shimoda City, Shizuoka Pref., Japan, File no. PRT 708646.

Type of Permit: Public Display.

Name and Number of Animals: Alaskan sea otter *(Enhydra lutris); -4-.*

Summary of Activity to be Authorized: The applicant proposes to Take (capture) these animals and export them to Shimoda Floating Aquarium for public display.

Source of Marine Mammals for Public Display: Prince William Sound, Green Island, Alaska, or as designated by Alaska Dept. of Fish and Game.

Period of Activity: Sept. 1, 1986 to Dec. 31, 1986.

Applicant: Name: Kamogawa Sea World, 1464-18, Higashico, Kamogawa City, Chiba Pref. 296, Japan, File no. PRT 708661.

Type of Permit: Public Display.

Name and Number of Animals: Alaskan sea otter *(Enhydra lutris); -4-.*

Summary of Activity to be Authorized: The applicant proposes to Take (capture) these animals and export them to Kamogawa Sea World for public display.

Source of Marine Mammals for Public Display: Prince William Sound, Green Island, Alaska, or as designated by Alaska Dept. of Fish and Game.

Period of Activity: Sept. 1, 1986 to Dec. 31, 1986.

Applicant: Name: Nagasaki Biopark, 2291-1, Naka yama, Seihi-cho, Nishisonogi, Nagasaki Pref. 851.33, Japan, File no. 708664.

Type of Permit: Public Display.

Name and Number of Animals: Alaskan sea otter *(Enhydra lutris); -4-.*

Summary of Activity to be Authorized: The applicant proposes to Take (capture) these animals and export them to Nagasaki Biopark for public display.

Source of Marine Mammals for Public Display: Prince William Sound, Green Island, Alaska, or as designated by Alaska Dept. of Fish and Game.

Period of Activity: Sept. 1, 1986 to Dec. 31, 1986.

Applicant: Name: Kanazawa Aquarium, 450 Higashi Mikage-cho, Kanazawa, Ishikawa Pref. 920, Japan, PRT 708659.

Type of Permit: Public Display.

Name and Number of Animals: Alaskan sea otter *(Enhydra lutris); -4-.*

Summary of Activity to be Authorized: The applicant proposes to Take (capture) these animals and export them Kanazawa Aquarium for public display.

Source of Marine Mammals for Public Display: Prince William Sound, Green Island, Alaska, or as designated by Alaska Dept. of Fish and Game.

Period of Activity: Sept. 1, 1986 to Dec. 31, 1986.

Applicant: Name: Okhotsk Aquarium Foundation, No. 1, Futatsuiwa, Azana, Abashiri, Hokkaido Pref. Japan, File no. PRT 708653.

Type of Permit: Public Display.

Name and Number of Animals: Alaskan sea otter *(Enhydra lutris); -4-.*

Summary of Activity to be Authorized: The applicant proposes to Take (capture) these animals and export them to Okhotsk Aquarium Foundation for public display.

Source of Marine Mammals for Public Display: Prince William Sound, Green Island, Alaska, or as designated by Alaska Dept. of Fish and Game.

Period of Activity: Sept. 1, 1986 to Dec. 31, 1986.

Concurrent with the publication of this notice in the **Federal Register**, the Federal Wildlife Permit Office is forwarding copies of these applications to the Marine Mammal Commission and the Committee of Scientific Advisors for their review.

Written data or comments, requests for copies of the complete applications should be submitted to the Director, U.S. Fish and Wildlife Service (FWPO), 1000 North Glebe Road, Room 611, Arlington, Virginia 22201, within 30 days of the publication of this notice. Anyone requesting a hearing should give specific reasons why a hearing would be appropriate. The holding of such hearing is at the discretion of the Director.

Documents submitted in connection with the above applications are available for review during normal business hours (7:45 am to 4:15 pm) in Room 601 N. Glebe Road, Arlington, Virginia.

Dated: June 19, 1986.

R.K. Robinson,

Acting Chief, Federal Wildlife Permit Office.

[FR Doc. 86-14496 Filed 6-25-86; 8:45 am]

BILLING CODE 4310-55-M

Receipt of Application for Permit

The public is invited to comment on the following application for pemit to conduct certain activities with marine mammals. The application was submitted to satisfy requirements of the Marine Mammal Protection Act of 1972, *as amended* (16 U.S.C. 1361 *et seq.*) and the regulations governing marine mammals (50 CFR Part 18).

Applicant Name: Minamichita Beachland Aquarium, Okuda, Mihama, Chita, Aichi Pref. 470-32, Japan, File no. PRT-708641.

Type of Permit: Public Display.

Name and Number of Animals: Alaskan sea otter *(Enhydra lutris)*; 4.

Summary of Activity to be Authorized: The applicant proposes to capture these animals and export them to Minamichita Beachland Aquarium for public display.

Source of Marine Mammals for Public Display: Prince William Sound, Green Island, Alaska, or as designated by Alaska Department of Fish & Game.

Period of Activity: Sept. 1, 1986, to December 31, 1986.

Concurrent with the publication of this notice in the **Federal Register**, the Federal Wildlife Permit Office is forwarding copies of this application to the Marine Mammal Commission and the Committee of Scientific Advisors for their review.

Written data or comments, requests for copies of the complete application, or requests for a public hearing on this application should be submitted to the Director, U.S. Fish and Wildlife Service (FWPO), 1000 North Glebe Road, Room 611, Arlington, Virginia 22201, within 30 days of the publication of this notice. Anyone requesting a hearing should give specific reasons why a hearing would be appropriate. The holding of such hearing is at the discretion of the Director.

Documents submitted in connections with the above application are available for review during normal business hours (7:45 am to 4:15 pm) in Room 601 N. Glebe Road, Arlington, Virginia.

Dated: June 19, 1986.

R.K. Robinson,

Acting Chief, Federal Wildlife Permit Office.

[FR Doc. 86-14498 Filed 6-25-86; 8:45 am]

BILLING CODE 4310-55-M

Minerals Management Service

Development Operations Coordination Document; Amoco Production Co.

AGENCY: Minerals Management Service, Interior.

ACTION: Notice of the receipt of a proposed development operations coordination document (DOCD).

SUMMARY: Notice is hereby given that Amoco Production Company has submitted a DOCD describing the activities it proposes to conduct on Lease OCS-G 1248, Block 161, South Timbalier Area, offshore Louisiana. Proposed plans for the above area provide for the development and production of hydrocarbons with support activities to be conducted from an onshore base located at Fourchon, Louisiana.

DATE: The subject DOCD was deemed submitted on June 19, 1986.

ADDRESSES: A copy of the subject DOCD is available for public review at the Office of the Regional Director, Gulf of Mexico OCS Region, Minerals Management Service, 3301 North Causeway Blvd., Room 147, Metairie, Louisiana (Office Hours: 9 a.m. to 3:30 p.m., Monday through Friday).

FOR FURTHER INFORMATION CONTACT: Michael J. Tolbert; Minerals Management Service; Gulf of Mexico OCS Region; Rules and Production; Plans, Platform and Pipeline Section; Exploration/Development Plans Unit; Phone (504) 838-0875.

SUPPLEMENTARY INFORMATION: The purpose of this Notice is to inform the public, pursuant to sec. 25 of the OCS Lands Act Amendments of 1978, that the Minerals Management Service is considering approval of the DOCD and that it is available for public review.

Revised rules governing practices and procedures under which the Minerals Management Service makes information contained in DOCDs available to affected States, executives of affected States, local governments, and other interested parties became effective December 13, 1979, (44 FR 53685). Those practices and procedures are set out in revised § 250.34 of Title 30 of the CFR.

Dated : June 19, 1986.

J. Rogers Pearcy,

Regional Director, Gulf of Mexico, OCS Region.

[FR Doc. 86-14420 Filed 6-25-86; 8:45 am]

BILLING CODE 4310-MR-M

Development Operations Coordination Document; Huffco Petroleum Corp.

AGENCY: Minerals Management Service, Interior.

ACTION: Notice of the receipt of a proposed development operations coordination document (DOCD).

SUMMARY: Notice is hereby given that Huffco Petroleum Corporation has submitted a DOCD describing the activities it proposes to conduct on Lease OCS-G 2319, Block 342, Eugene Island Area, offshore Louisiana. Proposed plans for the above area provide for the development and production of hydrocarbons with support activities to be conducted from an onshore base located at Kaplan, Louisiana.

DATE: The subject DOCD was deemed submitted on June 18, 1986.

ADDRESSES: A copy of the subject DOCD is available for public review at the Office of the Regional Director, Gulf of Mexico OCS Region, Minerals Management Service, 3301 North Causeway Blvd., Room 147, Metairie, Louisiana (Office Hours: 9 a.m. to 3:30 p.m., Monday through Friday).

FOR FURTHER INFORMATION CONTACT: Michael J. Tolbert; Minerals Management Service, Gulf of Mexico OCS Region, Rules and Production, Plans, Platform and Pipeline Section, Exploration/Development Plans Unit; Phone (504) 838-0875.

SUPPLEMENTARY INFORMATION: The purpose of this Notice is to inform the public, pursuant to sec. 25 of the OCS Lands Act Amendments of 1978, that the Minerals Management Service is considering approval of the DOCD and that it is available for public review.

Revised rules governing practices and procedures under which the Minerals Management Service makes information contained in DOCDs available to affected States, executives of affected States, local governments, and other interested parties became effective December 13, 1979 (44 FR 53685). Those practices and procedures are set out in revised § 250.34 of Title 30 of the CFR.

Dated: June 19, 1986.

J. Rogers Pearcy,

Regional Director, Gulf of Mexico OCS Region.

[FR Doc. 86-14421 Filed 6-25-86; 8:45 am]

BILLING CODE 4310-MR-M

Development Operations Coordination Document; Tenneco Oil Exploration and Production

AGENCY: Minerals Management Service, Interior.

ACTION: Notice of the receipt of a proposed development operations coordination document (DOCD).

SUMMARY: Notice is hereby given that Tenneco Oil Exploration and Production has submitted a DOCD describing the activities it proposes to conduct on Lease OCS-G 4231, Block 181, Ship Shoal Area, offshore Louisiana. Proposed plans for the above area provide for the development and production of hydrocarbons with support activities to be conducted from an onshore base located at Intracoastal City, Louisiana.

DATE: The subject DOCD was deemed submitted on June 19, 1986.

ADDRESSES: A copy of the subject DOCD is available for public review at the Office of the Regional Director, Gulf of Mexico OCS Region, Minerals Management Service, 3301 North Causeway Blvd., Room 147, Metairie, Louisiana (Office Hours: 9 a.m. to 3:30 p.m., Monday through Friday).

FOR FURTHER INFORMATION CONTACT: Michael J. Tolbert; Minerals Management Service; Gulf of Mexico OCS Region; Rules and Production; Plans, Platform and Pipeline Section; Exploration/Development Plans Unit; Phone (504) 838-0875.

SUPPLEMENTARY INFORMATION: The purpose of this Notice is to inform the public, pursuant to sec. 25 of the OCS Lands Act Amendments of 1978, that the Minerals Management Service is considering approval of the DOCD and that it is available for public review.

Revised rules governing practices and procedures under which the Minerals Management Service makes information contained in DOCDs available to affected States, executives of affected States, local governments, and other interested parties became effective December 13, 1979 (44 FR 53685). Those practices and procedures are set out in revised § 250.34 of Title 30 of the CFR.

Dated: June 19, 1986.

J. Rogers Pearcy,

Regional Director, Gulf of Mexico OCS Region.

[FR Doc. 86-14422 Filed 6-25-86; 8:45 am]

BILLING CODE 4310-MR-M

Oil and Gas and Sulphur Operations in the Outer Continental Shelf; Conoco Inc.

AGENCY: Minerals Management Service, Interior.

ACTION: Notice of the receipt of a proposed development operations coordination document.

SUMMARY: This Notice announces that Conoco Inc., Unit Operator of the Grand Isle/CATCO Federal Unit Agreement No. 14-08-001-2021, submitted on June 13, 1986, a proposed Development Operations Coordination Document describing the activities it proposes to conduct on the Grand Isle/CATCO Federal unit.

The purpose of this Notice is to inform the public, pursuant to Section 25 of the OCS Lands Act Amendments of 1978, that the Minerals Management Service is considering approval of the plan and that it is available for public review at the offices of the Regional Director, Gulf of Mexico OCS Region, Minerals Management Service, 3301 N. Causeway Blvd., Room 147, Metairie, Louisiana 70002.

FOR FURTHER INFORMATION CONTACT: Minerals Management Service, Records Management Section, Room 143, open weekdays 9:00 a.m. to 3:30 p.m., 3301 N.

Causeway Blvd., Metairie, Louisiana 70002, phone (504) 838-0519.

SUPPLEMENTARY INFORMATION: Revised rules governing practices and procedures under which the Minerals Management Service makes information contained in the proposed development operations coordination document available to affected States, executives of affected local governments, and other interested parties became effective on December 13, 1979 (44 FR 53685). Those practices and procedures are set out in a revised § 250.34 of Title 30 of the Code of Federal Regulations.

Dated: June 19, 1986.

J. Rogers Pearcy,

Regional Director, Gulf of Mexico OCS Region.

[FR Doc. 86-14504 Filed 6-25-86; 8:45 am]

BILLING CODE 4310-MR-M

Outer Contentinal Shelf (OCS) Advisory Board, Scientific Committee; Notice and Agenda of Meeting

This notice is issued in accordance with the provisions of the Federal Advisory Committee Act, Pub. L. 92-463, 5 U.S.C., Appendix I, and the Office of Management and Budget Circular A-63, Revised.

The Scientific Committee of the OCS Advisory Board will meet July 21-23, 1986, at the Fort Mason Center Firehouse, Laguna and Marina Boulevards, San Francisco, California 94123.

The Social and Economics Effects Subcommittee, the Environmental Effects Subcommittee, and the Study Design and Information Transfer Subcommittee will meet from 1 p.m. to 5 p.m. on July 21. The Scientific Committee will meet in plenary session from 8 a.m. to 5 p.m. on July 22, and from 8 a.m. to 12:30 p.m. on July 23.

The agenda for the meeting will include the following subjects:

- Update on the Regional and Washington Office Environmental Studies Programs
- Discussion of the Fisheries Program
- Status of the National Academy of Science Review of the Environmental Studies Program
- Status of the 5-Year Management Plan for the Environmental Studies Program
- Discussion with Representatives of Pacific States
- Report on the Environmental Studies Program Marine Mammal Program
- Report on the Environmental Studies Program Endangered Species Program
- Discussion with Representative of the California Coastal Commission
- Discussion of Offshore Nonenergy Minerals.

This meeting is open to the public. Approximately 30 visitors can be accommodated on a first-come/first-served basis. All inquiries concerning this meeting should be addressed to:

Dr. Don V. Aurand, Chief, Branch of Environmental Studies, Offshore Environmental Assessment Division (644), Minerals Management Service, U.S. Department of the Interior, 18th & C Streets, NW., Washington, DC 20240; telephone (202) 343-7744.

Dated: June 19, 1986.

John B. Rigg,

Associate Director for Offshore Minerals Management.

[FR Doc. 86-14505 Filed 6-25-86; 8:45 am]

BILLING CODE 4310-MR-M

INTERSTATE COMMERCE COMMISSION

[Finance Docket No. 30845]

AT&L Railroad Co.—Ememption—Operation—the State of Oklahoma

AT&L Railroad Company has filed a notice of exemption to operate a line of railroad between milepost 534.9, at Geary, OK, and milepost 544.5, near Bridgeport, OK, a distance of approximately 9.6 miles, in Blaine and Caddo Counties, OK, pursuant to rights granted by the State of Oklahoma. Comments must be filed with the Commission and served on: T. J. Mendenhall, P.O. Box 29, Watonga, OK, Phone: (405) 623-7223.

The notice is filed under 49 CFR 1150.31. If the notice contains false or misleading information the exemption is void *ab initio*. Petitions to revoke the exemption under 49 U.S.C. 10505(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the transaction.

Dated: June 5, 1986.

By the Commission, Jane F. Mackall, Director, Office of Proceedings.

Noreta R. McGee,

Acting Secretary.

[FR Doc. 86-14450 Filed 6-25-86; 8:45 am]

BILLING CODE 7035-01-M

[Finance Docket No. 30840]

Marinette, Tomhawk and Western Railroad Co.—Trackage Rights—Soo Line Railroad Co., Notice of Exemption

Soo Line Railroad Company has agreed to grant overhead trackage rights to Marinette, Tomahawk and Western Railroad Company between Wausau (milepost 91.1) and Tomahawk, WI (milepost 132.8), a distance of approximately 43.26 miles. The trackage rights became effective June 15, 1986.

This notice is filed under 49 CFR 1180.2(d)(7). Petitions to revoke the exemption under 49 U.S.C. 10505(d) may be filed at any time. The filing of a petition to revoke will not stay the transaction.

As a condition to use of this exemption, any employees affected by the trackage rights will be protected pursuant to *Norfolk and Western Ry. Co.—Trackage Rights—BN*, 354 I.C.C. 605 (1978), as modified in *Mendocino Coast Ry. Inc.—Lease and Operate*, 360 I.C.C. 653 (1980).

Dated: June 16, 1986.

By the Commission, Louis E. Gitomer, Acting Director, Office of Proceedings.

Noreta R. McGee,

Secretary.

[FR Doc. 86-14452 Filed 6-25-86; 8:45 am]

BILLING CODE 7035-01-M

[Finance Docket No. 30839]

Soo Line Railroad Co.—Trackage Rights—Marinette, Tomahawk and Western Railroad Co.; Notice of Exemption

Marinette, Tomahawk and Western Railroad Company has agreed to grant overhead trackage rights to Soo Line Railroad Company between Tomahawk (milepost 132.8) and Bradley (milepost 197.6), WI, a distance of approximately 5.4 miles. The trackage rights will be effective on June 15, 1986.

This Notice is filed under 49 U.S.C. 1180.2(d)(7). Petitions to revoke the exemption under 49 U.S.C. 10505(d) may be filed at any time. The filing of a petition of revoke will not stay the transaction.

As a condition of this exemption, any employees affected by the trackage rights will be protected pursuant to *Norfolk and Western Ry. Co.—Trackage Rights—BN*, 354 I.C.C. 605 (1978), as modified in *Mendocino Coast Ry., Inc.—Lease and Operate*, 360 I.C.C. 653 (1980).

Dated: June 16, 1986.

By the Commission, Louis E. Gitomer, Acting Director, Office of Proceedings.

Noreta R. McGee,

Secretary.

[FR Doc. 86-14451 Filed 6-25-86; 8:45 am]

BILLING CODE 7035-01-M

DEPARTMENT OF JUSTICE

United States v. Superior Oil Co.; Lodging of Consent Decree Pursuant to Clean Air Act

In accordance with Departmental policy, 28 CFR 50.7, notice is hereby given that on June 3, 1986 a proposed consent decree in *United States v. Superior Oil Co.*, Civil Action No. G-85-434 was lodged with the United States District Court for the Southern District of Texas. The proposed consent decree concerns a complaint filed by the United States that alleged violations of the Clean Air Act, 42 U.S.C. 7475-7479, by Superior Oil at its Portillo plant near Sinton, Texas for Superior Oil's failure to obtain the requisite Prevention of Significant Deterioration ("PSD") permit prior to construction of a gas compressor engine. The complaint sought injunctive relief to require defendant to comply with the PSD permit requirements and civil penalties for past violations. Under the consent decree Superior Oil is required to pay a civil penalty of $255,000 in settlement of the government's civil penalty claims, and is enjoined to comply with the Clean Air Act.

The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments relating to the proposed consent decree. Comments should be addressed to the Assistant Attorney General of the Land and Natural Resources Division, Department of Justice, Washington, DC 20530, and should refer to *United States v. Superior Oil Co.*, D.J. Ref. 90-5-2-1-854.

The proposed consent decree may be examined at the office of the United States Attorney for the Southern District of Texas, 12000 Federal Building and U.S. Courthouse, 515 Rusk Avenue, Houston, Texas 77002 and at the Region VI Office of the United States Environmental Protection Agency, 1201 Elm Street, Dallas, Texas 75270. Copies of the consent decree may also be examined at the Environmental Enforcement Section, Land and Natural Resources Division of the Department of Justice, Room 1517, Ninth Street and Pennsylvania Avenue, NW., Washington, DC 20530. A copy of the proposed consent decree may be obtained from the Environmental Enforcement Section, Land and Natural Resources Division of the Department of Justice.

F. Henry Habicht II,

Assistant Attorney General, Land and Natural Resources Division.

[FR Doc. 86-14506 Filed 6-25-86; 8:45 am]

BILLING CODE 4410-01-M

MERIT SYSTEMS PROTECTION BOARD

Notice of Call for GPO Printing Riders for Two Merit Systems Protection Board Reports

AGENCY: Merit Systems Protection Board.

ACTION: Notice of call for printing riders for two reports: *Getting Involved: Improving Federal Management With Employee Participation* and *Report on the Significant Actions of the Office of Personnel Management During 1984-1985.*

SUMMARY: The purpose of this notice is to inform Federal agencies that the Merit Systems Protection Board (MSPB) is printing a very limited number of copies of the following two reports: *Getting Involved: Improving Federal Management With Employee Participation,* and *Report on the Significant Actions of the Office of Personnel Management During 1984-1985.* Departments and agencies may order copies of the reports by riding MSPB's printing requisitions with the Government Printing Office. The requisition for the report on employee participation is #6-00131. The requisition for the report on OPM's significant actions is #6-00132.

DATE: Agency requisitions (Standard Form 1) must be submitted no later than July 30, 1986.

ADDRESS: Interested departments and agencies should send requisitions—through their Washington DC headquarters offices authorized to procure printing—to the Government Printing Office, Requisitions Section, Room 836, Washington, DC 20401. Agencies may estimate the cost by using the current Government Printing Office price list of printing services and the printing information contained in the **"SUPPLEMENTARY INFORMATION"** section below.

FOR FURTHER INFORMATION CONTACT: Concerning the report on employee involvement, call John M. Palguta on 202-653-7701. Concerning the report on OPM's significant actions, call Harry C. Redd III on 202-653-8877. The address for both is: Office of Assistant Managing Director for Management, External Review and Studies Division, MSPB, 1120 Vermont Avenue, NW, Washington, DC 20419.

SUPPLEMENTARY INFORMATION: *Getting Involved: Improving Federal Management With Employee Involvement* is one of a series of reports prepared by MSPB under its statutory authority to conduct special studies of the civil service system. Reports of those studies are addressed to Congress and the President. This particular report provides consolidated information on those systems, policies, or procedures identified by major Federal departments and agencies as ones which they have in place and which allow or encourage employees to identify or help resolve agency-related problems. The report discusses Quality Circles, Suggestion Programs, Hotlines, and a number of other programs or systems which are unique to particular agencies. All of the identified programs and systems have the potential to foster constructive employee involvement. Telephone numbers for the responsible offices in each agency are provided so that the report may serve as a resource document for interested parties. This 124-page, bound report is printed in one color on 8½ x 11 inch paper. The cost per copy will depend on the volume of agency orders.

The *Report on the Significant Actions of the Office of Personnel Management During 1984-1985* is an annual report to the President and the Congress concerning the significant actions of the Office of Personnel Management. It is required by 5 U.S.C. 1209(b). The 1984-1985 issue analyzes, evaluates and makes recommendations concerning OPM's grade bulge initiative; OPM's revised approach to personnel management evaluation; and the following related issues which address the broad subject of attracting and retaining a quality work force: college recruiting, hiring for entry-level professional and administrative positions, Senior Executive Service (SEC) Candidate Development Programs, SES attrition and bonuses, Federal white-collar compensation issues, and expanded authority to make temporary limited appointments. This 178-page, bound report is printed in one color on 8½ x 11 inch paper. The cost per copy will depend on the volume of agency orders.

Dated: June 19, 1986.

Robert E. Taylor,

Clerk of the Board.

[FR Doc. 86-14362 Filed 6-25-86; 8:45 am]

BILLING CODE 7400-01-M

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

Records Schedules; Request for Comments

AGENCY: National Archives and Records Administration, Office of Records Administration.

ACTION: Notice of availability of proposed records schedules; request for comments.

SUMMARY: The National Archives and Records Administration (NARA) publishes a notice at least monthly of all agency requests for records disposition authority (records schedules) which includes records being proposed for disposal or which reduce the records retention period for records already authorized for disposal. The first notice was published on April 1, 1985. Records schedules identify records of continuing value for eventual preservation in the National Archives of the United States and authorize agencies to dispose of records of temporary value. NARA invites public comment on proposed records disposals as required by 44 U.S.C. 3303a(a).

DATE: Comments must be received in writing on or before August 25, 1986.

ADDRESS: Address comments and requests for single copies of schedules identified in this notice to the Records Appraisal and Disposition Division (NIR), National Archives and Records Administration, Washington, DC 20408. Requestors must cite the control number assigned to each schedule when requesting a copy. The control number appears in parenthesis immediately after the title of the requesting agency.

SUPPLEMENTARY INFORMATION: Each year U.S. government agencies create billions of records in the form of paper, film, magnetic tape, and other media. In order to control the accumulation of records, Federal agencies prepare records schedules which specify when the agency no longer needs them for current business and what happens to the records after the expiration of this period. Destruction of the records requires the approval of the Archivist of the United States, which is based on a thorough study of their potential value for future use. A few schedules are comprehensive; they list all the records of an agency or one of its major subdivisions. Most schedules cover only one office, or one program, or a few series of records, and many are updates of previously approved schedules.

This public notice identifies the Federal agencies and their appropriate subdivisions requesting disposition authority, includes a control number assigned to each schedule, and briefly identifies the records scheduled for disposal. The complete records schedule contains additional information about the records and their disposition. Additional information about the disposition process will be furnished with each copy of a records schedule requested.

Schedules Pending Approval

1. Department of the Army, (N1-AU-86-51). Firefighter training records.
2. Department of the Army, (NC1-AU-85-27). Raw data pertaining to potential civil works projects and headquarters duplicates of Survey Reports and other Corps of Engineers records maintained permanently by Corps field offices.
3. Department of the Army (NC1-AU-85-78). Manpower requirements criteria development files from offices without Army-wide responsibilities.
4. Department of Agriculture, Agriculture Marketing Service, Dairy Division (NC1-136-85-1). Comprehensive schedule covering the grading, inspection, and standardization activities of the division.
5. Department of Commerce, International Trade Administration, Office of World Fairs and International Exhibitions (NC1-151-85-3). Comprehensive schedule covering records relating to the Federal recognition of and participation in international expositions held in the United States.
6. Environmental Protection Agency, Grants Administration Division (NC1-412-85-25). Comprehensive schedule covering records relating to the processing and administration of the agency's grants programs.
7. United States Information Agency, Board of Foreign Scholarships (N1-306-86-2). Routine administrative correspondence, reference copies of reports, treaties, and Commission meetings, and personnel files for non-U.S. applicants for positions on Binational Commissions.
8. Department of Justice, Immigration and Naturalization Service, (N1-85-86-1). Counterfeit and fraudulently obtained reentry permits and related correspondence (1925-48).
9. National Archives and Records Administration (N1-GRS-86-2). Minor change in government-wide disposition standard for routine contracts and related bids and proposals to conform with the Federal Acquisition Regulations (48 CFR).
10. Department of State, Bureau of European Affairs, Office of Regional Pol-Econ Affairs (N1-59-86-5). Copies of documents received by the Department of State from the Organization for Economic Cooperation and Development and routed through the executive branch of the government by the OECD Registry.
11. Department of Transportation, Board of Correction of Military Records (N1-398-86-2). Records relating to the correction of Coast Guard military records.
12. Department of Treasury, Office of the Secretary, Office of the National Advisory Council (N1-56-86-1). Studies and reports from various international financial institutions concerning such matters as loan standing of a country or development under a particular loan.
13. Department of the Treasury, Internal Revenue Service, Office of Examination Planning and Research (N1-58-86-2). Files created in the course of conducting the following four projects: (1) Child and Dependent Care Project; (2) Office Examination Audit Quality Study; (3) Reverse Information Returns Processing Study; (4) HUD Walkaway project.

Dated: June 20, 1986.

Frank G. Burke,

Acting Archivist of the United States.

[FR Doc. 86-14462 Filed 6-25-86; 8:45 am]

BILLING CODE 7515-01-M

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

Media Arts Advisory Panel (Children's TV Series Section);

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 (Children's TV Series Secton) to the National Council on the Acts will be held on July 15, 1986, from 10:00 a.m. — 5:30 p.m. in room M-14 of the Nancy Hanks Center, 1100 Pennsylvania Avenue, NW. Washington, DC 20506.

This meeting is for the purpose of the 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 grant applicants. In accordance with the determination of the Chairman published in the Federal Register of February 13, 1980, these sessions will be closed to the public pursuant to subsection (c) (4), (6) (B) of section 552b of Title 5, United States Code.

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, DC 20506, or call (202) 682-5433.

Dated: June 20, 1986.

John H. Clark,

Director, Council and Panel Operations, National Endowment for the Arts.

[FR Doc. 86-14423 Filed 6-25-86; 8:45 am]

BILLING CODE 7537-01-M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-23345; File No. SR-CBOE-86-16]

Self-Regulatory Organizations; Proposed Rule Change by Chicago Board Options Exchange, Inc., Relating to Exchange Charges in Connection With Currency Options

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934, 15 U.S.C. 78s(b)(1), notice is hereby given that on June 9, 1986 the Chicago Board Options Exchange, Incorporated filed with the Securities and Exchange Commission the proposed rule change as described in Items I, II and III below, which items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

From Monday, September 1, 1986, through Monday, August 31, 1987, the Exchange will not charge any currency options transaction fees or currency options floor charges; the Exchange reserves the right to begin charging currency options transaction fees for public customers and firm proprietary orders before August 31, 1987. In addition, the Exchange will not collect any dues from currency options rights or permit holders and will not collect due in connection with currency options memberships until September 1, 1988.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments its received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below and is set forth in sections (A), (B), and (C) below.

(A) Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

The purpose of this proposed rule change is to encourage the trading of foreign currency option contracts as part of a currency options permit and incentive program, which is described in a separate filing (SR-CBOE-86-13). The statutory basis for this proposed rule change is section 6(b)(5) of the Securities Exchange Act of 1934 (the Act), in that it is designed to facilitate transactions in foreign currency options.

(B) Self-Regulatory Organization's Statement on Burden on Competition

The proposed rule change will not impose a burden on competition.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve such proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submission should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying at the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC. Copies of such filing will also be available for inspection and copying at the principal office of the above-mentioned self-regulatory organization. All submissions should refer to the file number in the caption above and should be submitted by July 17, 1986.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Dated: June 19, 1986.

Shirley E. Hollis,

Acting Secretary.

[FR Doc. 86-14436 Filed 6-25-86; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 34-23331; File No. SR-CBOE-85-16 Amt. No. 4]

Self-Regulatory Organizations; Proposed Rule Change by the Chicago Board Options Exchange, Inc.; Relating to Retail Automatic Execution System ("RAES") in Equity Options

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934, 15 U.S.C. 78s(b)(1), notice is hereby given that on June 5, 1986, the Chicago Board Options Exchange, Incorporated filed with the Securities and Exchange Commission the proposed rule change as described in Items I, II and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule changed interested persons.

I. Text of the Proposed Rule Change

The proposed rules change would establish a six-month pilot program for operation of the Exchange's Retail Automatic Execution System ("RAES) in equity options with limited exceptions to the Exchange's current book priority rule. Those exceptions would be in the IBM options class and in any options class where unusual market conditions impair the ability to integrate manually RAES with the public customer order book.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below and is set forth in sections (A), (B), and (C) below.

(A) Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

The statement of purpose and statutory basis of this proposed rule change were set forth in the original filing.[1] To the extent this amendment number 4 modifies the proposed rule change, the same purposes and basis apply.

This amendment modifies the Exchange's proposed six month pilot of RAES in equity options to allow for manual integration of the limit order book in all pilot options except IBM.[2] The CBOE presently intends manual integration to operate as follows: The RAES trade acknowledgement tickets ("TAT") will print behind the order book. The Order Book Official ("OBO") or his staff will compare the TAT to the book. If there are orders on the book in that series at the price of the RAES trade, the OBO will cause the market-maker who was contra-broker on the RAES trade to execute a trade with such booked order or orders, up to the number of contracts on the RAES trade. For example, the market in the AB series is 2 bid-2¼ offer. A market order to buy five contracts in AB is sent by a firm on RAES. The trade is immediately executed at 2¼ for five contracts, with the next market-maker in the RAES rotation shown as contra-broker. This execution is immediately reported to the customer's firm and also printed behind the book on a TAT. The OBO reads the ticket and compares it to the book. If the book's best offer is higer than 2¼, the TAT is given to the assigned market-maker and the transaction is concluded. If the best offer on the book is 2¼, the assigned market-maker is given his RAES TAT, and also is informed of the number of contracts he has bought from the book at 2¼ (up to the number of contracts in the RAES trade).

Options on IBM are the most active of any equity option. Average daily volume in March and April 1986, for example, was in excess of 50,000 contracts, which meets or exceeds the aggregate options contract volume of several options exchanges. Operationally, given the manual handling of booked orders, and the various steps necessary to integrate the book with RAES, there is an activity level at which RAES would materially interfere with normal book operations. Activity in IBM clearly exceeds that level.

The amendment also provides for the Exchange to suspend book priority in other pilot options classes in unusual market conditions. Although not expected to be used, such a suspension would be called for if the activity level in an option class materially interfered with the ability of Exchange personnel to handle the manual tasks necessary to integrate the book with RAES, such as assigning trades and book bids and offers with RAES trade prices. The concurrence of the Exchange president and vice-chairman, or their respective designees, is required to suspend or reinstate book interaction with RAES.

(B) Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that this proposed rule change will impose any burden on competition.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange believes that the Commission's file reflects the comments on the proposed rule change.[3]

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve such proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submission should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying at the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC. Copies of such filing will also be available for inspection and copying at the principal office of the above-mentioned self-regulatory organization. All submissions should refer to the file number in the caption above and should be submitted by July 17, 1986.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.

Dated: June 17, 1986.

Shirley E. Hollis,

Acting Secretary.

[FR Doc. 86-14437 Filed 6-25-86; 8:45 am]

BILLING CODE 8010-01-M

[1] *See* Securities Exchange Act Release Nos. 22050 (May 20, 1985), 50 FR 21531 and 22270 (July 26, 1985), 50 FR 31449.

[2] The Exchange currently intends to pilot RAES in five equity options in addition to IBM.

[3] To date, the Commission has received five comment letters from retail firms concerning the CBOE proposal to pilot RAES in equity options. These letters are on file in the Commission's Public Reference Room.

[Release No. 34-23342; File No. SR-DTC-86-5]

Self-Regulatory Organizations; Filing and Immediate Effectiveness of Proposed Rule Change of Depository Trust Company

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934, 15 U.S.C. 78s(b)(1), notice is hereby given that on May 2, 1986, the Depository Trust Company ("DTC") filed with the Securities and Exchange Commission the proposed rule change described below. The Commission is publishing this notice to solicit comments on the proposed rule change.

I. Introduction

The proposed rule change modifies DTC's Institutional Delivery ("ID") System to identify "when-issued" trades on ID confirmations and to provide for the automated book-entry settlement of "regular-way" syndicate trades in depository-eligible issues.[1] DTC issued Important Notices to its participants on September 7, 1983, January 10, 1985, and February 3, 1986; each Notice describing successive versions of the proposal. DTC received four participant comments, all in response to DTC's September 1983, Notice.[2] Those commenters supported the modifications.[3] In addition, DTC

[1] DTC stated in a recent notice to participants that it is modifying its ID System to process "when-issued" trades in the same manner broker-dealers process these trades internally. For a detailed description of ID system operations, *see* DTC's Participant Operating Procedures, Section M.

[2] The four commenters were Goldman Sachs; Alex Brown & Sons; Piper, Jaffray and Hopwood ("Piper"); and the Morgan Bank.

[3] Three of the commenters did not specifically address the proposal but stated their general approval of the proposed modifications. One commenter, Piper, expressed some concern about whether the new system might reduce participants' ID affirmation rates. Piper noted that the proposal would enable brokers to confirm but would not allow customers to affirm "when-issued" trades. DTC will solve this problem by separately tracking ID affirmations of "when-issued" trades in its monthly ID Qualify Control Report.

convened a special user panel to review and make recommendations of DTC's initial version of the proposal.[4] All the panel's comments were incorporated in later versions of the proposal.

A. Description of Current Underwriting Distribution Procedures

Since 1975, DTC has provided a service to its participants for handling the distribution of new securities issues or secondary offerings of outstanding securities. First, the managing underwriter must apply to DTC to make the issue eligible. Once DTC has made it eligible, DTC instructs the issuer to issue in DTC's nominee name, Cede & Co., the number of certificates and certificate denominations that DTC believes will be needed at closing. The managing underwriter prepares and delivers to DTC a hardcopy "Miscellaneous Deliver Order" ("MDO") that instructs DTC to effect on closing the book-entry transfer of securities from its account to the accounts of other participating underwriters and members of the selling group.[5] The other underwriters and members of the selling group submit additional book-entry delivery instructions reflecting "downstream" transactions. All of these instructions are submitted to DTC the evening before closing date (*i.e.*, settlement date).

After the managing underwriter notifies DTC that closing has occurred,[6] DTC credits the account of the managing underwriter for the securities being distributed by book-entry, processes the managing underwriter's previously filed instructions and credits the accounts of other underwriters and selling group members to reflect positions they have "taken down." DTC then processes the delivery instructions from selling group members by effecting book-entry transfers to institutional customers or their agent banks. Last, in the afternoon of closing day, DTC folds into its single daily net dollar settlement figure for each participant the net dollar pay or receive figure generated by this activity.

B. Current ID Processing of New Issues

Currently, when a broker-dealer submits "when-issued" trade data to DTC's ID System, DTC generates an "ineligible confirmation."[7] If the broker's institutional customer (or its agent bank) subsequently affirms the trade, the ID System produces deliver and receive instructions for the settling participants. If the issue is expected to become DTC-eligible in time for settlement, each participant can use these instructions to prepare MDOs that can be delivered to, and processed by, DTC on closing date.[8] Participants, however, cannot choose to let these trades settle through DTC's PDQ service.[9] Alternatively, participants can arrange for physical certificate delivery according to the deliver and receive instructions if the underwriting is settling outside of DTC.[10]

II. Description of the Proposal

A. "When-Issued" Trade Input and Output

To identify properly a "when-issued" trade and to trigger DTC's underwriting processing procedures, the broker-dealer participant must use one of a number of new "when-issued" codes as part of its ID system input.[11] A properly-identified "when-issued" trade will be reported to appropriate participants as a " 'NEW ISSUE' ineligible ID confirmation." DTC processing ends at this point. "When-issued" trades will not be posted to regular ID history files and the trade will not be affirmed and settled during the regular cycle.

B. "Regular-Way" Processing of Syndicate Trades with Institutional Investors [12]

Once the closing date for a new issue is set, syndicate group members must resubmit trade data with respect to each trade previously confirmed as a "Syndicate Trade—To Be Issued." [13] The resubmission must include all information necessary for affirmation and settlement.[14] DTC then generates a new "Syndicate Trade—New Issue" confirmation. If the trade is affirmed,[15] DTC will determine whether the security has been made eligible for automated book-entry settlement at DTC.[16] If DTC already has made the issue eligible, DTC will report the trade to the appropriate parties on the Eligible Trade Report. If an issue remains ineligible at the time of affirmation, DTC will include the information on the participants' Ineligible Trade Report for that day. (These trades will have to be settled

[4] The panel was comprised of representatives of broker-dealers, banks and investment managers.

[5] While the managing under writer must provide DTC a MDO in hardcopy form, delivery instructions of other underwriters and the selling group usually are submitted in automated form through DTC's Participant Terminal System ("PTS"), Computer-to-Computer Facility ("CCF") or Automated Participant Interface ("API").

[6] For DTC to process the underwriting, the closing must occur by 1:30 p.m. on the closing date.

[7] "When-issued" securities issues usually are not eligible for depository book-entry services because they have no settlement date and have not been assigned CUSIP numbers.

[8] For an issue to become DTC eligible (and thus eligible for automatic book-entry transfer services under the proposal's modified ID system procedures), the managing underwriter must ensure that, two days before closing date, DTC has all necessary eligibility information, such as the issue's CUSIP number, settlement date, net settlement dollar amount, share price, quantity and principal amount.

[9] PDQ is DTC's automatic, book-entry delivery vehicle. Participants can use PDQ for "regular-way" trades by providing DTC with standing instructions to deliver automatically ID-confirmed and affirmed transactions. Participants thus are relieved from submitting delivery instructions for each transaction.

During the ordinary PDQ cycle, DTC determines on the night before settlement date whether participants have sufficient securities in their accounts to make the deliveries scheduled for settlement date. Because underwriters and syndicate group members do not receive securities needed for delivery until settlement (*i.e.*, closing) date, PDQ services have been unavailable to them. Participants, however, can use MDOs on closing date to book-entry settle trades in issues made DTC-eligible by that day.

[10] The underwriting might settle "ex-DTC" for several reasons. For example, the participants may make that choice; the closing might have occurred too late in the day for DTC processing; or the issue might not have received a CUSIP number assignment.

[11] These codes are "When-Issued," "When-Distributed," and "When-Iss/Dist". Additionally, DTC has provided a new code for participants to indicate that a trade is syndicate-related: "Syndicate Trade—To Be Issued."

[12] The ID system modifications will affect only the processing of transactions between the syndicate group and their institutional customers. DTC will continue to use its routine deposit and delivery procedures described above to process distributions from the managing underwriter to other underwriters and to the syndicate group members.

[13] DTC refers to the date these trades are resubmitted as "Offering Date," "Trade Date" or "T." These trades must be confirmed, affirmed and scheduled for settlement once a closing date is set. Usually, the settlement date for these trades will be the closing date, unless fewer than five business days remain when syndicate members resubmit relevant trade data.

[14] *I.e.*, CUSIP number, settlement date, net settlement dollar amount, share price, quantity and principal amount. If participants cannot resubmit this information, they will be unable to use the proposed, streamlined ID procedures and will have to rely on DTC's current procedures, described above.

[15] Institutional customers or their agent banks may affirm these trades from T+1 through T+3. Syndicate group members receive daily Unaffirmed Trade Reports listing unaffirmed trades.

[16] Under current ID procedures, DTC determines the eligibility of a security for book-entry settlement when the broker-dealer or dealer bank submits initial trade data. As noted above, for an issue to be made depository-eligible, DTC, among other things, must be notified of its CUSIP number two days before trade data is submitted. Now issues, however, often are not assigned CUSIP numbers until resubmission date when price and other terms are finalized. To help solve this timing problem, DTC has extended the time for its eligibility determination through the evening of T+3 (*i.e.*, three business days after the resubmission date and two business days before closing date).

physically outside DTC, unless the issue can be made eligible before the closing date).[17] On the evening of T+3, DTC adds all affirmed eligible trades to the participants' Cumulative Eligible Trade Reports, which are distributed to participants on the morning of T+4. These reports indicates those trades scheduled to settle on closing date. Also on T+4, DTC pends for PDQ settlement on T+5 those affirmed trades between syndicate (*i.e.*, selling group) members and institutional customers participating in DTC directly or through agent banks that can be settled via PDQ.[18]

C. Settlement Date Processing

After DTC's Underwriting Department has received notification from the managing underwriter that the closing has occurred, the Department will process pending ID syndicate deliveries by CUSIP number on closing date (*i.e.*, T+5). To facilitate settlement of syndicate trades, DTC has modified its PDQ procedures by creating a separate file of "New—Issue' PDQ delivery instructions that are received and processed by DTC's Underwriting Department on the closing date. Thus, the initial deposit of securities into the managing underwriter's DTC account not only will trigger book-entry deliveries to the DTC accounts of both underwriters and syndicate members, that deposit also will trigger PDQ redeliveries to institutional customers or their agent banks. Participants will be notified of all these deliveries through DTC's PTS Unsolicited Message System. Moreover, if a delivery to a syndicate member is dropped for insufficient position or if DTC is advised that a closing will not occur, DTC will notify interested participants through the Daily Receive and Deliver Report, distributed daily around 2:30 P.M.

D. Controlling Settlement Processing

DTC also has modified procedures by which participants can monitor their trades to accommodate "when-issued" trades. As discussed above, DTC will provide participants daily reports on the status of their trades, including Eligible and Ineligible Trade Reports on T+2, T+3 and T+4 and a Cumulative Eligible Trade Report on T+4. To exclude eligible syndicate trades from PDQ ID settlement processing, a participant must use DTC's PDQ Authorization/Exception mechanism.[19] Excepted trades will be reported to the institutional customer or its agent bank on the PDQ Not Delivered List.

E. DTC's Rationale

DTC believes that the proposed rule change should be effective on filing under section 19(b)(3)(A) because it effects a change in an existing service of DTC that does not adversely affect the safeguarding of securities or funds in the custody or control of DTC for which it is responsible and does not significantly affect the rights or obligations of DTC or its participants. DTC believes the proposed rule change is consistent with the requirements of the Act, particularly section 17A, because it promotes the prompt and accurate clearance and settlement of securities transactions.

III. Request for Comments

The foregoing rule change has become effective pursuant to section 19(b)(3)(A) of the Securities Exchange Act of 1934 and subparagraph (e) of Securities Exchange Rule 19b–4. At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate the change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors or otherwise in furtherance of the purpose of the Securities Exchange Act of 1934.

Interested persons are invited to submit written data, views and arguments concerning the proposal. Persons making written submissions should file six copies with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the filing, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC 20549. Copies of the filing will also be available for inspection and copying at the principal office of DTC. All submissions should refer to the file number in the caption above and should be submitted by July 17, 1986.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Dated: June 18, 1986.

Shirley E. Hollis,

Acting Secretary.

[FR Doc. 86–14438 Filed 6–25–86; 8:45 am]

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[17] If DTC makes the issue eligible after T+3, but before closing date, participants may use MDOs to settle trades on closing date by book-entry transfer.

[18] As discussed immediately below in section C, DTC has modified its PDQ preocedures to accommodate syndicate trades.

[19] The PDQ Authorization/Exception mechanism allows a participant to exclude from automatic settlement on settlement date any schedule deliveries. *See* DTC's Participant Operating Procedures, section C.

[Release No. 34-23330; File No. SR-CBOE-86-14]

Self-Regulatory Organizations; Proposed Rule Change by the Chicago Board Options Exchange, Inc., Relating to Retail Automatic Executive System ("RAES") in Options Class on Standard & Poor's 500 Index ("SPX")

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934, 15 U.S.C. 78s(b)(1), notice is hereby given that on June 5, 1986, the Chicago Board Options Exchange, Incorporated filed with the Securities and Exchange Commission the proposed rule change as described in Items I, II and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Text of the Proposed Rule Change

The proposed rule change would establish a six-month pilot program for operation of the Exchange's Retail Automatic Execution System in options on the Standard & Poor's 500 Index with a limited exception to the Exchange's current book priority rule in the event unusual market conditions impair the ability to integrate manually RAES with the public customer order book.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below and is set forth in sections (A), (B), and (C) below.

(A) Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

This proposed rule change will allow the Exchange to pilot the use of RAES in

SPX. The benefits of RAES have been discussed in great detail in SR-CBOE-85-16 (equity options) and SR-CBOE-85-32 (OEX).[1]

Comparable benefits are hoped to be achieved in SPX. SPX is emerging as a successful options index, with substantial institutional participation. Increased retail small order activity is anticipated. The Exchange is willing to pilot SPX with deferral to book priority to determine how this affects market quality and willingness of market-makers to participate in the system.

The exchange believes that the proposed rule change is consistent with the Exchange Act, and in particular section 6(b)(5) in that RAES is expected to enhance audit trail, market efficiency, and order execution turnaround time; to improve quote liability, and to free floor brokers and other market participants from handling paper-intensive small orders.

(B) Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that this proposed rule change will impose any burden on competition.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants or Others

The Exchange believes that the Commission's file reflects the comments on the proposed rule change.[2]

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) by order approve such proposed rule change, or

(B) Institute proceeding to determine whether the proposed rule change should be disapproved.

[1] The CBOE proposals for a RAES pilot in equity options, and to implement RAES in OEX on a permanent basis, were noticed, respectively, in the Securities Exchange Act Release Nos. 22270 (July 26, 1985), 50 FR 31449 (File No. SR-CBOE-85-16, Amendment No. 2) and 22274 (July 29, 1985), 50 FR 31264 (File No. SR-CBOE-85-32).

[2] In connection with the CBOE proposals to operate RAES in OEX and selected equity options, the Commission received five comment letters from retail firms. Copies of these letters are on file in the Commission's Public Reference Room.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submission should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, Washington, D.C. 20549. Copies of the submission, all subsequent amendment, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, NW., Washington DC. Copies of such filing will also be available for inspection and copying at the principal office of the above-mentioned self-regulatory organization. All submissions should refer to the file number of the caption above and should be submitted by July 17, 1986.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.

Dated: June 17, 1986.

Shirley E. Hollis,

Acting Secretary.

[FR Doc. 86-14439 Filed 6-25-86; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 34-23336; File Nos. SR-NASD-85-9, SR-NYSE-86-3, SR-MSE-86-2, SR-PSE-86-6, SR-Phlx 86-10, SR-MSRB-85-8]

Self-Regulatory Organizations; Order Approving Proposed Rule Changes by National Association of Securities Dealers, Inc., et al.; Order Approving Proposed Rule Change by Municipal Securities Rulemaking Board on an Accelerated Basis

I. Proposed Rule Changes

The National Association of Securities Dealers, Inc. ("NASD") on April 3, 1985,[1] the New York Stock Exchange, Inc. ("NYSE") on January 22, 1986, the Midwest Stock Exchange, Inc. ("MSE") on February 6, 1986, the Pacific Stock Exchange, Inc. ("PSE") on April 14, 1986, the Philadelphia Stock Exchange, Inc. ("Phlx") on April 25, 1986, and the Municipal Securities Rulemaking Board ("MSRB") on March 5, 1985,[2] submitted copies of proposed rule changes pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act") and Rule 19b-4 thereunder, to conform their arbitration procedures to the recent amendments made to the Uniform Arbitration Code by the Securities Industry Conference on Arbitration.[3]

Notice of the proposed rule changes of the NASD, the NYSE, the MSE, the PSE, and the Phlx, together with the terms of substance of the proposed rule changes was given by the issuance of a Commission release (Securities Exchange Act Release No. 23211, May 7, 1986) and by publication in the **Federal Register** (51 FR 17701, May 14, 1986). No comments were received with respect to the proposed rule filings.

The MSRB also submitted a proposal amending its arbitration rules. Notice of the MSRB's proposed rule change and an amendment thereto together with the terms of substance of the proposed rule change was given by publication of a Commission release (Securities Exchange Act Release No. 23286, May 30, 1986) and by publication in the **Federal Register** (51 FR 20567, June 5, 1986). No comments were received with respect to the proposed rule filing. The MSRB has requested that the Commission grant accelerated effectiveness of the proposed rule change.[4]

II. Discussion

The Commission finds that the proposed rule changes are consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities association and a national securities exchange and, in particular, the requirements of sections 15A, 6, and 15B, and the rules and regulations thereunder.

The Commission also finds that good cause exists to approve the MSRB's proposed rule change prior to the thirtieth day after publication of notice for comment in the **Federal Register** and is therefore granting the MSRB's request for approval on an accelerated basis. The MSRB rule is substantially similar to the American Stock Exchange's amended arbitration rule [5] and the

[1] The NASD filed an amendment to its proposed rule change on April 8, 1986.

[2] The MSRB filed an amendment to its proposed rule change on May 21, 1986.

[3] The Boston Stock Exchange also has filed a proposed rule change to conform its arbitration procedures to the recent amendments to the Uniform Arbitration Code. *See* Securities Exchange Act Release No. 23337, June 18, 1986 publishing the proposal for comment and granting accelerated approval.

[4] *See* letter from Tom Hutton, Arbitration Administrator, MSRB to Alden Adkins, Branch Chief, SEC, (May 29, 1986).

[5] *See* Securities Exchange Act Release No. 23179, April 28, 1986; 51 FR 16414 (May 2, 1986).

proposed amendments to the NASD, NYSE, MSE, PSE and Phlx arbitration rules that were published for comment for twenty-one days. Accelerated effectiveness of the MSRB's rule change should ensure that uniform arbitration procedures are in effect on the same date. Finally, because the proposal is the product of an industry-wide effort, no purpose would be served were the Commission to delay the effectiveness of the MSRB proposal until the thirtieth day after publication in the **Federal Register.**

It is therefore ordered, pursuant to section 19(b)(2) of the Act, that the above-mentioned proposed rule changes be, and hereby are approved.

For the Commission, by the Division of Market Regulation pursuant to delegated authority, 17 CFR 200.30-3(a)(12).

Dated: June 18, 1986.

Shirley E. Hollis,

Acting Secretary.

[FR Doc. 86-14432 Filed 6-25-86; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 34-23346; File No. SR-NYSE-86-15]

Self-Regulatory Organizations; New York Stock Exchange, Inc.; Order Granting Accelerated Effectiveness of Proposed Rule Change

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934, 15 U.S.C. 78s(b)(1), notice is hereby given that on May 16, 1986, the New York Stock Exchange, Inc. filed with the Securities and Exchange Commission the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is proposing to amend Rule 716, governing "Withdrawal of Approval of Underlying Stocks and Groups", as follows: (Italics indicate language added.)

Rule 716. (a) through (c) No change . . . Supplementary Material: .10 through .40 No change *.50 If a stock underlying options trading on the Exchange is also the subject of options trading on or through the facilities of a Participating Exchange or Association, at the time the Exchange determines that approval for continued options trading on such underlying stock should be withdrawn, then the Exchange may apply to the Securities and Exchange Commission to delist such options prior to the time all series of such options have expired. Member organizations will be notified prior to the delisting.*

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in item IV below. The self-regulatory organization has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

The Exchange is proposing an addition to Rule 716, new Supplementary Material .50, that will allow the Exchange to delist options on underlying stocks prior to the expiration of all open series. Under the current rules, when the Exchange determines it is appropriate to withdraw approval for continued options trading on an underlying stock, it must wait until all the then open-series expire before it can delist the option. This provision provides investors who have established option positions the opportunity to close their positions in the secondary market.

This provision protects investors in options which trade only in one market; investors in multiply-traded options can choose from several marketplaces. If one marketplace decides to withdraw from trading an option, the investor still has available other markets to close any open option position. Therefore, the Exchange is proposing that, if the option it has chosen to delist is also available in another marketplace, the Exchange may delist the option prior to the expiration of all open series.

The statutory basis of the proposed rule change is section 6(b)(5) of the Securities Exchange Act of 1934 (the "Act"), in particular, its requirements that the rules of a national securities exchange remove impediments to and perfect the mechanism of a free and open market, and protect investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes the proposed rule change imposes no burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Comments on the proposed rule change were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange requests that the proposed rule change be given accelerated effectiveness pursuant to section 19(b)(2) of the Act because the rule change will not impede holders of the affected options classes from closing out their open options positions. The provision effects only multiply-traded options, and thus investors who have established options positions will be able to close their positions in another market.

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange, and in particular, the requirements of section 6 and the rules and regulations thereunder.

The Commission finds good cause for approving the proposed rule change prior to the thirtieth day after the date of publication of the notice of filing thereof because the rule change is applicable only to multiply-traded options. Any option delisted by the Exchange prior to expiration pursuant to the provision must also be available in another market. Investors in multiply-traded options can close out existing positions in an alternative marketplace. Thus the proposed rule change will not impact negatively on the rights of options investors.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission

and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552 will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC 20549. Copies of such filing will also be available for inspection and copying at the principal office of the NYSE. All submissions should refer to the file number in the caption above and should be submitted by July 17, 1986.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Dated: June 19, 1986.

Shirley E. Hollis,

Acting Secretary.

[FR Doc. 86-14440 Filed 6-25-86; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 34-23327; File No. PHLX 86-17]

Self-Regulatory Organizations; Proposed Rule Change by the Philadelphia Stock Exchange, Inc., Relating to Reduction of Transaction Value Charges

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934, 15 U.S.C. 78s(b)(1), notice is hereby given that on June 4, 1986 the Philadelphia Stock Exchange, Inc. filed with the Securities and Exchange Commission the proposed rule change as described in Items I, II and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Philadelphia Stock Exchange, Inc. ("PHLX") proposes to reduce Transaction Value Charges in equities and options for monthly transaction values over $300,000 as follows:

Brackets indicates deletions; Italics indicate additions.

Total monthly transaction value ranges	Rate per $1,000
0 to $10,000,000	$0.12
$10,000,000 to $50,000,000	.10
$50,000,000 [and over] to $300,000,000	.08
$300,000,000 to $500,000,000	.04
In excess of $500,000,000	.02

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statements of the Purpose of, and Statutory Basis for the Proposed Rule Change

The purpose of the proposed rule change is to provide additional volume discounts for transactions over $300,000,000. The proposed rule change, which provides discounts for large transactions, is consistent with section 6(b)(4) of the Securities Exchange Act of 1934 ("Act") which requires that the rules of the Exchange provide for equitable allocation of fees.

B. Self-Regulatory Organizations Statement on Burden on Competition

The PHLX believes that the proposed rule change will not impose any burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No comments were solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to section 19(b)(3)(A) of the Securities Exchange Act of 1934 and subparagraph (e) of Securities Exchange Act Rule 19b-4. At any time within 60 days of the filing of such proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Securities Exchange Act of 1934.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, D.C. 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC 20549. Copies of such filing will also be available for inspection and copying at the principal office of the above-mentioned self-regulatory organization. All submissions should refer to the file number in the caption above and should be submitted by July 17, 1986.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Dated: June 16, 1986.

Shirley E. Hollis,

Acting Secretary.

[FR Doc. 86-14441 Filed 6-25-86; 8:45 am]

BILLING CODE 8010-01-M

[File No. 22-15255]

Application and Opportunity for Hearing; Petro Lewis Corp.

June 19, 1986.

Notice is hereby given that Petro Lewis Corp., a Colorado Corporation (the "Company"), has filed an application (the "Application") pursuant to section 310(b)(1)(ii) of the Trust Indenture Act of 1939 (the "Act") for a finding by the Securities and Exchange Commission that the trusteeships of J. Henry Schroder Bank & Trust Company ("Schroder") under indentures dated as of April 1, 1985 (the "Previous Indenture") which was heretofore qualified under the Act, and May 1, 1986, (the "Unit Indenture") which is intended to be qualified under the Act, are not so likely to involve a material conflict of interest as to make it necessary in the public interest or for the protection of investors to disqualify Schroder from continuing to act as trustee under both the Previous and Unit Indentures.

Section 310(b) of the Act provides in part that if a trustee under an indenture qualified under the Act has or shall acquire any conflicting interest (as defined in the section), it shall, within ninety days of ascertaining that it has

such conflicting interest, either eliminate such conflicting interest or resign. Subsection (1) of that section provides, with certain exceptions stated therein, that a trustee under a qualified indenture shall be deemed to have a conflicting interest if such trustee is trustee under another indenture of the same obligor.

The Company alleges that:

(1) The obligations of the Company under both Indentures, and particularly with respect to the Notes issued thereunder, are wholly secured by separate and distinct collateral, and that as to all other assets of the Company, the Notes will rank equally without seniority or subordination of one to the other.

(2) No default has at any time existed under either of the Indentures.

(3) No material differences exist under the Indentures.

The Company has waived notice of hearing, hearing and any and all rights to specify procedures under the Rules of Practice of the Securities and Exchange Commission in connection with this matter.

For a more detailed statement of the matters of fact and law asserted, all persons are referred to said application which is on file in the Commission's Public Reference Section, File Number 22-15255, 450 Fifth Street, NW., Washington, DC 20549.

Notice is further given that any interested persons may, not later than July 14, 1986, request in writing that a hearing be held on such matter stating the nature of his interest, the reasons for such request and the issues of law or fact raised by such application which he desires to controvert, or he may request that he be notified if the Commission orders a hearing thereon. Any such request should be addressed: Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. At any time after said date, the Commission may issue an order granting the application, upon such terms and conditions as the Commission may deem necessary or appropriate in the public interest and for the protection of investors, unless a hearing is ordered by the Commission.

For the Commission, by the Division of Corporation Finance, pursuant to delegated authority.

Shirley E. Hollis,

Acting Secretary.

[FR Doc. 86-14444 Filed 6-25-86; 8:45 am]

BILLING CODE 8010-01-M

[File No. 22-15260]

Application and Opportunity for Hearing; Petro-Lewis Corp.

June 19, 1986.

Notice is hereby given that Petro Lewis Corp., a Colorado Corporation (the "Company"), has filed an application (the "Application") pursuant to section 310(b)(1)(ii) of the Trust Indenture Act of 1939 (the "Act") for a finding by the Securities and Exchange Commission that the trusteeships of Manufacturing Hanover Trust Company ("MHTC") under indentures dated as of November 1, 1985 (the "Previous Indenture") which was heretofore qualified under the Act, and May 1, 1986, (the "Series Indenture") which is intended to be qualified under the Act, are not so likely to involve a material conflict of interest as to make it necessary in the public interest or for the protection of investors to disqualify MHTC from continuing to act as trustee under both the Previous and Series Indentures.

Section 310(b) of the Act provides in part that if a trustee under an indenture qualified under the Act has or shall acquire any conflicting interest (as defined in the section), it shall, within ninety days of ascertaining that it has such conflicting interest, either eliminate such conflicting interest or resign. Subsection (1) of that section provides, with certain exceptions stated therein, that a trustee under a qualified indenture shall be deemed to have a conflicting interest if such trustee is trustee under another indenture of the same obligor.

The Company alleges that:

(1) The obligations of the Company under both Indentures, and particularly with respect to the Notes issued thereunder, are wholly secured by separate and distinct collateral, and that as to all other assets of the Company, the Notes will rank equally without seniority or subordination of one to the other.

(2) No default has at any time existed under either of the Indentures.

(3) No material differences exist under the Indentures.

The Company has waived notice of hearing, hearing and any and all rights to specify procedures under the Rules of Practice of the Securities and Exchange Commission in connection with this matter.

For a more detailed statement of the matters of fact that law asserted, all persons are referred to said application which is on file in the Commission's Public Reference Section, File Number 22-15260, 450 Fifth Street, NW, Washington, DC 20549.

Notice is further given that any interested persons may, not later than July 14, 1986, request in writing that a hearing be held on such matter stating the nature of his interest, the reasons for such request and the issues of law or fact raised by such application which he desires to controvert, or he may request that he be notified if the Commission orders a hearing thereon. Any such request should be addressed: Secretary, Securities and Exchange Commission, 450 Fifth Street, NW, Washington, DC 20549. At any time after said date, the Commission may issue an order granting the application, upon such terms and conditions as the Commission may deem necessary or appropriate in the public interest and for the protection of investors, unless a hearing is ordered by the Commission.

For the Commission, by the Division of Corporation Finance, pursuant to delegated authority.

Shirley E. Hollis,

Acting Secretary.

[FR Doc. 86-14435 Filed 6-25-86; 8:45 am]

BILLING CODE 8010-01-M

[Release No. IC-15156; (812-6320; 812-6387)]

Santa Barbara Funding I, Inc., and Santa Barbara Funding II, Inc.; Notice of Application for Collateralized Mortgage Obligations

June 19, 1986.

Notice is hereby given that Santa Barbara Funding I, Inc. ("Funding I") filed an application on March 19, 1986, and amendments thereto on May 15, and June 5, 1986, and that Santa Barbara Funding II, Inc. ("Funding II") filed an application on May 15, 1986, and an amendment thereto on June 5, 1986, (Funding I and Funding II, collectively, "Applicants"), both Applicants at 3908 State Street, Santa Barbara, California 93105, for separate orders of the Commission pursuant to section 6(c) of the Investment Company Act of 1940 (the "Act"), exempting Applicants from all provisions of the Act. All interested persons are referred to the applications on file with the Commission for a statement of the representations contained therein, which are summarized below, and to the Act and rules thereunder for the text of the relevant provisions thereof.

According to each application, Applicants were organized for the purpose of, among other things, acquiring, owning, holding and pledging

mortgages, mortgage-backed securities and other mortgage-related collateral ("Mortgage Collateral"), including Mortgage Certificates (as described below), issuing and selling series of bonds and other obligations collateralized by Mortgage Collateral, and engaging in activities incidental thereto. Applicants state that each series of bonds (the "Bonds") will be separately secured by collateral consisting primarily of Mortgage Collateral, including mortgage passthrough certificates ("GNMA Certificates") which are fully guaranteed as to principal and interest by the Government National Mortgage Association ("GNMA"), Mortgage Participation Certificates ("FHLMC Certificates") issued and guaranteed by the Federal Home Loan Mortgage Corporation ("FHLMC") and/or Guaranteed Mortgage Pass-Through Certificates ("FNMA Certificates") issued and guaranteed by the Federal National Mortgage Association ("FNMA"). ("Mortgage Certificates" means GNMA Certificates, FHLMC Certificates and/or FNMA Certificates). Applicants also state that Mortgage Certificates included in the Mortgage Collateral pledged to secure the Bonds may or may not represent the entire beneficial interest in the related mortgage pools.

Each Applicant represents that the Mortgage Collateral securing each series of Bonds will be acquired by Applicants primarily using the net proceeds of sale of such Bonds. Until such Bonds are paid, Applicants will not be permitted to release from the lien of the Indenture (as defined below) Mortgage Collateral pledged to secure the Bonds except in certain limited circumstances described in the application.

Each Applicant further represents that each series of Bonds will be issued pursuant to an Indenture between each Applicant and an independent trustee (the "Trustee") as supplemented by one or more supplemental indentures for such series (the "Indenture"). It is presently contemplated by Applicants that each series of Bonds will be registered under the Securities Act of 1933 (the "Securities Act"), unless offered in a transaction exempt from registration under section 4(2) of the Securities Act. Indentures for each public offering will be qualified under the provisions of the Trust Indenture Act of 1939.

According to each application, the Mortgage Collateral collateralizing each series of Bonds will be pledged to and held by a Trustee or on behalf of a Trustee by an independent custodian, and such Trustee will have a first lien perfected security interest in such Mortgage Collateral. Each Applicant states that, under the Indenture, the proceeds of the Mortgage Certificates held by the Trustee pending distribution to Bondholders may only be invested in United States obligations and other eligible investments meeting requirements of rating agencies rating the Bonds of such series. Applicants represent that each such series of Bonds will be structured so that it will receive the highest rating from one or more nationally recognized rating agencies, which is not affiliated with either Applicant.

Each Applicant states that the cash flow generated by the Mortgage Collateral together with other collateral securing the Bonds will be sufficient to pay principal of and interest on the Bonds. Applicants submit that certain series of Bonds may provide for optional and mandatory redemptions on terms specified for the Bonds. A series may provide for mandatory redemptions to the extent that payments on the Mortgage Collateral cannot be invested at a rate which will provide sufficient income to pay interest on the Bonds. The terms of certain offerings may provide for redemptions at the option of Bondholders to the extent that payments received on the Mortgage Collateral are available for such redemptions. Except in limited circumstances arising upon an event of default under the Indenture, Bondholders will not be entitled to compel the liquidation of the Mortgage Collateral in order to redeem the Bonds prior to maturity. Applicants state that none of these redemptions would make the Bonds a "redeemable security" for purpose of the Act.

Each Applicant agrees that their future offerings of Bonds will be limited to Bond offerings meeting the conditions set forth below:

(1) Each series of Bonds will be registered under the Securities Act of 1933 ("Securities"), unless offered in a transaction exempt from registration pursuant to section 4(2) of the Securities Act.

(2) The Bonds will be "mortgage related securities" within the meaning of section 3(a)(41) of the Securities Exchange Act of 1934, as amended. However, the Mortgage Collateral underlying the Bonds (whether owned by Applicants or pledged to collateralized obligations) will be limited to: mortgages that are first liens on single (one-to-four) family residences ("Mortgages") and Mortgage Certificates.

(3) If new Mortgage Collateral is substituted, this substitute collateral must: (i) Be of equal or better quality than the collateral replaced; (ii) have similar payment terms and cash flow as the collateral replaced; (iii) be insured or guaranteed to the same extent as the collateral replaced; and (iv) meet the conditions set forth in paragraphs (2), (4) and (6) hereof. In addition, new collateral will not be substituted for more than 20% of the aggregate face amount of the Mortgages initially pledged as Mortgage Collateral or for more than 40% of the aggregate face amount of the Mortgage Certificates initially pledged as Mortgage Collateral. New Mortgages may be substituted for Mortgages initially pledged as Mortgage Collateral only in the event of default, late payments or defect in the collateral being replaced. In no event will any new Mortgage Collateral be substituted for any substitute Mortgage Collateral. New collateralized obligations may be substituted for collateral obligations initially pledged only if the substitution of Mortgage Collateral underlying those instruments would be permitted under this condition.

(4) All Mortgages, Mortgage Certificates, funds, accounts or other collateral securing a series of Bonds ("Bond Collateral") will be held by the Trustee or on behalf of the Trustee by an independent custodian (the "Custodian"). The Custodian may not be an affiliate (as the term "affiliate" is defined in Securities Act Rule 405, 17 CFR 230.405) of the Applicants, or of the master servicer or originating lender of any Mortgages that are pledged as Mortgage Collateral. If there is no master servicer, no servicer of those Mortgages may be an affiliate of the Custodian. The Trustee will have a first priority perfected security or lien interest in and to all Bond Collateral.

(5) Each series of Bonds will be rated in one of the two highest bond rating categories by at least one nationally recognized statistical rating organization that is not affiliated with the Applicants. The Bonds will not be considered redeemable securities within the meaning of section 2(a)(32) of the Act.

(6) The master servicer of any Mortgages that are pledged as Mortgage Collateral may not be an affiliate of the Trustee. If there is not master servicer, no servicer of those Mortgages may be an affiliate of the Trustee. Any master servicer and servicer of such Mortgages will be approved by the "FNMA" or "FHLMC" as an eligible seller/servicer" of conventional, residential mortgage loans. The agreement governing the servicing of Mortgages shall obligate the

servicer to provide substantially the same services with respect to those Mortgages as it is then currently required to provide in connection with the servicing of mortgage loans insured by FHA, guaranteed by the VA or eligible for purchase by FNMA or FHIMC.

(7) No less often than annually, an independent public accountant will audit the books and records of each Applicant and in addition will report on whether the anticipated payments of principal and interest on the Mortgage Collateral continue to be adequate to pay the principal and interest on the Bonds in accordance with their terms. Upon completion, copies of the auditor's report(s) will be provided to the Trustee.

Each Applicant asserts that the exemptive relief sought is both consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Each Applicant further asserts that its activities will facilitate the financing of mortgage loans to expand the availability of residential mortgages, a critical national need.

Notice is further given that any interested person wishing to request a hearing on the application may, not later than July 11, 1986, at 5:30 p.m., do so by submitting a written request setting forth the nature of the interest, the reasons for the request, and the specific issues, if any, of fact or law that are disputed, to the Secretary, Securities and Exchange Commission, Washington, DC 20549. A copy of the request should be served personally or by mail upon Applicant(s) at the address stated above. Proof of service (by affidavit or, in the case of an attorney-at-law, by certificate) shall be filed with the request. After said date, an order disposing of the application will be issued unless the Commission orders a hearing upon request or upon its own motion.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Shirley E. Hollis,

Acting Secretary.

[FR Doc. 86-14434 Filed 6-25-86; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 34-23337; File No. SR-BSE-86-2]

Self-Regulatory Organizations; Filing and Order Granting Accelerated Approval of Proposed Rule Change by the Boston Stock Exchange, Inc.

The Boston Stock Exchange, Inc. ("BSE") submitted on May 19, 1986, copies of a proposed rule change pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act") to conform its arbitration procedures to the recent amendments made to the Uniform Arbitration Code by the Securities Industry Conference on Arbitration.[1]

Interested persons are invited to submit written data, views and arguments concerning the proposed rule change. Persons making written submissions should file six copies thereof with the Secretary of the Commission, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying at the Commission's Public Reference Section. Copies of the filing and of any subsequent amendments also will be available at the principal office of the BSE. All submissions should refer to file number SR-BSE-86-2 and should be submitted by Jule 17, 1986.

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to the BSE and in particular, the requirements of section 6 and the rules and regulations thereunder.

The Commission also finds that good cause exists to approve the proposed rule change prior to the thirtieth day after the date of publication of notice of filing thereof, in that the BSE rule change is substantially similar to the American Stock Exchange's amended arbitration rule [2] and the proposed amendments to the NASD, NYSE, MSE, PSE and Phlx arbitration rules that were published for comment for twenty one days. Accordingly, the Commission finds that notice of the BSE proposal prior to approval is unnecessary. Accelerated effectiveness of the proposed rule change should ensure that uniform arbitration procedures are in effect on the same date. Finally, because the proposal is the product of an industry-wide effort, no purpose would be served were the Commission to delay the effectiveness of the BSE proposal until the thirtieth day after the publication in the **Federal Register.**

It is therefore ordered, pursuant to section 19(b)(2) of the Act, that the above-mentioned proposed rule change be, and hereby is approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority, 17 CFR 200.30-3(a)(12).

Dated: June 18, 1986.

Shirley E. Hollis,

Acting Secretary.

[FR Doc. 86-14448 Filed 6-26-86; 8:45 am]

BILLING CODE 8010-01-M

[1] The National Association of Securities Dealers Inc. ("NASD"), the New York Stock Exchange, Inc. ("NYSE"), the Midwest Stock Exchange, Inc. ("MSE"), the Pacific Stock Exchange, Inc. ("PSE"), the Philadelphia Stock Exchange, Inc. ("Phlx") and the Municipal Securities Rulemaking Board ("MSRB") have submitted similar amendments to their arbitration rules that are being approved today in a companion release. *See* Securities Exchange Act Release No. 23336 (June 18, 1986).

[2] *See* Securities Exchange Act Release No. 23179, April 28, 1986; 51 FR 16414 (May 2, 1986).

[Release No. 34-23326; File No. SR-CBOE-85-44]

Self-Regulatory Organizations; Proposed Rule Change by Chicago Board Options Exchange, Inc.; Evaluation of Trading Crowd Performance

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934, 15 U.S.C. 78s(b)(1), notice is hereby given that on May 19, 1986, the Chicago Board Options Exchange, Incorporated filed with the Securities and Exchange Commission the proposed rule change as described in Items I, II and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Text of the Proposed Rule Change

The Exchange is adding a new rule 8.12 which is entitled Evaluation of Trading Crowd Performance.[1] The rule provides for a two year pilot program for the Market Performance Committee ("Committee") to periodically conduct an evaluation of members, individually and/or collectively as trading crowds, to determine whether they have fulfilled performance standards relating to quality of markets, competition among market-makers, ethics, compliance with Exchange rules and other administrative factors. The Committee may consider any information as relevant, but in particular the rule provides that a trading crowd evaluation will be conducted every six months. These

[1] The current filing is Amendment No. 1 to File No. SR-CBOE-85-44 which was originally submitted to the Commission on November 4, 1985. The CBOE submitted Amendment No. 1 in response to comment by the Commission staff relating to the proposed rule change.

questionnaires will have a series of questions with numerical totals, totaled on a raw basis and a weighted basis. Trading crowds rated in the bottom 10% of the aggregate results of the survey will be presumptively deemed to have failed to meet minimum performance standards. Members of a trading crowd will be presumptively deemed to be responsible for the aggregate trading crowd evaluation.

The Committee may call an informal meeting for a failure to meet minimum performance standards, which meeting will be for the purpose of attempting to reach accommodations to improve market performance standards and explore possible remedies.

The Committee may also conduct formal meetings, at which rights of confrontation and rights to counsel will apply, and the Committee will have the authority, based on the information adduced at the hearing, to suspend, terminate or restrict a market-maker's registration, appointment to one or more options classes, restrictions on additional restrictive market-makers appointments to additional option classes, relocate option classes, and prohibit a member from trading in a particular trading station. The proceedings resulting in remedial measures may be reviewed by the Board.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below and is set forth in sections (A), (B), and (C) below.

(A) Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

This proposed rule change provides a procedure for evaluation of trading crowds at the Exchange. Listed options classes are grouped at trading stations on the Exchange floor. A trading station is a physically discrete portion of a trading post, where the display screens for the group of option classes are located, and all transactions in such option classes are effected.

In the competitive market-maker system, the best possible markets are established by the competition among market-makers. Market-makers are appointed to make markets in classes of option contracts, and generally become regular participants in particular trading crowds where certain groups of their appointed options classes are located. Public and professional customers, as well as the Exchange itself, evaluate activity at a trading station based on the activity of all members in that trading crowd. Differentiation among individual members of a crowd is usually neither practical nor useful. Therefore, the Exchange believes it is appropriate to evaluate the performance of trading crowds and to take remedial measures if performance of a particular trading crowd does not meet minimum standards.

Exchange Rules 8.2 and 8.3 permit the Floor Procedure Committee ("FPC") or Market Performance Committee ("MPC") to suspend or terminate a member's registration as market-maker and to suspend or terminate a member's appointment to particular option classes. The Exchange also selects the location where option classes are to be traded. Under the proposed rule change, all of these powers will be employed by MPC, as appropriate, to remedy deficient trading crowd performance. The MPC will also have the authority to take other related remedial measures in appropriate cases, including restricting market-maker registration and market-maker appointments, and prohibiting trading at a particular trading station. The prohibition against trading at a particular station is an implementation of the prohibition against congregating, set forth in Exchange Rule 8.7.

The process by which trading crowds will be evaluated and corrective action taken incorporates appropriate safeguards. When a trading crowd is found not to meet minimum standards of performance, members of the crowd will be given notice and an opportunity to be heard at one or more meetings. The presentation made by a member can be on his own behalf, on behalf of the trading crowd, or both.

If any remedial measures are taken, MPC will issue findings supporting its determination, and affected members may seek review by the Board of Directors. The proposed rule change confines the review to matters presented to MPC. This limitation will encourage members to present all pertinent information to MPC, enabling MPC to make an informed decision and insuring that the Board of Directors will not be unduly and inappropriately burdened by de novo hearings. The Board will affirm MPC's decision unless MPC is found to have acted without basis, clearly erroneously, or arbitrarily and capriciously.

Under subpart (d) of the rule, the Market Performance Committee may also call an informal meeting at which it would be expected that particular problems would be discussed with the trading crowd in the hope that the trading crowd will take steps to correct the situation. To assure that such informal meetings encourage free and open discussion, and to avoid a technical or adversarial contest, the rule specifies that such meetings will not be transcribed and that, ordinarily, counsel will not participate. Counsel may be present at the more formal meetings described in subpart (e) of the rule.

The proposed rule change is consistent with the Securities Exchange Act of 1934 and in particular section 6(b)(5) in that the proposed rule change is designed to enforce exchange rules, to promote just and equitable principles of trade, and to protect investors and the public interest.

(B) Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that this proposed rule change will impose any burden on competition.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve such proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submission should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to

the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying at the Commission's Public Reference Section, 450 Fifth Street, NW, Washington, DC. Copies of such filing will also be available for inspection and copying at the principal office of the above-mentioned self-regulatory organization. All submissions should refer to the file number in the caption above and should be submitted by July 17, 1986.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.

Dated: June 16, 1986.

Shirley E. Hollis,

Acting Secretary.

[FR Doc. 86-14433 Filed 6-25-86; 8:45 am]

BILLING CODE 8010-01-M

Self-Regulatory Organizations; Applications for Unlisted Trading Privileges and of Opportunity for Hearing; Midwest Stock Exchange, Inc.

June 18, 1986.

The above named national securities exchange has filed applications with the Securities and Exchange Commission pursuant to section 12(f)(1)(B) of the Securities Exchange Act of 1934 and Rule 12f-1 thereunder, for unlisted trading privileges in the following securities:

International Banknote Company, Inc.
Warrants (File No. 7-9024)
AFG Industries
Common Stock, $1.00 Par Value (File No. 7-9025)
Mauna Loa Macadamia Partners
Depositary Receipts, Class A Units (File No. 7-9026)
Rodman and Renshaw
Common Stock, $0.09 Par Value (File No. 7-9027)
Calton, Inc.
Common Stock, $.01 Par Value (File No. 7-9028)
Decision Industries Corporation
Common Stock, $0.01 Par Value (File No. 7-9029)
France Fund, Inc. (The)
Common Stock, $0.01 Par Value (File No. 7-9030)
NACCO Industries, Inc.
Common Stock Class A, Par Value $1.00 (File No. 7-9031)
MEI Diversified Inc.
Common Stock, $0.05 Par Value (File No. 7-9032)

These securities are listed and registered on one or more other national securities exchange and are reported in the consolidated transaction reporting system.

Interested persons are invited to submit on or before July 10, 1986, written data, views and arguments concerning the above-referenced applications. Persons desiring to make written comments should file three copies thereof with the Secretary of the Securities and Exchange Commission, Washington, DC 20549. Following this opportunity for hearing, the Commission will approve the applications if it finds, based upon all the information available to it, that the extensions of unlisted trading privileges pursuant to such applications are consistent with the maintenance of fair and orderly markets and the protection of investors.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Shirley E. Hollis,

Acting Secretary.

[FR Doc. 86-14445 Filed 6-25-86; 8:45 am]

BILLING CODE 8010-01-M

Self-Regulatory Organizations; Applications for Unlisted Trading Privileges and of Opportunity for Hearing; Philadelphia Stock Exchange, Inc.

June 20, 1986.

The above named national securities exchange has filed applications with the Securities and Exchange Commission pursuant to section 12(f)(1)(B) of the Securities Exchange Act of 1934 and Rule 12f-1 thereunder, for unlisted trading privileges in the following securities:

Lincoln National Corporation
Common Stock, $1.25 Par Value (File No. 9033)
Portland General Corporation (Holding Company)
Common Stock, $3.75 Par Value (File No. 9034)
DPL, Inc. (Holding Company)
Common Stock, $7.00 Par Value (File No. 8035)
British Telecommunications PLC
Final Installment American Depositary Receipts (File No. 9036)

These securities are listed and registered on one or more other national securities exchange and are reported in the consolidated transaction reporting system.

Interested persons are invited to submit on or before July 14, 1986 written data, views and arguments concerning the above-referenced application. Persons desiring to make written comments should file three copies thereof with the Secretary of the Securities and Exchange Commission, Washington, DC 20549. Following this opportunity for hearing, the Commission will approve the application if it finds, based upon all the information available to it, that the extensions of unlisted trading privileges pursuant to such application are consistent with the maintenance of fair and orderly markets and the protection of investors.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Shirley E. Hollis,

Acting Secretary.

[FR Doc. 86-14446 Filed 6-25-86; 8:45 am]

BILLING CODE 8010-01-M

Self-Regulatory Organizations; Applications for Unlisted Trading Privileges and of Opportunity for Hearing; Philadelphia Stock Exchange, Incorporated

June 18, 1986.

The above named national securities exchange has filed applications with the Securities and Exchange Commission pursuant to section 12(f)(1)(B) of the Securities Exchange Act of 1934 and Rule 12f-1 thereunder, for unlisted trading privileges in the following securities:

G. Heileman Brewing Co., Inc.
Common Stock, $1.00 Par Value (File No. 7-9021)
Campanelli Industries, Inc.
Common Stock, $0.01 Par Value (File No. 7-9022)
Marsh & McLennan Companies, Inc.
Common Stock, $1.00 Par Value (File No. 7-9023)

These securities are listed and registered on one or more other national securities exchange and are reported in the consolidated transaction reporting system.

Interested persons are invited to submit on or before July 10, 1986, written data, views and arguments concerning the above-referenced application. Persons desiring to make written comments should file three copies thereof with the Secretary of the Securities and Exchange Commission, Washington, DC 20549. Following this opportunity for hearing, the Commission will approve the application if it finds, based upon all the information available to it, that the extensions of unlisted trading privileges pursuant to such application are consistent with the maintenance of fair and orderly markets and the protection of investors.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Shirley E. Hollis,

Acting Secretary.

[FR Doc. 86-14447 Filed 6-25-86; 8:45 am]

BILLING CODE 8010-01-M

DEPARTMENT OF TRANSPORTATION

Research and Special Programs Administration

Applications for Renewal or Modification of Exemptions or Applications To Become Party to an Exemption

AGENCY: Research and Special Programs Administration, DOT.

ACTION: List of applicants for renewal or modification of exemptions or application to become a party to an exemption; correction.

SUMMARY: This document corrects a notice published in the **Federal Register** on Monday, May 12, 1986 on page 17436. The applicant name should have been Montana Sulphur & Chemical Company instead of Transportation Supervisor.

Issued in Washington, DC, on June 17, 1986.

J. Suzanne Hedgepeth,

Chief, Exemptions Branch, Office of Hazardous Materials Transportation.

[FR Doc. 86-14460 Filed 6-25-86; 8:45 am]

BILLING CODE 4910-60-M

DEPARTMENT OF THE TREASURY

Secret Service

Appointment of Performance Review Board (PRB) Members

This notice announces the appointment of members of Senior Executive Service Performance Review Boards in accordance with 5 U.S.C. 4314(c)(4) for the rating period beginning July 1, 1985, and ending June 30, 1986. Each PRB will be composed of at least three of the Senior Executive Service members listed below.

Name and Title

L.B. Sheafe—Deputy Director, U.S. Secret Service

Joseph R. Carlon—Assistant Director, Protective Research (USSS)

Stephen E. Garmon—Assistant Director, Protective Operations (USSS)

Dennis T. Brosan—Assistant Director, Inspection (USSS)

Kevin R. Houlihan—Assistant Director, Investigations (USSS)

David C. Lee—Assistant Director, Administration (USSS)

Robert R. Snow—Assistant to the Director, Public Affairs (USSS)

Don A. Edwards—Assistant to the Director, Training (USSS)

H. Terrence Samway—Deputy Assistant Director, Protective Research (USSS)

Paul A. Buskirk—Deputy Assistant Director, Protective Operations (USSS)

Gary L. Wistrand—Deputy Assistant Director, Protective Operations (USSS)

George J. Opfer—Deputy Assistant Director, Protective Operations (USSS)

Richard J. Hankinson—Deputy Assistant Director, Investigations (USSS)

John J. Keeleher—Chief Counsel, U.S. Secret Service

FOR FURTHER INFORMATION CONTACT: Wesley Bishop, Chief, Personnel Division, Room 912 G Street, NW., Washington, DC 20223, Telephone No. 202-535-5800.

John R. Simpson,

Director.

[FR Doc. 86-14424 Filed 6-25-86; 8:45 am]

BILLING CODE 4810-42-M

Sunshine Act Meetings

Federal Register
Vol. 51, No. 123
Thursday, June 26, 1986

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

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1

FEDERAL DEPOSIT INSURANCE CORPORATION

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that at 10:20 a.m. on Monday, June 23, 1986, the Board of Directors of the Federal Deposit Insurance Corporation met in closed session, by telephone conference call, to consider the following matters:

(A) Application of the Connecticut National Bank, Hartford, Connecticut, for consent to purchase certain assets of and assume the liability to pay deposit made in the Cromwell (Cromwell Commons), Wallingford (Main Street), and Meriden (West Main Street), Connecticut, offices of Jefferson Federal Savings and Loan Association, Meriden, Connecticut, a non-FDIC-insured institution.

(B) Application of the New Haven Savings Bank, New Haven, Connecticut, an insured mutual saving bank, for consent to purchase certain assets of and assumed the liability to pay deposits made in the Middletown and Milford, Connecticut, offices of Jefferson Federal Savings and Loan Association, Meriden, Connecticut, a non-FDIC-insured institution, and for consent to establish those two offices as branches of The New Haven Savings Bank.

(C) Application of The Liberty Bank for Savings, Middletown, Connecticut, an insured mutual savings bank, for consent to purchase certain assets of and assume the liability to pay deposits made in the Cromwell (Main Street), Connecticut, office of Jefferson Federal Savings and Loan Association, Meriden, Connecticut, a non-FDIC-insured institution, and for consent to establish that office as a branch of The Liberty Bank for Savings.

(D) Application of Home Bank and Trust Company, Meriden, Connecticut, an insured State nonmember bank, for consent to purchase certain assets of and assume the liability to pay deposits made in the New Haven, Connecticut, office of Jefferson Federal Savings and Loan Association, Meriden, Connecticut, a non-FDIC-insured insitituion, and for consent to establish that office as a branch of Home Bank and Trust Company.

(E) Application of Citytrust, Bridgeport, Connecticut, an insured State nonmember bank, for consent to purchase certain assets of and assume the liability to pay deposits made in the Wallingford (Turnpike Road), Connecticut, office of Jefferson Federal Savings and Loan Association, Meriden, Connecticut, a non-FDIC-insured institution, and for consent to establish that office as a branch of Citytrust.

(F) Application of Colonial Bank, Waterbury, Connecticut, an insured State nonmember bank, for consent to purchase certain assets of and assume the liability to pay deposits made in the Southington, Connecticut, office of Jefferson Federal Savings and Loan Association, Meriden, Connecticut, a non-FDIC-insured institution, and for consent to establish that office as a branch of Colonial Bank.

At that same meeting, the Board also considered a personnel matter.

In calling the meeting, the Board determined, on motion of Chairman L. William Seidman, seconded by Director C.C. Hope, Jr. (Appointive), concurred in by Director Robert L. Clarke (Comptroller of the Currency), that Corporation business required its consideration of the matters on less than seven days' notice ot the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting pursuant to subsections (c)(2), (c)(6), (c)(8), and (c)(9) (A)(ii) of the "Government in the Sunshine Act" (5 U.S.C. 552b(c)(2), (c)(6), (c)(8), and (c)(9)(A)(ii)).

Dated: June 23, 1986.

Federal Deposit Insurance Corporation.

Hoyle L. Robinson,

Executive Secretary.

[FR Doc. 86-14530 Filed 6-24-86;11:14 am]

BILLING CODE 6714-01-M

2

FEDERAL DEPOSIT INSURANCE CORPORATION

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that at 4:57 p.m. on Friday, June 20, 1986, the Board of Directors of the Federal Deposit Insurance Corporation met in closed session, by telephone conference call, to adopt: (1) A resolution (a) making funds available for the payment of insured deposits made in The American Bank, Alma, Wisconsin, which was closed by the Commissioner of Banking for the State of Wisconsin on Friday, June 20, 1986; (b) accepting the bid of Bank of Alma, Alma, Wisconsin, a newly-chartered State nonmember bank, for the transfer of the insured and fully secured or preferred deposits of the closed bank; (c) designating Bank of Alma, Alma, Wisconsin, as the agent for the Corporation for the payment of insured and fully secured or preferred deposits of the closed bank; and (2) an Order approving the applications of Bank of Alma, Alma, Wisconsin, for Federal deposit insurance, for consent to purchase certain assets of and assume the liability to pay deposits made in The American Bank, Alma, Wisconsin, and for consent to establish the two branches of The American Bank as branches of Bank of Alma.

In calling the meeting, the Board determined, on motion of Director C.C. Hope, Jr. (Appointee), seconded by Mr. Dean S. Marriott, acting in the place and stead of Director Robert L. Clarke (Comptroller of the Currency), that Corporation business required its consideration of the matters on less than seven days' notice to the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideratin of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting pursuant to subsections (c)(8), (c)(9)(A)(ii), and (c)(9)(B) of the "Government in the Sunshine Act" (5 U.S.C. 552b(c)(8), (c)(9)(A)(ii), and (c)(9)(B)).

Dated: June 23, 1986.

Federal Deposit Insurance Corporation.

Hoyle L. Robinson,

Executive Secretary.

[FR Doc. 86-14587 Filed 6-24-86; 3:17 pm]

BILLING CODE 6714-01-M

3

FEDERAL MARITIME COMMISSION

TIME AND DATE: 10:00 a.m., June 25, 1986.

PLACE: Hearing Room One, 1100 L Street, NW., Washington, D.C. 20573

STATUS: Closed.

MATTER TO BE CONSIDERED:

1. The Use of High-Cube Containers in Japan.

CONTACT PERSON FOR MORE INFORMATION: John Robert Ewers, Secretary, (202) 523-5725.

John Robert Ewers,

Secretary.

[FR Doc. 86-14590 Filed 6-24-86; 3:18 pm]

BILLING CODE 6730-01-M

4

FEDERAL RESERVE SYSTEM

TIME AND DATE: 10:00 a.m., July 2, 1986.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, NW., Washington, D.C. 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Proposed use of credit cards for official travel expenses.
2. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.
3. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the board; (202) 452-3204. You may call (202) 452-3207, beginning at approximately 5 p.m. two business days before this meeting, for a recorded announcement of bank and bank holding company applications scheduled for the meeting.

Dated: June 24, 1986.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 86-14594 Filed 6-24-86; 3:58 pm]

BILLING CODE 6210-01-M

5

MERIT SYSTEMS PROTECTION BOARD

Sunshine Act Meeting; Change

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: Vol. 51, No. 115, 21825, June 16, 1986.

PREVIOUSLY ANNOUNCED TIME AND DATE OF MEETING: June 26, 1986, 10:00 a.m.

PLACE: Eighth Floor, 1120 Vermont Avenue, NW., Washington, DC.

STATUS: Open.

CHANGE IN THE MEETING: The hearing scheduled in *Woods* v. *U.S. Customs Service*, MSPB Docket No. PH07528310145, has been postponed until further notice.

CONTACT PERSON FOR ADDITIONAL INFORMATION: Robert E. Taylor, Clerk of the Board, (202) 653-7200.

Dated: June 24, 1986.

Robert E. Taylor,

Clerk of the Board.

[FR Doc. 86-14597 Filed 6-24-86; 4:16 pm]

BILLING CODE 7400-01-M

federal register

Thursday
June 26, 1986

Part II

Office of Science and Technology Policy

Coordinated Framework for Regulation of Biotechnology; Announcement of Policy and Notice for Public Comment

OFFICE OF SCIENCE AND TECHNOLOGY POLICY

Coordinated Framework for Regulation of Biotechnology

AGENCY: Executive Office of the President, Office of Science and Technology Policy.

ACTION: Announcement of policy; notice for public comment.

SUMMARY: This **Federal Register** notice announces the policy of the federal agencies involved with the review of biotechnology research and products. As certain concepts are new to this policy, and will be the subject of rulemaking, the public is invited to comment on these aspects which are specifically identified herein.

DATE: Comments must be received on or before August 25, 1986.

Public Participation: The Domestic Policy Council Working Group on Biotechnology through the Office of Science and Technology Policy, is seeking advice on certain refinements published herein to the previously published proposed coordinated framework for regulation of biotechnology. These new aspects include the Biotechnology Science Coordinating Committee's (BSCC's) definitions for an "intergeneric organism (new organism)" and for "pathogen." These definitions are critical to the coordinated framework for the regulation of biotechnology because they establish the types of the organisms subject to certain kinds of review.

It is the intention of the Domestic Policy Council Working Group on Biotechnology, the Biotechnology Science Coordinating Committee (BSCC), the Department of Agriculture (USDA), the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), the National Science Foundation (NSF), and the Occupational Safety and Health Administration (OSHA) that the policies contained herein be effective immediately. In consideration of comments, modifications, if any, may be published either in a separate notice or as part of proposed rulemaking by the involved agencies.

Information submitted to an agency that is trade secret information or confidential business information should be clearly marked so that it can be accorded the protection provided to such by each respective agency.

ADDRESS: Comments specific to the BSCC definitions or overall comments to the Coordinated Framework for the Regulation of Biotechnology statements should be addressed to: BSCC: Docket #BSCC 0001, Office of Science and Technology Policy, Executive Office of the President, NEOB-Room 5005, Washington, DC 20506.

Comments relating to the policy statements of a particular agency should be sent directly to the agency contact identified at the beginning of the respective agency policy statement.

FOR FURTHER INFORMATION CONTACT: Dr. David T. Kingsbury, Assistant Director for Biological, Behavioral, and Social Sciences, National Science Foundation, 1800 G Street, N.W., Washington, D.C. 20550, (202-357-9854).

Jerry D. Jennings,

Executive Director, Office of Science and Technology Policy

June 18, 1986

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- A. Food and Drug Administration
- B. Environmental Protection Agency
- C. U.S. Department of Agriculture
- D. Occupational Safety and Health Administration
- E. National Institutes of Health

A. Introduction

This notice describes the comprehensive federal regulatory policy for ensuring the safety of biotechnology research and products. Specifically addressed are agency policies that formed part of the previously proposed Coordinated Framework for the Regulation of Biotechnology, published in the **Federal Register** December 31, 1984 (49 FR 50856, hereinafter "the December 84 Notice"). These agency policies build upon experience with agricultural, pharmaceutical, and other commercial products developed by traditional genetic modification techniques.

Existing statutes provide a basic network of agency jurisdiction over both research and products; this network forms the basis of this coordinated framework and helps assure reasonable safeguards for the public. This framework is expected to evolve in accord with the experiences of the industry and the agencies, and, thus, modifications may need to be made through administrative or legislative actions.

The application of traditional genetic modification techniques is relied upon broadly for enhanced characteristics of food (e.g., hybrid corn, selective breeding), manufactured food (e.g., bread, cheese, yogurt), waste disposal (e.g., bacterial sewage treatment), medicine (e.g., vaccines, hormones), pesticides (e.g. *Bacillus thuringiensis*) and other uses. Federal agencies implement an array of laws which seek to ensure the safety of these products. A concise index of these U.S. laws was published in the **Federal Register** November 14, 1985 (50 FR 47174, hereinafter "the November 85 Notice"). These laws are product-specific because they regulate certain product uses, such as foods or pesticides. This approach provides the opportunity for similar products to be treated similarly by particular regulatory agencies.

Biotechnology also includes recently developed and newly emerging genetic manipulation technologies, such as recombinant DNA (rDNA), recombinant RNA (rRNA) and cell fusion, that are sometimes referred to as genetic engineering. While the recently developed methods are an extension of traditional manipulations that can produce similar or identical products, they enable more precise genetic modifications, and therefore hold the promise for exciting innovation and new areas of commercial opportunity.

Concerns were raised as to whether products resulting from the recently developed techniques would pose greater risks than those achieved through traditional manipulation techniques. For example, what might be the possible environmental consequences of the many anticipated agricultural and environmental applications that will take place outside the physical constraints of a contained facility? In particular, the environmental application of genetically engineered microorganisms may elicit concern because they are of microscopic size, and some may be able to reproduce, proliferate, and become established.

The underlying policy question was whether the regulatory framework that pertained to products developed by traditional genetic manipulation techniques was adequate for products obtained with the new techniques. A similar question arose regarding the sufficiency of the review process for research conducted for agricultural and environmental applications.

The Administration, recognizing its responsibility to confront these concerns, formed an interagency working group under the former White House Cabinet Council on Natural Resources and the Environment in the spring of 1984. The working group sought to achieve a balance between regulation

adequate to ensure health and environmental safety while maintaining sufficient regulatory flexibility to avoid impeding the growth of an infant industry.

Upon examination of the existing laws available for the regulation of products developed by traditional genetic manipulation techniques, the working group concluded that, for the most part, these laws as currently implemented would address regulatory needs adequately. For certain microbial products, however, additional regulatory requirements, available under existing statutory authority, needed to be established.

The existing health and safety laws had the advantage that they could provide more immediate regulatory protection and certainty for the industry than possible with the implementation of new legislation. Moreover, there did not appear to be an alternative, unitary, statutory approach since the very broad spectrum of products obtained with genetic engineering cut across many product uses regulated by different agencies.

Because of the rapid growth in the scientific knowledge base, the working group felt strongly that the federal agencies needed to have an interagency mechanism for sharing scientific information related to biotechnology, particularly information on research and product applications submitted to the agencies.

The December 1984 Notice described the regulatory framework envisioned by the working group, and recognizing the evolutionary nature of its development, asked for comments. In summary, the Notice stated that the Food and Drug Administration (FDA) would regulate genetic engineering products no differently that those achieved through traditional techniques. The Environmental Protection Agency (EPA) described existing and proposed new policies for regulating pesticidal and nonpesticidal microorganisms. The Department of Agriculture (USDA) stated that under its different legislative authorities it could broadly regulate genetically engineered plants and animals, and plant and animal pathogens. The Notice also proposed an interagency science coordinating mechanism.

Many comments were received in response to the Notice. These contributed to the refinement of both the regulatory requirements and the interagency science coordination mechanism.

The interagency coordination mechanism, the Biotechnology Science Coordinating Committee (BSCC), discussed in more detail in section C, of this Preamble, came into being while the agencies were still in process of refining their regulatory proposals. Consequently, the BSCC was able to play a helpful role in the formulation of two basic principles: (1) Agencies should seek to adopt consistent definitions of those genetically engineered organisms subject to review to the extent permitted by their respective statutory authorities; and, (2) agencies should utilize scientific reviews of comparable rigor.

The regulatory framework anticipates that future scientific developments will lead to further refinements. Experience with earlier basic scientific research has shown that as the science progressed and became better understood by the public, regulatory regimens could be modified to reflect more complete understanding of the potential risks involved. Similar evolution is anticipated in the regulation of commercial products as scientists and regulators learn to predict more precisely particular product use that require greater or lesser controls or even exemption from any federal review.

This framework has sought to distinguish between those organisms that require a certain level of federal review and those that do not. This follows a traditional approach to regulation. Within agriculture, for example, introductions of new plants, animals and microorganisms have long occurred routinely with only some of those that are not native or are pathogenic requiring regulatory approval. It should be noted that microorganisms play many essential and varied roles in agriculture and the environment and that for decades agricultrual scientists have endeavored to exploit their advantages through routine experimentation and introduction into the environment; and as a rule these agricultural and environmental introductions have taken place without harm to the environment.

B. The Coordinated Framework for the Regulation of Biotechnology

General Comments

This notice includes separate descriptions of the regulatory policies of FDA, EPA, OSHA and USDA and the research policies of the National institutes of Health (NIH), NSF, EPA and USDA. The agencies will seek to operate their programs in an integrated and coordinated fashion and together should cover the full range of plants, animals and microorganisms derived by the new genetic engineering techniques. To the extent possible, responsibility for a product use will lie with a single agency. Where regulatory oversight or review for a particular product is to be performed by more than one agency, the policy establishes a lead agency, and consolidated or coordinated reviews. While this preamble seeks to convey an overview of the coordinated framework, it must be noted that the regulatory requirements are highly technical; reliance only on the simplified summary statements herein could be misleading and, thus, the agency policy statements must be consulted for specific details. In the event that questions arise regarding which federal agency has jurisdiction, an information contact is provided at the beginning of this notice.

While in part certain USDA and EPA requirements are new, the underlying regulatory regimens are not new. Members of the agricultural and industrial communities are familiar with the general requirements under these laws which include the Federal Plant Pest Act, The Plant Quarantine Act, the Toxic Substances Control Act (TSCA), and the Federal insecticide, Fungicide, and Rodenticide Act (FIFRA).

Because this comprehensive regulatory framework uses a mosaic of existing federal law, some of the statutory nomenclature for certain actions may seem inconsistent. Certain laws, such as USDA's Federal Plant Pest Act, require a "permit" before a microorganism pathogenic to plants may be transported or imported. Under other laws such as FIFRA, the agencies "license" or "approve" the use of particular products. TSCA requires a "premanufacturing notification (PMN)". There are also some variations among the agencies in the use of the phrase "genetic enginering." Regardless of the nomenclature, the public should be aware that the reviews conducted by each of the regulatory agencies are intended to be of comparable rigor. Agencies have agreed to have scientists from each other's staff participate in reviews. Each regulatory review will require that the safety, or safety and efficacy, of a particular agricultural or industrial product be satisfactorily demonstrated to the regulatory agency prior to commercialization.

The National Environmental Policy Act (NEPA) imposes procedural requirements on all federal agencies to prepare an analysis prior to making a decision to take any action that may significantly affect the environment. Depending on the characteristics of a proposal, an environmental assessment, or a broader environmental impact statement may need to be prepared in connection with the release of

genetically manipulated organisms. EPA's actions under most of its environmental statutes have been considered to be the functional equivalent of NEPA compliance.

For the handling of microorganisms, agencies of the Department of Health and Human Services have established recommendations for the safe use of infectious agents. The CDC/NIH publication, *Biosafety in Microbiological and Biomedical Laboratories,* describes combinations of standard and special microbiological practices, safety equipment and facilities which are recommended for working with a variety of infectious agents in research laboratories, academic and industrial. The USDA also has issued guidance on other infectious agents.

The NIH has published guidelines for the contained use of DNA organisms in the *NIH Guidelines for Research Involving Recombinant DNA Molecules,* **Federal Register,** May 7, 1986 (51 FR 16958, NIH guidelines). The guidelines recommend physical containment at specific levels for different experiments, and exempt other experiments from containment requirements. However, they recommend Biosafety Level 1, the least stringent level of physical containment, for some "exempt" experiments. For large-scale exempt experiments, the NIH guidelines recommend "Biosafety Level 1-Large-Scale" although following review by the Institutional Biosafety Committee, "some latitude" in the application of these requirements is permitted.

The appropriate large-scale containment requirements for many low risk DNA derived industrial microorganisms will be no greater than those appropriate for the unmodified parental organisms. This concept is discussed further in the Organization for Economic Cooperation and Development (OECD) document, described in the International Aspects section below.

OSHA in its **Federal Register** Notice of April 12, 1984 (50 FR 14468) stated that its authority under the Occupational Safety and Health Act of 1970 (29 U.S.C. et seq.) provides an adequate and enforceable basis for protecting the safety and health of employees in the field of biotechnology and that no additional regulation is necessary. After consideration of comments in the April 1984 notice, OSHA is publishing this policy statement in final form without change.

Product Regulation

Agencies involved with regulating agriculture, foods, medical devices, drugs, biologics and pesticides have had extensive experience with products that involve living organisms in their manufacture and/or ultimate use including releases into the environment for these purposes. By the time a genetically engineered product is ready for commercialization, it will have undergone substantial review and testing during the research phase, and thus, information regarding its safety should be available. The manufacture by the newer technologies of food, the development of new drugs, medical devices, biologics for humans and animals, and pesticides, will be reviewed by FDA, USDA and EPA in essentially the same manner for safety and efficacy as products obtained by other techniques. The new products that will be brought to market will generally fit within these agencies' review and approval regimens.

The regulatory scheme for products is described in Chart I *Coordinated Framework—Marketing Approval of Biotechnology Products.*

CHART I.—COORDINATED FRAMEWORK—APPROVAL OF COMMERCIAL BIOTECHNOLOGY PRODUCTS

Subject	Responsible agency(ies)
Foods/Food Additives	FDA,* FSIS.[1]
Human Drugs, Medical Devices and Biologics	FDA.
Animal Drugs	FDA.
Animal Biologics	APHIS.
Other Contained Uses	EPA.
Plants and Animals	APHIS,* FSIS[1], FDA.[2]
Pesticide Microorganisms Released in the Environment All.	EPA,* APHIS.[3]
Other Uses (Microorganisms):	
Intergeneric Combination	EPA,* APHIS.[3]
Intrageneric Combination:	
Pathogenic Source Organism:	
1. Agricultural Use	APHIS.
2. Non-Agricultural use	EPA,*[4] APHIS.[3]
No Pathogenic Source Organisms	EPA Report.
Nonengineered Pathogens:	
1. Agricultural Use	APHIS.
2. Non-agricultural Use	EPA,* APHIS.[3]
Nonengineered Nonpathogens	EPA Report.

*Lead agency.
[1] FSIS, Food Safety and Inspection Service, under the Assistant Secretary of Agriculture for Marketing and Inspection Services is responsible for food use.
[2] FDA is involved when in relation to a food use.
[3] APHIS, Animal and Plant Health Inspection Service, is involved when the microorganism is plant pest, animal pathogen or regulated article requiring a permit.
[4] EPA requirements will only apply to environmental release under a "significant new use rule" that EPA intends to propose.

Jurisdiction over the varied biotechnology products is determined by their use, as has been the case for traditional products. The detailed description of the products and their review are found in the individual agency policy statements contained in this **Federal Register** Notice. The following is a brief summary of jurisdiction as described in Chart I.

Foods, food additives, human drugs, biologics and devices, and animal drugs are reviewed or licensed by the FDA. Food products prepared from domestic livestock and poultry are under the jurisdiction of the USDA's Food Safety Inspection Service (FSIS).

Animal biologics are reviewed by the Animal and Plant Health Inspection Service, (APHIS). APHIS also reviews plants, seeds, animal biologics, plant pests, animal pathogens and "regulated articles", i.e., certain genetically engineered organisms containing genetic material from a plant pest. An APHIS permit is required prior to the shipment (movement) or release into the environment of regulated articles, or the shipment of a plant pest or animal pathogen.

"Other contained uses" refers to the closed system uses of those microorganisms, subject the TSCA, that are intergeneric combinations, i.e., deliberately formed microorganisms which contain genetic material from dissimilar source organisms. These are subject to EPA's PMN requirement. EPA is considering promulgating a rule to exempt certain classes of microorganisms from this requirement.

Microbial pesticides will be reviewed by EPA, with APHIS involvement in cases where the pesticide is also a plant pest, animal pathogen, or regulated article requiring a permit. (FDA may become involved in implementing pesticide tolerances for foods.)

"Other uses (microorganisms)" include uses involving release into the environment. For these, jurisdiction depends on the characteristics of the organism as well as its use. "Intergeneric combination"* microorganisms will be reported to EPA under PMN requirements, with APHIS Involvement in cases where the microorganism is also a regulated article requiring a permit.

"Intrageneric combinations" are those microorganisms formed by genetic engineering other than intergeneric combinations. For these, when there is a pathogenic [1] source organism, and the microorganism is used for agricultural purposes, APHIS has jurisdiction. If the microorganism is used for nonagricultural purposes, then EPA has jurisdiction, with APHIS involvement in cases where the microorganism is also a

[1] "Intergeneric organisms (new organisms)" and "pathogen" are defined in section D. of the preamble.

regulated article requiring a permit. Intrageneric combinations with no pathogenic source organisms are under EPA jurisdiction although EPA will only require an informational report.

"Nonengineered pathogens" that are used for an agricultural use will fall under APHIS jurisdiction. Those that are for a nonagricultural use come under EPA jurisdiction, with APHIS involvement in cases where the microorganism is also a plant pest or animal pathogen requiring a permit. Nonengineered nonpathogenic microorganisms are under EPA jurisdiction which will require only an informational report.

Research

The coordinated framework for the regulation of biotechnology establishes requirements for the conduct of research.

Approximately ten years ago the NIH issued the NIH guidelines describing the manner in which research with organisms derived by rDNA techniques should be conducted. Since then the guidelines have been modified many times with gradual relaxation of these requirements. The guidelines prescribe the conditions under which institutions which receive NIH funds must conduct experiments. For a very small category of NIH funded experiments including environmental release, the guidelines require that the Director, NIH, approve each experiment on an individual basis. For each of these experiments, the RAC conducts a scientific review with an opportunity for public comment, and makes a recommendation to the NIH Director. As research experiments have expanded out of the biomedical area to environmental applications both agricultural and nonagricultural, other agencies have become involved, with shifting of responsibility for research approval to NSF (described in the November 85 Notice), USDA's S&E, and EPA. These other agencies' policies build, in part, on the NIH guidelines and NIH experience.

The S&E guidelines for agricultural research published separately for comment in this issue of the **Federal Register** have adopted the NIH guidelines with certain modifications including expansion of the scope to manipulation techniques other than rDNA; the table included with the S&E guidelines shows where particular elements of the NIH guidelines are used.

It should be noted that not all experiments involving the environmental release of genetically engineered organisms require prior federal approval. In plant applications there is a substantial body of research indicating that such experiments are of low risk. For certain categories of microorganisms modified by traditional genetic modification techniques, there is also a substantial body of research indicating low risk for environmental experiments.

Chart II—*Coordinated Framework—Biotechnology Research Jurisdiction* shows which agency has responsibility for a particular experiment. If more than one agency has potential jurisdiction, one agency has been designated as the lead agency and it is marked with an asterisk on Chart II. The lead agency designation depends on which research agency is funding the research (e.g., NIH, S&E, or NSF) or which regulatory agency reviews specific purpose research (e.g. pesticides). In the chart and in this discussion, the authority refers to approval of the actual execution of experiments and not to their funding.

CHART II.—COORDINATED FRAMEWORK—BIOTECHNOLOGY RESEARCH JURISDICTION

Subject	Responsible agency(ies)
Contained Research, No Release in Environment:	
1. Federally Funded	Funding agency.[1]
2. Non-Federally Funded	NIH or S&E voluntary review, APHIS.[2]
Foods/Food Additives, Human Drugs, Medical Devices, Biologics, Animal Drugs:	
1. Federally Funded	FDA*, NIH guidelines & review.
2. Non-Federally Funded	FDA*, NIH voluntary review.
Plants, Animals and Animal Biologics:	
1. Federally Funded	Funding agency,[1]* APHIS.[2]
2. Non-Federally Funded	APHIS*, S&E voluntary review.
Pesticide Microorganisms:	
Genetically Engineered:	
Intergeneric	EPA,* APHIS,[2] S&E voluntary review.
Pathogenic Intrageneric	EPA,* APHIS,[2] S&E voluntary review.
Intrageneric Nonpathogen	EPA,* S&E voluntary review.
Nonengineered:	
Nonindigenous Pathogens	EPA,* APHIS.
Indigenous Pathogens	EPA,*[3] APHIS.
Nonindigenous Nonpathogen	EPA.*
Other Uses (Microorganisms) Released in the Environment:	
Genetically Engineered:	
Intergeneric Organisms:	
1. Federally Funded	Funding agency,*[1] APHIS,[2] EPA.[4]
2. Commercially Funded	EPA, APHIS, S&E voluntary review.
Intrageneric Organisms:	
Pathogenic Source Organism:	
1. Federally Funded	Funding agency,*[1] APHIS,[2] EPA.[4]
2. Commercially Funding	APHIS,[2] EPA (* if non-agricul. USE).
Intrageneric Combination:	
No Pathogenic Source Organisms	EPA Report.
Nonengineered	EPA Report,* APHIS.[2]

* Lead Agency.
[1] Review and approval of research protocols conducted by NIH, S&E, or NSF.
[2] APHIS issues permits for the importation and domestic shipment of certain plants and animals, plant pests and animal pathogens, and for the shipment or release in the environment of regulated articles.
[3] EPA jurisdiction for research on a plot greater than 10 acres.
[4] EPA reviews federally funded environmental research only when it is for commercial purposes.

For contained federally funded research for biomedical and agricultural purposes, research approval will be granted by the funding agency. The NIH guidelines relate primarily to biomedical experiments and only to those using rDNA techniques. Research on foods/food additives, human drugs, medical devices and biologics will continue to rely on the NIH guidelines, with NIH approval required for certain experiments such as human gene therapy, and FDA permission for clinical trials.

Fashioned after the NIH guidelines, the S&E guidelines apply to agricultural research on plants, animals, and microorganisms and provide guidance for laboratory and field testing of organisms derived using rDNA manipulation and other technologies. Adherence to the appropriate set of guidelines is required for institutions receiving financial support from NIH, S&E, or NSF. These guidelines specify what type of review procedures are required for specific categories of experiments. Some experiments require individual approval by the respective agency providing institutional support. For those experiments that require agency approval, advisory committees at NIH, S&E, and NSF, composed primarily of nongovernment scientists, may be asked to provide expert review. In addition, research on plants, animals, and animal biologics will come under APHIS permit requirements if a regulated article, plant pest, animal pathogen is involved. An APHIS permit

is required prior to the shipment (movement) or release of a regulated article, or the importation or shipment of a plant pest or regulated article used in any research experiment.

EPA has authority for all environmental research on microbial pesticides regardless of whether research is federally funded or not. EPA will regulate research under a two level review system based upon its evaluation of the potential risks posed by various types of microorganisms with lesser notification required for level I reporting and full review for level II.

For the "other uses" category from Chart II (research involving nonpesticide microorganisms released into the environment), jurisdiction for release may be under S&E, NSF, APHIS, or EPA depending primarily upon the source of the funding, but also upon the purpose of the research and the characteristics of the genetically engineered microorganism, Thus, federally funded research conducted for an agricultural use will require adherence to S&E guidelines and approval of certain experiments by S&E or NIH depending on which is the funding agency. EPA will review commercial research. APHIS's jurisdiction applies to issuing permits for regulated articles, plant pests, or animal pathogens. EPA will require an informational report for nonengineered microorganisms released into the environment, with APHIS involvement for the review of plant pests or animal pathogens.

There may be situations where one agency may choose to defer to, or ask advice from, another agency. If experiments requiring NIH, NSF or S&E review/approval are submitted for review to another agency, then NIH, NSF, or S&E may determine that such review serves the same purpose, and based upon that determination, notify the submitter that no NIH, NSF, or S&E review will take place, and the experiment may proceed upon approval from the other agency.

C. Interagency Coordination Mechanisms

The Domestic Policy Council Working Group on Biotechnology

The Domestic Policy Council Working Group on Biotechnology has been responsible for this coordinated framework for the regulation of biotechnology; it also considers policy matters related to agency jurisdiction, commercialization, and international biotechnology matters. The Working Group monitors developments in biotechnology and is ready to identify problems and make appropriate recommendations for their solution. The Domestic Policy Council Working Group on Biotechnology is a continuation of a similar group established under the former Cabinet Council on Natural Resources and the Environment.

Although at the present time existing statutes seem adequate to deal with the emerging processes and products of modern biotechnology, there always can be potential problems and deficiencies in the regulatory apparatus in a fast moving field. The Working Group will be alert to the implications these changes will have on regulation, and in a timely fashion will make appropriate recommendations for administrative or legislative action.

The Biotechnology Science Coordinating Committee (BSCC)

The BSCC is responsible for coordination and consistency of scientific policy and scientific reviews. The BSCC, established October 31, 1985 as part of the Federal Coordinating Council for Science, Engineering and Technology (FCCSET), consists of senior policy officials of agencies involved in the oversight of biotechnology research and products. FCCSET is a statutory interagency coordinating mechanism managed by the Office of Science and Technology Policy, Executive Office of the President, with a mission to coordinate federal science activities among federal agencies. The November 85 Notice described the structure and activities of the BSCC.

One of the primary activities of the BSCC has been the development of definitions because a common scientific approach is essential to a coordinated federal regulatory framework. The underlying scientific issue, therefore, was defining those organisms subject to certain types of agency review.

The definitions are included in the following section of this preamble and have been incorporated, with modification, into the individual policy notices of the involved agencies. Explanatory material is also included in the agency policy statements. As mentioned elsewhere, the BSCC is seeking comments on these definitions.

Research to develop genetically modified organisms for environmental and agricultural applications (as for research on traditionally modified organisms) generally proceeds in a step-wise manner from highly contained facilities to progressively lesser degrees of containment as the investigator determines the safety and efficacy of experimental applications; these are conducted sequentially under controlled laboratory conditions, greenhouse testing, small field trials, and full field trials. The BSCC recognizes the need for further work to define the nature and extent of physical and biological barriers that limit or manage environmental release of modified organisms during greenhouse testing and field research.

The BSCC is authorized to hold public meetings in order to discuss public concerns about scientific and other issues. Accordingly, the BSCC will hold its first public meeting shortly after publication of this notice for discussion of the scientific aspects of this notice and the receipt of comments from the public. The public meeting will be held in July 1986. Details regarding time and location will be separately announced in the **Federal Register.**

D. BSCC Definitions

Any proposal to regulate the research and products of genetic manipulation techniques quickly confronts the issue of what organisms should be considered appropriate for certain types of review. The BSCC formulated definitions are effective immediately but are open to comment; the text following the definition of "pathogen" contains details of the request for comments.

Organisms meeting two different sets of criteria are proposed. First are organisms formed by deliberate combination of genetic material from sources in different genera. It was recognized, however, that in certain precisely constructed "Intergeneric organisms" the genetic material is not considered to pose an increased risk to human health or the environment; thus, such combinations are excluded from the definition. A detailed explanation of the scientific basis for these exclusions is found in the footnote after the definition of pathogen. The BSCC specifically requests comments on whether also to consider for exclusion those organisms that exchange DNA by known physiological processes, as explained in the text immediately following the definition of "intergeneric organism (new organism)."

The second definition is "pathogen." This includes microorganisms that belong to a pathogenic species or that contain genetic material from source organisms that are pathogenic. In certain precisely constructed modified organisms, the genetic material from a pathogenic donor is not considered to pose an increased risk to human health or the environment; and, therefore, such combinations are excluded from the definition.

The BSCC definitions of "intergeneric organism (new organism)" and

"pathogen" describe the combinations genetic material that would cause a modified organism to come under review. This does not mean to suggest that the behavior of a genetically manipulated organism exempted from these definitions is wholly predictable (since any biological organism is never 100% predictable), but that the probability of any incremental hazard compared to the unmodified organism host is low. Also, this does not mean that any product manufacture or research experiment using an organism exempted from the definition should be conducted without adherence to proper manufacturing standards or research guidelines.

Given the statutory differences in the laws that they administer, the agencies adopted the principles underlying the definitions in ways consistent with their legislation. EPA, APHIS, and S&E are using the definitions to identify levels of review for microbial products within their jurisdiction. EPA, APHIS, FDA, S&E, and NSF are using the definitions as factors to consider in the review of products or experiments.

The BSCC is attempting to define what constitutes "release into the environment." The BSCC is establishing a working group on greenhouse containment and small field trials in order to develop scientific recommendations. The concept of "containment" has traditionally been used to describe physical conditions which severely limit release (for example, a contained laboratory fermentation facility). Containment can also be "biologic" because the ability of an organism to reproduce, exchange genetic information, or become established can be effectively limited biologically. Thus, the BSCC's exploration of the conditions that constitute release into the environment will consider circumstances of both physical and biological containment for particular organisms and the circumstances of their release. While the concept of physical containment may imply the high containment conditions found in certain laboratories and greenhouses, in agricultural practice many simpler effective barriers are rountinely used; these include microplots for soil bacteria and fungi, paddocks for noninfective animals, and removing or covering the reproductive parts of plants and animals.

Release into the environment, for the time being, will have somewhat varying definitions for the regulatory and research review of the different agencies. There may be minor differences between agricultural and nonagricultural approaches and betweeen macro-and microorganisms.

Intergeneric Organism (New Organism)

Those organisms deliberately formed to contain an intergeneric combination of genetic material; excluded are organisms that have resulted from the addition of intergeneric materials that is well-characterized and contains only non-coding regulatory regions such as operators, promoters, origins of replication, terminators and ribosome binding regions.

"Well-characterized and contains only non-coding regulatory regions" means that the producer of the microorganism can document the following:

a. The exact nucleotide base sequence of the regulatory region and any inserted flanking nucleotides;

b. The regulatory region and any inserted flanking nucleotides do not code independently for a protein, peptide of functional RNA molecules;

c. The regulatory region solely controls the activity of other sequences that code for protein or peptide molecules or act as recognition sites for the initiation of nucleic acid or protein synthesis.

Pathogen

A pathogen is a virus or microorganism (including its viruses and plasmids, if any) that has the ability to cause disease in other living organisms (i.e., humans, animals, plants, microorganisms).

A microorganism (including viruses) will be subject to regulatory policies regarding pathogens if;

a. The microorganism belongs to a pathogenic species, according to sources identified by the agency, or from information known to the producer that the organism is a pathogen; excepted are organisms belonging to a strain used for laboratory research or commercial purposes and generally recognized as non-pathogenic according to sources identified by a federal agency, or information known to the producer and the appropriate federal agency (an example of a nonpathogenic strain of a species which contains pathogenic strains is *Escherichia coli* K-12; examples of nonpathogenic species are *Bacillus subtilis, Lactobacillus acidohilus,* and *Saccharomyces* species); or

b. The microorganism has been derived form a pathogen or has been deliberately engineered such that it contains genetic material from a pathogenic organism as defined in item a. above. Excepted are genetically engineered organisms developed by transferring a well-characterized, non-coding regulatory region from a pathogenic donor to a non-pathogenic recipient.

"Well-characterized, non-coding regulatory region" means that the producer of the microorganism can document the following:

a. The exact nucleotide base sequence of the regulatory region and any inserted flanking nucleotides;

b. The regulatory region and any inserted flanking nucleotides do not code independently for a protein, peptide, or functional RNA molecules; and,

c. The regulatory region solely controls the activity of other sequences that code for protein or peptide moldecules or act as recognition sites for the initiation of nucleic acid or protein systhesis.

This definition excludes organisms such as competitors or colonizers of the same substrates, commensal or mutualistic microorganisms, or opportunistic pathogens.

The footnote contains the scientific basis for exempting non-coding regulatory regions from the definitions of intergeneric organisms and pathogen.[2]

[2] The BSCC has based the exemption of intergeneric transfers of regulatory regions on their lack of coding capacity for the production of proteins, peptides or functional RNA molecules. It has been recommended by other members of the scientific community that there should be additional exemptions such as ribosomal proteins, ribosomal RNAs and transfer RNAs. The BSCC has chosen to examine these suggestions in more detail during the next few months. At the present the BSCC has excluded:

1. Origins of replications;
2. Ribosome binding sites;
3. Promoters;
4. Operators; and,
5. Terminators.

The basis for these exemptions is as follows. Each of these regulatory elements has no coding capacity for the production of any gene product and therefore does not promote the production of any new material. What these elements are responsible for is the initiation and modulation of nucleic acid synthesis at the specific region where they appear in the chromosome.

Bacterial genes are precisely regulated and this regulation is based on a series of regulatory elements. The principal regulatory unit is the *operon.* Operons are controlled primarily, but not exclusively, through the regulation of the rate of initiation of messenger RNA synthesis. This regulation is based on the interaction of two short nucleotide sequences in the DNA, the *promoter,* which is the site of RNA polymerase binding and the *operator,* which follows closely and acts as an off-on switch for the movement of the polymerase into the structural gene which follows. The function of the operator is to *bind* a cellular repressor protein which is synthesized in response to changing nutritional stimuli. *Terminator* regions are short nucleotide sequences which signal the termination of mRNA synthesis by the polymerase. They act as a signal for the dissociation of the polymerase from the DNA.

Replication of DNA in every biological system that has been examined is initiated at a specific site or group of sites in the chromosome. Those sites have broad specificity and a DNA molecule without the appropriate site will not be replicated. The sites which are critical to the initiation of replication are known as *origins of replication.* These regions are short nucleotide sequences which serve as initiation sites for specific enzyme action during the DNA replication process. For example, in order for mammalian DNA to replicate in bacteria, it must be associated with a bacterial origin of replication and vice versa.

Ribosome binding sites are short nucleotide segments at the beginning of messenger RNA molecules which signal the attachment of ribosomes for the initiation of protein synthesis. Functioning in this role they are not translated into the protein or peptide being processed.

The BSCC is requesting comments on these definitions during the period of sixty days following the date of this notice and specifically seeks comments addressing the following:

1. The suitability and applicability of these definitions to applications involving release into the environment, contained industrial large-scale applications, foods/food additives, drugs, medical devices, and other possible products.

2. Whether combinations of genetic material from organisms that exchange DNA by known physiological processes should be excluded from the definition of intergeneric organisms: i.e., should organisms be excluded which contain intergeneric combinations of certain specified rDNA molecules that consist entirely of DNA segments from different genera that exchange DNA by known physiological processes? As certain rDNA organisms are exempted under section III-D-4 of the NIH guidelines, the question was raised whether these organisms when used in the environment should be similarly exempted from federal product review. This exemption would not, however, exclude from review such "natural exchangers" that are also pathogens or plant pests. In the event that the exclusion of such different species that exchange DNA by known physiological processes is accepted as appropriate, a list of such species combinations that has been maintained and updated by the Office of Recombinant DNA Activities of the National Institutes of Health will be updated, in light of environmental use.

3. What are the most appropriate definitions of "release into the environment" for macro- and microorganisms.

E. International Aspects

The United States seeks to promote international scientific cooperation and understanding of scientific considerations in biotechnology on a range of technical matters. These activities add to scientific knowledge and ultimately contribute to protection of health and the environment.

The United States also seeks to reduce barriers to international trade. U.S. agencies apply the same regulation and approval procedures on domestic and foreign biotechnological products. We are seeking recognition among nations of the need to harmonize, to the maximum extent possible, national regulatory oversight activities concerning biotechnology. Barriers to trade in biotechnological products should be avoided as nations join together in working toward this mutual goal.

The U.S. agencies that have published separate policy statements as part of this notice are committed to the policy described in this section on international harmonization and have incorporated by reference the language in this International Aspects section as part of their respective agency policy statements.

Organization for Economic Cooperation and Development (OECD)

The approach of the comprehensive framework contained in this notice takes into account, *inter alia*, the broad goals described by an Ad Hoc Group of Government Experts convened by OECD in their recent report entitled, *"Recombinant DNA Safety Considerations, Safety Considerations for Industrial, Agricultural and Environmental Applications of Organisms Derived by Recombinant DNA Techniques."* The United States is pleased to have had the opportunity for its experts to work with those of other governments in the preparation of this report. The report includes the following concepts:

Summary of Major Points

Recombinant DNA techniques have opened up new and promising possibilities in a wide range of applications and can be expected to bring considerable benefits to mankind. They contribute in several ways to the improvement of human health and the extent of this contribution is expected to increase significantly in the near future.

The vast majority of industrial rDNA large-scale applications will use organisms of intrinsically low risk which warrant only minimal containment, Good Industrial Large-Scale Practice (GILSP).

When it is necessary to use rDNA organisms of higher risk, additional criteria for risk assessment can be identified and furthermore, the technology of physical containment is well known to industry and has successfully been used to contain pathogenic organisms for years. Therefore, rDNA microorganisms of higher risks can also be handled safely under appropriate physical and/or biological containment.

Assessment of potential risks of organisms for environmental or agricultural applications is less developed than the assessment of potential risks for industrial applications. However, the means for assessing rDNA organisms can be approached by analogy with the existing data base gained from the extensive use of traditionally modified organisms in agriculture and the environment generally. With step-by-step assessment during the research and development process, the potential risk to the environment of the applications of rDNA organisms should be minimized.

I. General Recommendations

1. Harmonization of approaches to rDNA technology can be facilitated by exchanging: Principles or guidelines for national regulations; developments in risk analysis; and practical experience in risk management. Therefore, information should be shared as freely as possible.

2. There is no scientific basis for specific legislation for the implementation of rDNA technology and applications. Member countries should examine their existing oversight and review mechanisms to ensure that adequate review and control may be applied while avoiding any undue burdens that may hamper technological developments in this field.

3. Any approach to implementing guidelines should not impede future developments in rDNA technology. International harmonization should recognize this need.

4. To facilitate data exchange and minimize trade barriers between countries, further developments such as testing methods, equipment design, and knowledge of microbial taxonomy should be considered by both national and international levels. Due account should be taken of ongoing work on standards within international organizations such as: World Health Organization; Commission of the European Communities; International Standards Organization; Food and Agricultural Organization; and, Microbial Strains Data Network.

5. Special efforts should be made to improve public understanding of various aspects of rDNA technology.

6. For rDNA applications in industry, agriculture and the environment, it will be important for OECD Member countries to watch the development of these techniques. For certain industrial applications and for environmental and agricultural applications of rDNA organisms, some countries may wish to have a notification scheme.

7. Recognizing the need for innovation, it is important to consider appropriate means to protect intellectual property and confidentiality interests while assuring safety.

II. Recommendations Specific for Industry

1. The large-scale industrial application of rDNA technology should wherever possible utilize microorganisms that are intrinsically of low risk. Such microorganisms can be handled under conditions of Good Industrial Large-Scale Practice (GILSP).

2. If, following assessment using the criteria outlined in the document, a rDNA microorganism cannot be handled merely by GILSP, measures of containment corresponding to the risk assessment should be used in addition to GILSP.

3. Further research to improve techniques for monitoring and controlling non-intentional release of rDNA organisms should be encouraged in large-scale industrial applications requiring physical containment.

III. Recommendations Specific for Environmental and Agricultural Applications

1. Considerable data on the environmental and human health effects of living organisms

exist and should be used to guide risk assessments.

2. It is important to evaluate rDNA modified organisms for potential risk, prior to applications in agricultural and the environment. However, the development of general international guidelines governing such applications is premature at this time. An independent review of potential risks should be conducted on a case-by-case basis prior to application. Case-by-case means an individual review of a proposal against assessment criteria which are relevant to the particular proposal; this is not intended to imply that every case will require review by a national or other authority since various classes of proposals may be excluded.

3. Development of organisms for agricultural or environmental applications should be conducted in a stepwise fashion, moving, where appropriate, from the laboratory to the growth chamber and greenhouse, to limited field testing and finally, to large-scale field testing.

4. Further research to improve the prediction, evaluation, and monitoring of the outcome of applications of rDNA organisms should be encouraged.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 84N-0431]

Statement of Policy for Regulating Biotechnology Products

AGENCY: Food and Drug Administration.

ACTION: Final policy statement for regulating biotechnology products.

SUMMARY: In the **Federal Register** of December 31, 1984 (43 FR 50878), the Food and Drug Administration (FDA) published a policy statement for regulating biotechnology products. The policy statement was part of a larger document that included an index of U.S. laws related to biotechnology, a description of the policies of the major regulatory agencies that are involved in reviewing the products of biotechnology, a description of a proposed scientific advisory mechanism for assessment of biotechnology issues, and an explanation of how the activities of the Federal agencies involving biotechnology will be coordinated. Of the comments FDA received on the policy statement, most favored the policy statement; some requested further clarification and guidance. The current action constitutes FDA's final policy statement which has been revised in response to the comments.

ADDRESS: Written comments should be submitted to the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Dr. Mary Ann Danello (HF-5), Food and Drug Administration, Room 14-90, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4650.

SUPPLEMENTARY INFORMATION: FDA's policy statement of December 31, 1984 stated the FDA regulation must be based on the rational and scientific evaluation of products, and not on *a priori* assumptions about certain processes. Accordingly, FDA's administrative review of products, including those that employ specialized biotechnological techniques, is conducted in the light of the intended use of a product on a case-by-case basis. FDA believes the agency need not establish new administrative procedures to deal with generic concerns about biotechnology.

These views were supported by the majority of comments received in response to FDA's notice. Thirty-four comments were received, with 12 from manufacturers of regulated products, 16 from associations and universities, and 6 from individuals. A summary of the comments and the agency's response to them follow:

1. Many commenters urged the agency to publish additional "Points to Consider" documents to provide further guidance for biotechnology product applicants. These commenters specifically requested guidance in the area of animal drugs (especially protein drugs) and human foods and food additives.

FDA agrees that "Points to Consider" documents provide useful guidance, especially in areas involving new biotechnology, and will consider developing these documents where appropriate.

2. Related comments raised questions on FDA's general requirements for approving biotechnology products that are animal drugs, human foods, or food additives.

In response to these comments, FDA has amended the animal drug section ("General Requirements for Animal Food Additives and Drugs") to be more informative and has added a new section concerning its policies on human foods and food additives (see "General Requirements for Human Foods and Food Additives").

3. Many comments questioned the need for new or supplemental marketing applications for biotechnology products that are identical to products derived from conventional technology.

The agency has re-examined this issue and continues to believe that, as a general principle, new marketing applications will be required for most products manufactured using new biotechnology. For example, use of recombinant DNA (rDNA) technology has the potential to lead to new structural features in the product, result in product micro-heterogeneity, or introduce new contaminants (e.g., associated with new cell substrates), each of which may affect the safety, efficacy and stability of the product. Because of potential differences in the products resulting from use of recombinant DNA technology, the resulting products may be "new" products requiring separate approval under the applicable statutory provisions. However, each case will be examined separately to determine the appropriate information to be submitted. In some instances complete new applications may not be required. For example, the sponsor of a conventionally produced animal drug product who manufactures an identical or virtually identical product using biotechnology may be required to submit only a supplemental application. However, if the animal drug product manufactured using biotechnology differs significantly from the product manufactured by conventional processes, a complete original application would be required. The agency believes that each product must undergo adequate and appropriate testing and review to ensure that it is safe and effective regardless of the technology employed. Sponsors are urged to communicate with FDA to establish the scope of information required for products of biotechnology.

4. Many comments questioned the need for the proposed review mechanism by a Biotechnology Science Board (BSB). These comments stated that the additional layer of review would cause delays in the product approval process.

A notice published in the **Federal Register** of November 14, 1985 (50 FR 47174) discussed the establishment of the Biotechnology Science Coordinating Committee (BSCC) within the Federal Coordinating Council for Science, Engineering and Technology. That notice addressed various criticisms of the BSB. FDA believes that the new BSCC will facilitate sharing of biotechnology information among agencies and will not delay agency reviews of product applications.

In view of the foregoing, FDA's final policy statement for regulating biotechnology products reads as follows:

Introduction

A small but important and expanding fraction of the products the Food and Drug Administration (FDA) regulates represents the fruits of new technological achievements. These achievements are in areas as diverse as polymer chemistry, molecular biology, and micro-miniaturization. It is also noteworthy that technological advancement in a given area may give rise to very diverse product classes, some or all of which may be under FDA's regulatory jurisdiction. For example, new developments in recombinant DNA research can yield products as diverse as food additives, drugs, biologics, and medical devices.

Although there are no statutory provisions or regulations that address biotechnology specifically, the laws and regulations under which the agency approves products place the burden of proof of safety as well as effectiveness of products on the manufacturer. The agency possesses extensive experience with these regulatory mechanisms and applies them to the products of biotechnological processes. In this notice, FDA proposes no new procedures or requirements for regulated industry or individuals. Rather, the administrative review of products using biotechnology is based on the intended use of each product on a case-by-case basis.

The marketing of new drugs and biologics [1] for human use, and new animal drugs, requires prior approval of an appropriate new drug application (NDA), biological product license, or new animal drug application (NADA). For new medical devices, including diagnostic devices for human use, either a premarket approval application (PMA) or reclassification petition is required. If the device is determined to be substantially equivalent to an already marketed device, a premarket notification under section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act) is required. For food products, section 409 of the act requires preclearance of food additives including those prepared using biotechnology. Section 706 of the act requires preclearance of color additives. The implementing regulations for food and color additive petitions and for affirming generally recognized as safe (GRAS) food substances are sufficiently comprehensive to apply to those involving new biotechnology.

Genetic manipulations of plants or animals may enter FDA's jurisdiction in other ways; for example, the introduction into a plant of a gene coding for a pesticide or growth factor may constitute adulteration of foodstuff derived from the plant, or the use of a new microorganism found in a food such as yogurt could be considered a food additive. Such situations will be evaluated case-by-case and in cooperation with the U.S. Department of Agriculture (USDA), where appropriate.

The Regulatory Process

Congress has provided FDA authority under the act and the Public Health Service (PHS) Act to regulate products regardless of how they are manufactured. Each request for product approval will be considered using the appropriate statutory and regulatory criteria. The following sections summarize general requirements for various kinds of products and address specific comments concerning particular product categories. Individual regulations should be consulted for additional details.

General Requirements for New Drugs and Biologics for Human Use

A new drug is, in general terms, a drug not generally recognized by qualified scientific experts as safe and effective for the proposed use. New drugs may not be marketed unless they have been approved as safe and effective for their intended uses. Clinical investigations on human subjects by qualified experts are a prerequisite for the determination of safety and effectiveness. Sponsors of investigations of new drugs or new uses of approved drugs file a Notice of Claimed Investigational Exemption for a New Drug (IND) to conduct clinical investigations on human subjects. The IND must contain information to demonstrate the safety of proceeding to test the drug in human subjects, including, for example, drug composition, manufacturing and controls data, results of animal testing, training and experience of investigators, and a plan for clinical investigation. In addition, assurance of informed consent and protection of the rights and safety of human subjects is required. FDA evaluates IND submissions and reviews ongoing clinical investigations. Significant changes in the conditions of the study, including changes in study design, drug manufacture or formulation, or proposals for additional studies, must be submitted to FDA as amendments to the IND.

FDA approval of an NDA or an abbreviated New Drug Application (ANDA) is required before the new drug can be marketed. The NDA must contain, among other information, the following:

- A list of components of the drug and a statement of the composition of the drug product;
- A description of the manufacturing and packaging procedures and controls for the drug product;
- A description of the nonclinical studies concerning the drug's pharmacological actions and toxicological effects;
- A description and analysis of each clinical study; and
- A description and analysis of any other data or information relevant to an evaluation of the safety and effectiveness of the drug product, including commercial marketing experience.

NDA holders who intend to market an approved drug under conditions other than those approved in the NDA must submit a supplemental NDA containing clinical evidence of the drug's safety and effectiveness for the added indications. Extensive changes such as a change in formula, manufacturing process, or method of testing differing from the conditions of approval outlined in the NDA may also require additional clinical testing.

Biological products must also be approved by FDA prior to marketing, as required by section 351 of the PHS Act. A biological product is "any virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product * * * applicable to the prevention, treatment, or cure of diseases or injuries of man * * *." Unapproved biological products are regulated under the same regulations as new drugs during the IND phase. Prior to marketing, separate licenses are issued for the manufacturing establishment and the biological product. The manufacturing establishment and the biological product must meet standards (including any FDA standards specific for the product) designed to ensure the safety, purity, potency, and efficacy of the product. To obtain a license, the facility must also pass a prelicensing inspection. Licensed products are subject to specific requirements for lot release of FDA.

Manufacturers of new drugs and biologics must operate in conformance with current good manufacturing practice (CGMP) regulations. These

[1] FDA endorses the BSCC definitions of "intergeneric" (new) organism or "pathogen" found in the preamble, believing that they describe the microorganisms appropriate for review when environmental or agricultural applications of the microorganisms are contemplated (and see pp. 22–25). As discussed below in this notice, "new" drugs, biologics, medical devices, and food additives are defined in the statutes establishing FDA's jurisdiction over such products.

regulations require adequately equipped manufacturing facilities, adequately trained personnel, stringent control over the manufacturing process, and appropriate finished product examination. CGMP's are designed to protect the integrity and purity of the product.

The sponsor's process techniques are also considered in FDA's reviews and communications for the development of appropriate information on which the submission of an NDA, ANDA, or biological product license application would be based. For example, the use of recombinant DNA technology to manufacture new drugs or biological products may result in products that differ from similar products manufactured with conventional methods. Determination of the extent of testing required will depend upon the nature of the particular product. In some instances the molecular structure of the product may differ from the structure of the active molecule in nature. For example, the first human growth hormone manufactured using recombinant microorganisms has an extra amino acid, an amino-terminal methionine; hence, it is an analogue of the native hormone. Such differences could affect the drugs's activity or immunogenicity and, consequently, could affect the extent of testing required.

Another consideration in the review of new drugs or biological products producted by recombinant techniques is whether the manufacturing process includes adequate quality controls. For example, the occurrence of mutations in the coding sequence of the cloned gene during fermentation could give rise to a subpopulation of molecules with an anomalous primary structure and altered activity. This is a potential problem inherent in the production of polypeptides in any fermentation process. As with conventionally produced products, assurance of adequate processing techniques and controls is important in the manufacturing of any biotechnology-produced new drug or biological product. Review of the production of human viral vaccines routinely involves a number of considerations including the purity of the media and the serum used to grow the cell substrate, the nature of the cell substrate, and the characterization of the virus. In the case of live viral vaccine, the final product is biologically active and is intended to replicate in the recipient. Therefore, the composition, concentration, subtype, immunogenicity, reactivity, and nonpathogenicity of the vaccine preparation are all considerations in the final review, whatever the techniques employed in "engineering" the virus. However, special considerations may arise based upon the specific technology employed. For example, a hepatitis B vaccine produced in yeast (via recombinant DNA techniques) would be monitored for yeast cell contaminants, while distinctly different contaminants would be of concern in a similar vaccine produced from the plasma of infected patients.

Nucleic acids or viruses used for human gene therapy will be subject to the same requirements as other biological drugs. It is possible that scientific reviews of these products will also be performed by the National Institutes of Health.

To provide guidance to current or prospective manufacturers of drugs and biological products, the FDA has developed a series of documents describing points that manufacturers might wish to consider in the production and testing of products. The "Points to Consider" documents generated to date include several topics: interferon, monoclonal antibodies, products of recombinant DNA technology, and the use of new cell substrates. These "Points to Consider" documents are available from the agency upon request from the Office of Biological Investigational New Drugs (301–443–4864). FDA plans to develop additional "Points to Consider" in areas of scientific interest to manufacturers of new drugs and biologics.

General Requirements for Animal Food Additives and Drugs

Animal food additives and drugs are subject to similar mandatory requirements of the act as the like products for use in humans. Animal biologics, however, are licensed by the U.S. Department of Agriculture (USDA) under the authority of the Virus-Serum-Toxin Act of 1913. Questions as to whether a product is an animal biological subject to USDA licensure, or a new animal drug to be regulated by FDA are referred to a standing committee of representatives from USDA and FDA.

New animal drugs must go through the Investigational New animal Drug (INAD) and New Animal Drug Application (NADA) process, a procedure similar to that required for human drugs, as discussed earlier. However, INAD regulations do not require advance agency approval for clinical investigations for the drug, although authorization is required for use of edible products derived from food-producing animals in which the drug has been used. The data must be specific for each animal species for which the drug is intended. For NADA approval, it must be shown that the product is safe and effective when used in accordance with approved label directions. Also, it must be shown that those drugs which are intended for use in food-producing animals and used in accordance with approved label directions, do not accumulate as unsafe residues in the edible tissues of the animal at the time of slaughter. Moreover, the manufacturer must submit acceptable methods for measurement of any drug residue in edible tissues. Further, animal drugs, including premixes for use in medicated feeds and medicated feeds, must be manufactured in conformance with CGMPs. Substances that are used in animal feeds, other than drugs, and that are produced by recombinant DNA technology, are considered to be food additives and require approval of a separate food additive petition (FAP), even though a similar substance is currently approved as a food additive.

There have been questions about the requirement of an orginal application for a biotechnology product, even when the product is identical to a currently approved animal drug held by the same applicant. FDA's Center for Veterinary Medicine (CVM) has determined that, when the new substance produced by biotechnology is identical or virtually identical to an approved substance produced by conventional technology, only a supplemental application is necessary. Of course, in this instance the sponsor of the biotechnology product must also be the sponsor of the conventionally produced product. If, on the other hand, the new substance produced by biotechnology is significantly different from that produced by conventional means, an original application will be needed.

Two examples, each involving the adoption of rDNA technology as an alternative means of producing a substance that is currently the subject of an approved NADA, will illustrate. In the first example, the drug is (or appears to be) unchanged by the new production method. Under the current regulations, such a departure in manufacturing procedure requires a supplemental application which requires approval before implementation. The supplement would be a Category II supplement under CVM's supplemental policy in that it involves a revised method of synthesis or fermentation for the new drug substance. However, in accordance with the CVM's supplemental policy the underlying safety and effectiveness data

supporting the original NADA usually would not be reviewed (for compliance with contemporary standards) since there is likely no increased risk of human exposure to the drug. Data may be required to demonstrate the new animal drug product is essentially biologically equivalent to the drug product for which approval has already been granted. Approval of such a supplemental NADA is not required to be published in the **Federal Register.**

In the second example, a new method of manufacture changes the molecular structure or chemcial composition of the active ingredient. Such a change in the identity of the new animal drug normally will require an original new animal drug application and subsequent publication of a notice of approval in the **Federal Register.** Ordinarily, an original NADA requires complete safety and effectiveness studies, meeting contemporary standards. However, reference to data in another NADA sometimes suffices to support a separate NADA approval, where the existing NADA is owned by the applicant of the new NADA, or where the new applicant obtains authorization to refer to another NADA. In this case, reference might be made to data contained in the NADA supporting approval of the drug as produced by conventional means.

It may be possible to regard the new application as if it were a Category II supplement. This finding would be dependent upon data showing the new substance to be sufficiently similar to the original in terms of its pharmacology, toxicology, bioequivalence, and metabolism.

Thus, regardless of the type of application required, there is no legal requirement for the generation of new safety and effectiveness data if the applicant has access to previously submitted data, and there is no scientific need.

General Requirements for Medical Devices

Medical devices for human use are regulated by requirements of the act as amended by the Medical Device Amendments of 1976. In general, a device is a health care product that does not achieve any of its principal intended purposes by chemical action in or on the body or by being metabolized. Devices include diagnostic aids such as reagents, antibiotic sensitivity discs, and test kits for *in vitro* diagnosis of disease.

The act establishes three classes of devices: Class I (general controls), class II (performance standards), and class III (premarket approval). Classification of a device is determined by the level of regulatory control needed to provide reasonable assurance of the safety and effectiveness of the device. A class I device is a device for which the "general controls" authorized by or under various sections of the act are sufficient to provide reasonable assurance of the safety and effectiveness of a device. A class II device is a device for which general controls by themselves are insufficient to provide reasonable assurance of the Safety and effectiveness of the device, for which there is sufficient information to establish a performance standard to provide such assurance, and for which it is therefore necessary to establish a performance standard to provide reasonable assurance of its safety and effectiveness. A class III device is a device that cannot be classified into class I or class II and that is purported or represented to be for use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human, health, or that presents a potential unreasonable risk of illness or injury. Premarket approval obtained in accordance with section 515 of the act is required to provide reasonable assurance of the safety and effectiveness of a class III device.

Before a manufacturer may introduce into commerce any medical device it has not previously marketed, the manufacturer must submit to FDA a premarket notification. This notification requirement is designed to assure that manufacturers do not intentionally or unintentionally circumvent the automatic classification into class III of devices not on the market prior to enactment of the Medical Device Amendments and not substantially equivalent to pre-amendment devices.

A new device, that, is one not substantially equivalent to a pre-amendments device, remains a class III device requiring FDA approval of a premarket approval application (PMA) unless FDA reclassifies it into class I or class II, usually in response to a manufacturer's petition. In the premarket approval process the manufacturer must establish by valid scientific evidence that the device is safe and effective for its intended use. This evidence usually is data from clinical investigations.

For a significant risk device, as defined in FDA's regulations, the sponsor must submit an application to FDA for approval to conduct a clinical investigation. This application seeks an Investigational Device Exemption. When the manufacturer believes that there are sufficient data to establish the safety and effectiveness of its device, the manufacuter files a PMA.

General Requirements for Foods

Several sections of the Food, Drug and Cosmetic Act apply to the Agency's regulation of food. No particular statutory provision or regulation deals expressly with food produced by new biotechnology. Accordingly, when confronted by an issue concerning the regulation of food produced by new biotechnology, the Agency will apply the relevant statutory or regulatory provisions. Most issues concerning the safety of a food will involve the application of either section 402(a)(1) or section 409 of the Act.

Section 402(a)(1) of the Act provides, in part, that a food is adulterated if it bears or contains any poisonous or deleterious "added substance" which may render it injurious to health." Courts have agreed with the agency's interpretation of this section that any substance that is not an inherent constituent of food may be regulated as an "added substance." *See,* for example, *United States* v. *Cartons of Swordfish,* 395 F. Supp. 1194 (S.D.N.Y. 1975). Furthermore, if the quantity of the constituent exceeds the amount that would normally be present because of some technological adjustment to the product, that excess quantity may also be viewed as "added substance" within the meaning of the section. *See United States* v. *Anderson Sea Foods, Inc.,* 622 F.2d 157 (5th cir. 1980). Thus, section 401(a)(1) applies to most of the harmful substances that may occur in human food. For example, is a food produced by new biotechnology contains a higher level of a substance than it might ordinarily have, then that level "may be injurious to health" and the agency could regulate the product under section 402(a)(1). Similarly, if a food produced by new biotechnology contains, as a result of the production process, a harmful or deleterious substances not contained ordinarily in the food, the food could be in violation of the section.

The other primary statutory provisoins that FDA relies upon in determining the safety of food and food constituents are sections 201(s) and 409, the food additive provisions of the Act. The definition of food additive appears in section 201(s) of the Act and includes both artificial and natural substances. The definition provides that:

> the term food additive means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including

any source of radiation intended for any such use), if such substance is not generally recognized as safe by qualified experts.

If the substance is generally recognized as safe (GRAS) for a given food use, the product is not a food additive.

Comments questioned whether a substance (including microbes) that is GRAS could lose its GRAS status solely because it was produced or modified by new biotechnology. The answer is yes, if the substance (and its contaminants) has been altered in such a way that it can no longer be generally recognized by qualifed experts to be safe. In this instance, the substance would be a food additive and the provisions of section 409 would apply. Section 409 provides that in order to be lawfully used in food, a food additive must be the subject of an approved food additive regulation, published upon approval of a food additive petition. The FDA may not approve a food additive regulation until certain basic evidentiary criteria are met. Most important of these is that the additive must be shown to be safe under the conditions that it will be used. This requires a demonstration to a reasonable certainty that the additive will not adversely affect the health of consumers.

FDA anticipates that the techniques of new biotechnology used in producing food will, for the most part, involve rDNA and microbial isolation. The agency applies certain general principles that it will follow in determining the safety of foods produced by such techniques.

When determining the safety of food produced by rDNA techniques, the agency takes into consideration, but is not restricted to, whether:

1. The cloned DNA as well as the vector used are properly identified;
2. The details of the construction of the production organism are available;
3. There is information documenting that the inserted DNA is well-characterized [2] and free from sequences that code for harmful products, and
4. The food produced is purified, characterized, and standardized.

When determining the safety of food produced by microbial isolation, the agency will take into consideration, but is not restricted to, whether:

1. The microbial isolate used for production is identified taxonomically, and if the strain of the isolate has been genetically manipulated, whether each strain contributing genetic information to the production strain is identified;
2. The cultural purity and genetic stability of isolate has been maintained;
3. Fermentation has been performed with a pure culture and monitored for purity;
4. The microbial isolate used for production also produces antibiotics or toxins;
5. The isolates are pathogenic;[3] and
6. Viable cells of the production strain are present in the final product.

As a general rule, the extent of testing required on a food product produced by biotechnology will depend upon many factors, including the novelty of the substances used to produce the food (e.g., whether a substance is an "intergeneric" organism, as defined by the BSCC definitions in the preamble), the purity of the resulting product, and the estimated consumption of the product.

The agency will require that the final product intended for commercialization be the article tested. A complete discussion of FDA's toxicology requirements is found in the FDA publication, "Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives Used in Food." This publication is available through the National Technical Information Service (publication # PB 83-170696) 5285 Port Royal Road, Springfield, VA 22161. Questions concerning the publication can be directed to Dr. Alan M. Rulis in the Center for Food Safety and Applied Nutrition (CFSAN) at (301) 472-5676.

[2] As defined by the BSCC definitions in the preamble, "well-characterized" means that the producer can document the exact nucleotide sequence of the insert and any flanking nucleotides.

[3] A pathogen is a virus or microoganism (including its viruses and plasmids, if any) that has the ability to cause disease in other living organisms (i.e., humans, animals, plants, microorganisms).

A microorganism will be included within this definition if:

a. The microorganism belongs to a pathogenic species, according to sources identified by the agency, or from information known to the producer that the organism is a pathogen; excepted are organisms belonging to a strain used for laboratory research or commercial purposes and generally recognized as nonpathogenic according to sources identified by a federal agency, or information known to the producer and the appropriate federal agency; an example of a nonpathogenic strain of species which contains a pathogenic strain is Escherichia coli K-12; examples of nonpathogenic species are Bacillus subtilis, Lactobacillus acidophilus, and Saccharomyces species; or

b. The microorganism has been derived from a pathogen or has been deliberately engineered such that it contains genetic material from a pathogenic organism as defined in item a. above. Excepted are genetically engineered organisms developed by transferring a well-characterized, non-coding regulatory region from a pathogenic donor to a non-pathogenic recipient.

"Well-characterized, non-coding regulatory region" means that the producer of the microorganism can document the following:

a. The exact nucleotide base sequence of the regulatory region and any inserted flanking nucleotides;

b. The regulatory region and any inserted flanking nucleotides do not code independently for protein, peptide, or functional RNA molecules; and,

c. The regulatory region solely controls the activity of other sequences that code for protein or peptide molecules or act as recognition sites for the initiation of nucleic acid or protein synthesis.

This definition excludes organisms such as competitors or colonizers of the same substrates, commensal or mutualistic microorganisms, or opportunistic pathogens.

Obligations Under the National Environmental Policy Act

All premarketing approvals of FDA-regulated products are subject to the requirements of the National Environmental Policy Act (NEPA) as defined by the Council on Environmental Quality's regulations (40 CFR Parts 1500-1508) and as further described by FDA's NEPA-implementing procedures (21 CFR Part 25, final rule published April 26, 1985; 50 FR 16636). For new products or major new uses for existing products, these procedures ordinarily require the preparation of an environmental assessment. An environmental impact statement is required if the manufacture, use, or disposal of the product is anticipated to cause significant environmental impacts.

International Aspects

FDA is committed to the policy described in the section entitled "International Aspects" in the Office of Science and Technology Policy General Preamble, published in today's **Federal Register.**

ENVIRONMENTAL PROTECTION AGENCY

[OPTS-00049A]

Statement of Policy; Microbial Products Subject to the Federal Insecticide, Fungicide, and Rodenticide Act and the Toxic Substances Control Act

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice describes how EPA is addressing certain microbial products of biotechnology under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Toxic Substances Control Act (TSCA). The notice outlines EPA's plan for review of microbial pesticides under FIFRA with particular emphasis on small-scale field testing of genetically engineered, nonindigenous, and pathogenic microbial pesticides. It also announces EPA's policy for addressing new microbial products that fall under TSCA authority. This includes EPA's interpretation of the new chemical premanufacture notification (PMN)

provisions of TSCA section 5 for new genetically engineered microorganisms used for commercial purposes, and the Agency's intentions to develop, under TSCA, a significant new use rule for pathogenic microorganisms; a rule modifying the PMN research and development exemption so that small scale field testing of microorganisms for TSCA purposes is subject to PMN; a section 8(a) reporting rule for other microorganisms prior to their release in the environment; and section 5(h)(4) exemptions as appropriate.

DATES: The following policies and requirements announced in this notice are effective June 26, 1986: (1) The notification and reporting requirements for small-scale field tests and the experimental use permit and registration requirements for microbial pesticides under FIFRA, described in Unit II.D of this notice; (2) premanufacture notice requirements under TSCA for "new" microorganisms, as defined in Unit III.C.1 and Unit IV of this notice, except those produced only in small quantities solely for research and development; (3) TSCA section 8(e) reporting requirements for information on substantial risks posed by microorganisms subject to TSCA, as described in Unit III.C.5 of this notice; and (4) FIFRA section 6(a)(2) reporting requirements for information on unreasonable adverse effects posed by microbial pesticides. EPA requests that persons voluntarily comply with other policies announced in this notice, as summarized in Unit I.C, until rules implementing them are promulgated.

ADDRESS: Comments on this EPA notice should be identified by Docket Number OPTS-00049A and addressed to: Document Control Officer (TS-790), Office of Toxic Substances, Environmental Protection Agency, Rm. E-201, 401 M, St. SW., Washington, DC 20460.

Information submitted as comments on this EPA notice may be claimed confidential by marking any part or all of that information as "Confidential Business Information." Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR Part 2. A sanitized copy of any material containing Confidential Business Information must be provided by the submitter for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Comments received on this notice, except those containing Confidential Business Information, will be available for review and copying from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays, in the TSCA Public Information Office, Rm. E-107 at the address given above.

FOR FURTHER INFORMATION CONTACT: For general information including copies of this EPA notice and related materials: Edward A. Klein, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Rm. E-543, 401 M St., SW., Washington, DC 20460,Toll-free: (800-424-9065), in Washington, DC: (202-554-1404), outside the USA: (Operator 202-554-1404).

For technical information regarding the FIFRA section of the EPA policy:

By mail: Frederick S. Betz, Hazard Evaluation Division (TS-769C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

Office location and telephone number: Rm. 1128, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA (703-557-9307).

For technical information regarding the TSCA sections of the EPA policy: Anne K. Hollander, Office of Toxic Substances (TS-794), Environmental Protection Agency, Rm. E-511, 401 M St., SW., Washington, DC 20460 (202-382-3852).

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I. Overview

A. Purpose

For centuries, humans have used organisms to generate commercial products or to perform useful functions. During the last decade, advances in the biological sciences have increased the ability of humans to change or combine the inherited characteristics of microorganisms, plants, and animals. These advances, along with more traditional genetic engineering and biological techniques, are expected to lead to a wide variety of useful products. Among these are microorganisms that will be used to degrade toxic pollutants, leach minerals, enhance oil recovery, produce industrial chemicals, and act as pesticides. As with chemicals used for the same types of purposes, many of these microorganisms will be reviewed by EPA for potential health and environmental risks.

Specifically, EPA reviews and may register pesticide products under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and reviews chemical substances (except those used as pesticides, foods, food additives,

cosmetics, drugs, and medical devices) under the Toxic Substances Control Act (TSCA). EPA's Office of Pesticides and Toxic Substances (OPTS) is responsible for implementing both FIFRA and TSCA.

This notice describes how EPA plans to address microbial products that are subject to FIFRA and TSCA, and explains the scope of coverage and procedures for review of these products under both statutes. The following questions are addressed in this notice:

1. What microbial products are subject to review under FIFRA and how will they be reviewed? (Unit II)

2. What microbial products are subject to review under TSCA and how will they be reviewed? (Unit III)

3. What definitions will be used to identify the products that will be addressed by the appropriate statute? (Unit IV)

In reviewing products, the Agency is required under both FIFRA and TSCA to consider the potential benefits to society as well as any potential risks. EPA will take both risks and benefits into account in its regulatory decisions concerning these products, and will implement the two statutes in as consistent a fashion as possible within statutory constraints.

B. Background

1. *December 1984 proposal.* EPA issued for comment a "Proposed Policy Regarding Certain Microbial Products" as part of the Office of Science and Technology Policy's "Proposal for a Coordinated Framework for Regulation of Biotechnology." This proposal was published in the **Federal Register** of December 31, 1984 (49 FR 50880) and is hereafter referred to as the "December 84 notice." Briefly, in the December 84 notice EPA proposed a mechanism for review of genetically engineered and nonindigenous microbial pesticides under FIFRA. It also described how EPA proposed to address certain genetically engineered microorganisms subject to the new chemical substance premanufacture notification (PMN) provisions of section 5 of TSCA.

2. *Comments on the December 84 notice.* EPA received comments on the December 84 notice from 68 organizations and individuals. All the comments received by EPA are available for review and copying from 8 a.m. to 5 p.m. Monday through Friday, except legal holidays, in the TSCA Public Information Office, Rm. E-107, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

The Agency has carefully evaluated these comments. Several of the proposed policies set forth in the December 84 notice have been revised or clarified in this notice in response to these comments and as a result of the regulatory experience EPA has gained over the past year.

One of the most frequent comments addressed EPA's authority under TSCA and FIFRA. The Agency has continued to evaluate the extent and limit of its statutory authority and has concluded that TSCA and FIFRA provide sufficient authority for the Agency to meet its goals and responsibilities in regulating biotechnology products. However, some new regulations will be required and others will have to be modified in order to fully implement certain aspects of EPA's policies. These regulations and modifications are discussed in Units II and III of this notice.

Numerous commenters addressed the scope of EPA's policy and raised questions about which microbial products are subject to TSCA and FIFRA. In Units II.B, and III.B, the Agency provides detailed explanations of which microorganisms are and are not subject to FIFRA and TSCA, and from among the products that are subject, which are subject to regulatory review prior to any environmental application.

Many commenters expressed concern that the Agency was relating a microorganism's potential for risk to the process by which it was made, particularly in the definition of which microorganisms are "new" and therefore subject to PMN under TSCA. First, commenters suggested that the process by which an organism was modified was too indirect as an indicator of its newness. They pointed out that while certain processes can be used to produce new combinations of traits in microorganisms, their use does not necessarily mean that new combinations of traits have been formed. Second, the process-based approach was believed to be an insufficient indicator of risk, because genetic engineering processes do not necessarily produce organisms that present risks, nor are non-engineered organisms necessarily safe. Finally, because the process-based approach would single out certain techniques for regulation, it would result in market distortions that favored the more traditional techniques even though the newer techniques could be as safe or safer.

After reviewing the comments, the Agency considered a number of alternatives to the "process-based" approach. In choosing among these alternatives, EPA carefully considered how well the options approximated risk (there was uncertainty with all the options in this respect), whether they could be implemented and enforced through criteria that were unambiguous to all affected persons, and (in the case of organisms subject to TSCA) the TSCA mandate to review "new" substances. The alternative EPA has chosen gives particular attention, under both FIFRA and TSCA, to microorganisms that (1) are used in the environment, (2) are pathogenic or contain genetic material from pathogens, or (3) contain new combinations of traits (e.g., organisms that are genetically modified to contain genetic material from dissimilar source organisms and organisms that are nonindigenous). EPA believes these categories have sufficiently high potential for widespread exposure, adverse effects, or uncertainty concerning potential effects to deserve particular regulatory scrutiny. This approach takes a significant step towards separating products on the basis of potential risk.

The Agency also received comments on the information and data to be submitted by companies filing notifications of intent to conduct field tests with certain microbial pesticides. These requirements have been clarified and additional references have been cited in the FIFRA unit of this notice that should provide useful guidance on what information to submit. The TSCA unit contains similar guidance on the submission of information.

Finally, several commenters addressed issues pertaining to confidential business information (CBI). Some expressed concern that CBI be adequately protected from disclosure, while others stressed the need for public access to information on new biotechnology products. EPA has summarized its position with respect to CBI and public disclosure later in this overview (Unit I.G).

A background document providing more detail on the Agency's response to comments on the December 84 notice has been placed in the public record for this notice and is available in the TSCA Public Information Office (address listed in Unit VI of this notice).

C. Summary of EPA Policy

This notice focuses on oversight and review procedures for microorganisms that are subject to FIFRA or TSCA. Microorganisms intended for use as pesticides are subject to FIFRA, and many microorganisms intended for general commercial and environmental applications (e.g., metal leaching, pollutant degradation, enhanced nitrogen fixation) are subject to TSCA. This notice addresses the rationale for various requirements and provides guidelines for compliance.

Specifically, EPA's policies that apply to microbial products subject to FIFRA or TSCA jurisdiction will include the following specific requirements:

1. Microorganisms deliberately formed to contain genetic material from dissimilar source organisms (inter-generic) will be subject to review before any environmental releases, including small-scale field testing and other environmental research and development (R&D). Under the statute, those that are subject to TSCA and used in closed systems (i.e., never intentionally released to the environment) must be reported before they are manufactured for non-R&D commercial purposes. However, EPA is considering promulgating a rule to exempt certain contained uses from this requirement.

2. Microorganisms formed by genetic engineering other than inter-generic combinations will be subject to the following provisions: (a) if any source organism is a pathogen, the resulting microbial products are subject to review under FIFRA or TSCA prior to any environmental release, except if used solely for non-pesticidal agricultural uses, in which case they are subject only to U.S. Department of Agriculture (USDA) review (see the USDA notice in this **Federal Register**) (b) if source organisms are not pathogens, the resulting microbial products are subject to abbreviated review under FIFRA (if they are pesticides) before any small-scale environmental release, or will be subject to the reporting requirements of sections 8 (a) and (e) of TSCA.

3. Nonengineered microorganisms: (a) indigenous pathogens will be reviewed under FIFRA or TSCA prior to use on greater than 10 acres of land and greater than 1 acre of water, except those that are solely for non-pesticidal agricultural purposes, which will be subject only to USDA authority; (b) nonindigenous pathogens will be reviewed under FIFRA prior to any environmental release, and under TSCA prior to release at greater than 10 acres, unless they are pathogens used solely for non-pesticidal agricutural purposes in which case they will be reviewed by USDA (see USDA notice in this **Federal Register**); (c) nonindigenous microbial pesticides that are not pathogens will be subject to abbreviated review under FIFRA before any small scale environmental release; (d) indigenous microbial pesticides that are not pathogens will be reviewed under FIFRA prior to use on greater than 10 acres.

4. All other microorganisms used or intended for use as pesticides and not covered in Unit I.C. 1 through 3, regardless of source, mode of action, or method of manufacture will be reviewed under FIFRA prior to use on greater than 10 acres unless exempted by regulation.

5. Manufacturers and importers of microorganisms under TSCA, if they are not otherwise subject to review, will be required to submit general information, before environmental release, that the Agency can use to monitor environmental uses and to determine if additional requirements are necessary in the future. EPA will gather such information by means of a TSCA section 8(a) reporting rule.

6. Manufacturers and importers of all microorganisms subject to TSCA must report any information on substantial risks under TSCA section 8(e). Registrants of microbial pesticides must report any information regarding unreasonable adverse effects of the pesticide on the environment under FIFRA section 6(a)(2).

A table at the end of Unit I summarizes the policies for prior notification and review of microorganisms applied in the environment.

This policy is immediately effective for microbial pesticides under FIFRA and for "new" microorganisms subject to premanufacture notification under TSCA. Implementing other aspects of the policy for TSCA substances, however, will require rulemaking. Until final rules are effective, EPA expects manufacturers to comply with most aspects of the policy voluntarily. The one exception is that manufacturers of microorganisms, described in Unit I.C.5, that are excluded from other TSCA notification requirements are not expected to report until a final section 8(a) rule is promulgated.

This notice also describes the types of information EPA expects to receive from persons subject to these policies to permit an evaluation of possible risks. EPA will determine specific information needs on a case-by-case basis, and will frequently use non-Agency experts with specific knowledge of the relevant microorganisms and uses to assist in reviews. In addition, EPA is establishing a biotechnology Science Advisory Committee (SAC) to provide peer review of specific cases and advice on technical issues. The SAC will be composed of non-Agency scientists and members of the lay public. More information on the SAC may be found in Unit I.F.

Although many of the policies described in this notice are immediately effective, the Agency recognizes that biotechnology is a repidly developing field and that newly available information may affect the judgments underlying these policies. Accordingly, EPA recognizes that modifications of these policies may be necessary in the future, and it is willing to make such modifications as may be appropriate. Therefore, EPA encourages all interested persons to provide comments on the policies described in this notice. Comments should be submitted to the address provided at the beginning of this EPA notice. The public will have additional opportunities for comment when the Agency proposes rules for those parts of its policy that require rulemaking procedures. Thse parts are specifically indicated in Units II and III.

D. Rationale for Approach

This unit provides a discussion of EPA's rationale for giving special focus to environmental release, pathogens, and microorganisms with new characteristics (e.g., containing genetic material from dissimilar source organisms or nonindigenous organisms).

1. Environmental releases. Physical containment can be used to mitigate undesirable or unexpected characteristics of a microorganism by providing the means to control a microorganism's growth, reproduction, and exposure to other organisms. However, microorganisms meant to be released in the environment are not subject to this control mechanism. Although many microorganisms will be biologically contained, that is, they will have existing and inherent limitations on their growth and survival, some of them may reproduce and thereby increase in number in the environment beyond the amounts originally released. Some will also have independent mobility, or may be spread beyond the area in which they are used. Thus, to ensure that environmental releases of microorganisms do not pose unreasonable adverse effects, the Agency has determined that it should review and evaluate proposals for certain environmental releases before they are allowed to proceed. The microorganisms to be subject to review before any environmental release are described in the following paragraphs, and in Units II and III of this notice.

The Agency acknowledges the difficulty of defining environmental release. For now, the Agency's approach will focus on when an organism is considered to be contained rather than when it is released. Guidance is provided in Unit IV on how to determine whether a microorganism is considered to be contained. The definition of environmental release will be refined in subsequent rulemaking activities.

2. *Pathogenic microorganisms.* Given their ability to cause disease in plants,

animals, humans, and microbes, EPA generally believes pathogenic microorganisms should be reviewed before they are released in the environment.

As used in this notice, a "pathogen" is a microorganism that has the ability to cause disease in living organisms. This includes previously documented pathogens, and microorganisms deliberately formed to contain genetic material from pathogens (e.g., through genetic engineering techniques). A complete discussion of the definition of pathogenicity is included in Unit IV, as well as guidance to aid in the determination of whether a particular microorganism falls within the scope of the EPA policies that address pathogens.

Pathogens are a clearly defined category of organisms known to cause adverse effects. In addition, because of the increased uncertainty about behavioral changes that may be associated with genetically engineered pathogens, the Agency has decided to review genetically engineered pathogens prior to any environmental release (including small-scale field testing). However, the Agency will defer review of nonengineered indigenous pathogens until they are used in larger scale applications (greater than 10 acres), because ample experience indicates that nonengineered, indigenous pathogens are sufficiently well controlled by natural mechanisms in small-scale environmental applications. Further, the Agency will not review pathogens used solely for non-pesticidal agricultural purposes (except those formed through inter-generic combinations, which are "new") because these are adequately reviewed by the USDA (see the USDA notice in this **Federal Register**).

The Agency's decision to focus on pathogens does not mean that EPA has concluded that nonpathogens are necessarily safe or that all pathogens present unreasonable risks. In fact, the Agency expects to identify widely varying degrees of risk among different uses of pathogens. It should be clear that other considerations besides pathogenicity will affect the evaluation of risk, e.g., functions of the recombined genes, possibilities for genetic transfer, environmental fate, and potential competition with other organisms. When other considerations indicate that it is appropriate, the Agency will consider excluding specific categories of pathogens from review, or may provide guidance that would limit the information requirements associated with its reviews of pathogens. As explained in Unit IV, the Agency has already exempted from review as pathogens organisms that incorporate only certain genetic material from pathogens.

3. *Microorganisms with new characteristics.* A third factor that makes potential adverse effects of microorganisms less predictable is the existence of new traits or characteristics. These traits may be new to the organism, or new to the environment in which the organism is released.

a. *Microorganisms having significant potential to exhibit new traits.* Modern genetic engineering techniques permit genetic material to be intentionally combined in organisms that would not normally share that genetic material. Some of these genetically engineered microorganisms may exhibit new or altered traits affecting, for example, their survivability, host range, substrate utilization, competition with other organisms, or protein or polysaccharide production. In some cases such microorganisms may be able to evade or overcome natural controls on their growth, or controls on their ability to cause adverse effects. In many other cases, their natural hardiness will be reduced.

In addition to the possibility that certain engineered organisms may exhibit new traits, if they are released they may be transported through natural dispersal mechanisms to other areas in the environment that have not previously contained organisms having these new combinations of traits.

Because of these considerations, EPA's policies will give particular regulatory attention to organisms that have a significant probability of exhibiting a new trait or combination of traits (standards for this are explained below). This approach accomplishes two important objectives. First, it identifies a group of microorganisms whose behavior in the environment poses significant uncertainty and thus warrants regulatory review. Simultaneously, it provides a way of defining "new" microorganisms that are subject to PMN requirements under TSCA (see Unit III.C.1).

EPA's policy, specifically, focuses on microorganisms that have been deliberately altered to contain genetic material from dissimilar source organisms, because such organisms are more likely to exhibit new combinations of traits and their behavior is therefore less predictable. Given this conceptual basis, the question then becomes how dissimilar two organisms must be before combinations of genetic material between them are likely to produce "new combinations of traits."

Based on the following considerations, EPA has decided that inter-generic combinations (combinations from source organisms of different genera) but not intra-generic combinations (source organisms from the same genus) are sufficiently likely to result in new combinations of traits that they should be given special attention. First, combinations of genetic material from microorganisms from different genera are more likely to result in new traits than combinations of genes from microorganisms within the same genus. Also, while genetic exchange occurs naturally and somewhat commonly among many microorganisms, it is more likely to occur in nature within a single genus than across many different genera (Refs. 2, 12, 13). Finally, genus designations provide a practical criterion for administrative and regulatory purposes.

The Agency has decided to exclude certain combinations from special consideration as inter-generic organisms. Excluded are inter-generic combinations in which the genetic material added to the recipient microorganism consists only of well-characterized, non-coding regulatory regions. The resulting organisms do not possess new combinations of traits; rather, they exhibit quantitative changes in preexisting traits. In addition, if experience or data indicate that certain other inter-generic combinations warrant exclusion, the Agency will use the appropriate statutory or policy mechanisms under FIFRA and TSCA to waive certain requirements for reviewing them. For example, EPA is considering exempting from PMN review under TSCA those inter-generic combinations used only in physically contained systems.

Although EPA considers intra-generic combinations to be less likely to produce new combinations of traits than inter-generic combinations, the Agency realizes that science provides no absolute standard for such distinctions. Nevertheless, EPA believes the approach it has adopted is practical and facilitates the identification of those microorganisms that should be subject to special attention and also that should be considered "new" under TSCA. If experience reveals that intra-generic combinations that could cause adverse effects will be developed, the Agency will modify its policies to require review of these products.

Unit IV contains more detailed guidance for determining if a given microorganism is the result of an inter-generic combination. The determinations are based on taxonomic

designations of organisms. The Agency is aware that microbial taxonomy is a dynamic and often controversial science (Refs. 4, 18) and that new information concerning microorganisms' properties and interrelationships will alter taxonomic designations. However, the Agency believes that its procedures can be sufficiently flexible to accommodate the developments that will occur, and that there are many significant advantages to using taxonomic standards. These advantages are discussed in more detail in Unit IV.

b. *Nonindigenous microorganisms.* Another category of organisms that are likely to exhibit traits new to an environment is nonindigenous microrganisms. Application of nonindigenous microorganisms in the environment could pose a high degree of uncertainty with respect to their behavior. Experience shows that scientists cannot always accurately predict how such organisms will behave in their new environment (Ref. 15, 16). It can be difficult to predict whether a nonindigenous microorganism will be subject to the physical and biological control factors present in the environment where it is to be introduced. In a small number of cases, nonindigenous pathogens such as the chestnut blight fungus and the Dutch elm disease fungus have caused significant adverse effects. As a result, there exist today regulations that govern the intentional movement of some, but not all, nonindigenous species (e.g., the Plant Pest Act administered by USDA). EPA believes that nonindigenous microorganisms whose uses are covered by FIFRA should be subject to Agency review and evaluation before they are released in the environment, to minimize the uncertainties with respect to their behavior. However, EPA does recognize that small-scale use of certain nonindigenous microbial pesticides (i.e., pathogens) may pose greater potential risk than others, and has accordingly adopted abbreviated review procedures for small-scale use of nonpathogenic nonindigenous microbial pesticides. Unit II addresses these issues, and Unit IV provides guidance on determining whether a microorganism is nonindigenous.

E. Explanation of Jurisdiction—EPA and USDA

Both EPA and USDA seek to assure the safety of microbial products and yet minimize impediments to intellectual and economic advances in biotechnology. Because some of the statutes the agencies administer entail overlapping responsibilities, the two agencies are eliminating duplicative requirements wherever possible and coordinating their reviews.

Where allowed by statute, EPA and USDA have sought to eliminate overlapping reviews altogether. This notice reflects many instances where this has been done. Where overlaps could not be avoided, the agencies have established mechanisms for coordinating their reviews. EPA and USDA will identify principal liaisons who will have the responsibility to share information, coordinate data requests, and keep one another informed of communications with submitters. Also, the agencies will form a coordinating committee to meet periodically and work out general coordination problems that may transcend specific reviews. Finally, the National Biological Impact Assessment Program that has been established within USDA will provide a common resource of scientists available to both agencies to review procedures, protocols, and projects on an advisory basis.

Submitters are encouraged to contact either agency if they have jurisdictional questions, but general guidelines are described below.

First, inter-generic microorganisms containing genetic material from a pathogenic source organism must be reported to both agencies (definitions of "inter-generic" and "pathogen" may be found in Unit IV). In this case, statutory constraints make it necessary for both EPA and USDA to review the products because the microbes are potential "pests" subject to the Plant Pest Act, and they are "new" and therefore subject to TSCA premanufacture notification (or they are pesticides and subject to FIFRA notification). However, the agency reviews have somewhat different purposes, in that the EPA review is for a general use of an organism under TSCA or for use as a pesticide under FIFRA, while the USDA review is for a specific permit application. The agencies will coordinate these reviews as explained earlier.

Second, persons developing inter-generic organisms that contain no genetic material from a pathogen and that do not meet the USDA definition of a "plant pest" will be expected to report only to EPA; they will not report to USDA at all. EPA will inform USDA and the submitter if any data suggest that the organism has pest qualities which may require a permit from USDA. This avoids unnecessary duplication of effort and is consistent with the non-discretionary responsibility under TSCA to review new organisms and under FIFRA to review pesticides.

Third, in the case of intra-generic engineered organisms that contain genetic material from a pathogen, the use of the organism will determine which agency reviews it. When used solely for non-pesticidal agricultural purposes, such organisms must be reported only to USDA under the Plant Pest Act. When used for non-agricultural purposes, such organisms should be reported to EPA, either voluntarily under the TSCA section 5(a)(2) rule EPA will be developing or, if the organism is a pesticide, under FIFRA. In both cases, the microorganisms should also be reported to USDA as potential plant or animal pathogens. When such dual reporting is necessary, the agencies will assist the submitter by coordinating through the mechanisms described above.

In the case of intra-generic microbes containing no genetic material from pathogens and nonengineered microorganisms, EPA will gather general information under section 8(a) of TSCA and conduct abbreviated reviews under FIFRA (see Units II and III of the EPA notice). Both agencies agree that members of this category of microbes, in general, present the lowest risk and therefore do not need a high level of scrutiny before any release into the environment. However, the FIFRA abbreviated reviews and the TSCA section 8(a) reporting will ensure that both agencies are aware of environmental releases of these organisms and can take appropriate action when necessary.

F. EPA Biotechnology Science Advisory Committee

EPA is establishing a Science Advisory Committee for biotechnology. The formation of this committee is consistent with intentions stated in two **Federal Register** notices issued by the Office of Science and Technology Policy (49 FR 50904, December 31, 1984 and 50 FR 47174, November 14, 1985). The committee's primary functions will be to provide peer review of specific product submissions under TSCA, FIFRA, and other EPA statutes and scientific oversight of the Agency's biotechnology programs.

The committee will consist of independent scientists and members of the lay public. It will be of sufficient size and diversity to provide the range of expertise required to assess the scientific and technical issues pertinent to its responsibilities. The committee will be supplemented by consultants when they are needed to extend the range of expertise of the standing committee, and will be authorized to

form subcommittees or panels for any purpose consistent with its charter.

Scientific members of the committee will be selected on the basis of their professional qualifications to examine the questions of hazard, exposure, and risk to humans, other non-target organisms, and ecosystems. Some committee members will serve as liaisons (holding joint membership) with the FIFRA Scientific Advisory Panel (SAP) and with the EPA Science Advisory Board (SAB). The SAC will also include nonvoting representatives from other Federal agencies that are involved in regulating products of biotechnology.

The Agency intends for meetings of the SAC to be open to the public. Meetings may be closed by the Chairperson when necessary, such as during discussion of issues subject to statutory confidentiality requirements, but EPA will encourage open public discussion of issues to the greatest extent possible (see unit I.G).

G. Confidential Business Information

Both FIFRA and TSCA generally prohibit the Agency from releasing certain confidential business information (CBI). These prohibitions apply to information on products of biotechnology, and the Agency will meet its obligations to protect information claimed confidential by applicants and other data submitters. However, the Agency also recognizes that there is strong public interest in many aspects of biotechnology, particularly in the possibility of adverse effects resulting from the environmental release of genetically engineered organisms. Accordingly, it is the Agency's policy to carry out as much of its review as possible in the open, in order to provide an opportunity for public participation and to increase public confidence in the review process. The Agency is encouraged by the extent to which industry and other submitters have been willing to authorize the release of relevant information to date and urges future data submitters to limit confidentiality claims as much as possible in order to foster an open review process.

H. International Aspects

EPA is committed to the policy described in the section entitled "International Aspects" in the Office of Science and Technology Policy Preamble, published in this **Federal Register.**

SUMMARY TABLE.—PRIOR NOTIFICATION AND REVIEW OF MICROORGANISMS APPLIED IN THE ENVIRONMENT

[Coverage by notification and review policy [1]]

Type of microbial product	FIFBRA		TSCA	
	< 10 acres	>10 acres	< 10 acres	> 10 acres
1. Genetically engineered microorganisms				
a. Formed by deliberate combinations of genetic material from dissimilar source organisms (inter-generic combinations).	X	X	X	X
b. Formed by genetic engineering other than inter-generic combinations				
i. pathogenic source organisms [2]	X	X	X	X
ii. nonpathogenic source organisms	O	X	O	O
2. Nonengineered microorganisms				
a. Nonindigenous pathogens [2]	X	X	O	X
b. Nonindigenous nonpathogens	O	X	O	O
c. Indigenous pathogens [2]		X	O	X
d. Indigenous nonpathogens		X	O	O

[1] "X" designates that the microorganism will be subject to EPA review prior to small-scale (10 acres or less) or large scale (greater than 10 acres) environmental applications, as indicated. Under TSCA, submitters would only notify the Agency once (at the first appropriate time), unless during the original review EPA specifies that further reporting is required.
"O" designates that the microorganism will be subject to abbreviated review prior to small-scale (10 acres or less) or large scale (greater than 10 acres) environmental applications, as indicated. Under FIFRA, this provision is effective immediately. Under TSCA, the abbreviated notification will be implemented through rulemaking.
[2] Pathogens in this category used solely for non-pesticidal agricultural purposes will not be subject to EPA notification requirements. They will be subject only to USDA review. See Unit IV for a definition of "agricultural uses" and "pathogens."

II. Applicability of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to Microbial Products

A. Background

Biological agents, including microorganisms, may be used as pesticides, and as such they are subject to regulation under FIFRA unless specifically exempted by regulation. FIFRA establishes EPA's authority over the distribution, sale, and use of pesticide products. Before EPA can register a pesticide, it must have sufficient data to determine that the product, when used in accordance with widespread and commonly recognized practice, will not cause (or significantly increase the risk of) unreasonable adverse effects to humans or the environment. In recent years, the Agency has put in place policies, procedures, and regulations to address the human health and environmental concerns raised by the application of biological pesticides (including genetically engineered and nonindigenous microbial products) in the environment. This unit outlines EPA's regulatory mechanism for these products and updates its policy on small-scale field testing of microbial pesticides.

Regulations promulgated under FIFRA and appearing at 40 CFR 162.5(c)(4) specify that microorganisms, when used as pesticides, are regulated under FIFRA. The specific kinds of data and information that are required to support the registration of each microbial pesticide under FIFRA are detailed in 40 CFR 158.65, 158.170, and 162.163. The Agency has also published guidance for developing these data in the Pesticide Assessment Guidelines: Subdivision M—Biorational Pesticides (Ref. 20).

The Agency must conduct a complete evaluation and review of the data submitted to support any pesticide registration before determining whether the pesticide should be registered. This evaluation is conducted with respect to the general criteria set forth in 40 CFR 162.7(d) and (e) and 162.167. Prior to registration, producers may test their pesticide products under an experimental use permit (EUP), issued pursuant to section 5 of FIFRA and 40 CFR Part 172. The data and information needed to support the issuance of an EUP for microbial pesticides are specified at 40 CFR 158.170.

The regulations governing EUPs include a generally applicable presumption that EUPs will not be required for certain small-scale experimental uses of new pesticides (or new uses of previously registered pesticides). Recently, however, the Agency issued a statement of interim policy on small-scale field testing of nonindigenous and genetically altered microbial pesticides, published in the **Federal Register** of October 17, 1984 (49 FR 40659); see also 49 FR 50882, December 31, 1984. Briefly, the policy statement announced that the small-scale field test provision of 40 CFR 172.3 would not automatically apply to, and that the Agency should be notified before the initiation of, any field testing of genetically altered or nonindigenous microbial pesticides to determine if EUPs are required. This policy is being revised by this notice and is discussed in detail in Unit II.D.

B. Scope of FIFRA

1. *Pesticides addressed by this notice.* All pesticides whose active ingredient(s) consist of microorganism(s) (i.e., all microbial pesticides) are addressed by

this notice. Microbial pesticides may include bacteria and blue-green algae, fungi, viruses, and protozoa used as pest control agents.

2. *Pesticides not addressed by this notice.* The Agency has determined that certain nonmicrobial organisms which fall within the definition of biological control agents are already addressed by other agencies, specifically USDA and the Department of the Interior. Examples of these biological control agents are vertebrates, insect predators, nematodes, and macroscopic parasites. Therefore, pursuant to section 25(b) of FIFRA and 40 CFR 162.5(c)(4), these nonmicrobial biological control agents have been exempted from regulation under FIFRA. However, if EPA, in cooperation with other agencies, determines that certain biological control agents exempted by § 162.5(c)(4) are not being adequately regulated, these organisms will be referred to the attention of the appropriate agency or added to the exceptions in § 162.5(c)(4) by amendment. In the latter case, those organisms would no longer be considered exempt from the provisions of FIFRA.

This unit of the notice does not address any chemical pesticide product or byproduct produced by microorganisms. Such chemicals are covered under current pesticide regulations, registration procedures, data requirements, and testing guidelines (see 40 CFR Parts 158 through 180; and Subdivisions D through O of the Pesticide Assessment Guidelines).

3. *Information-gathering policy.* In order to expand its level of knowledge and expertise, monitor the industry, and determine whether its current policy needs modification, the Agency needs as complete a data base as possible. Accordingly, those developing microbial products intended for use as pesticides that are not otherwise subject of FIFRA review are encouraged to keep the Agency apprised of their activities. In addition, registrants of microbial pesticides are reminded that, pursuant to FIFRA section 6(a)(2), they must report any information regarding unreasonable adverse effects of the pesticide on the environment.

C. Microbial Pesticides—History and Long-Term Regulatory Strategy

1. *History.* Microbial pesticides have been in use for many years. In 1948, the Federal Government registered the first such product, *Bacillus popilliae,* to control Japanese beetle larvae in turf. However, it was not until the late 1960s and early 1970s that interest in microbial pesticides began to increase. At that time, EPA began to develop policies and procedures to specifically address microbial pesticide products. In 1983, EPA's Office of Pesticide Programs issued testing guidelines for microbial pesticides (Ref. 20). A year later, EPA issued a final regulation (40 CFR Part 158) specifying the data requirements for pesticide registration (including genetically engineered microbial pesticides). As of 1985, there were 14 microbial pesticides used in several hundred separate products registered for use in agriculture, forestry, mosquito control, and homes.

As indicated in Unit II.A above, EPA issued an interim policy on small-scale field testing of genetically altered and nonindigenous microbial pesticides in October 1984 (49 FR 40659). To date, under this policy, EPA has received and reviewed five notifications for genetically engineered microbial pesticides and two notifications for nonindigenous microbial pesticides. Three EUP applications, required in part to address unresolved issues identified in the review of these notifications, have since been received. These applications were for genetically engineered microbial pesticides.

2. *Long-term regulatory strategy.* Although EPA has an established regulatory mechanism for microbial pesticides, the Agency envisions some further modifications in the future to specify certain policies in more detail, keep the assessment process current with existing scientific knowledge, and ensure an efficient review mechanism. Some of these anticipated modifications are discussed here.

As noted in Unit I, EPA intends to revise the EUP regulations (40 CFR Part 172) to incorporate the concepts embodied in the interim policy on small-scale field testing. Specifically, Part 172 will be revised to specify more clearly which applicants must notify EPA before conducting small-scale field tests with microbial pesticides and the content of notification.

As noted in the overview to this EPA notice (Unit I.F), EPA is forming a Science Advisory Committee. The Scientific Advisory Panel, an advisory group mandated by FIFRA, will continue to serve in its advisory capacity on specific submissions under FIFRA, until the SAC is formed.

FIFRA requires EPA to review and periodically update its guidelines, and OPP has begun this process for the Subdivision M Pesticide Assessment Guidelines. The Guidelines are currently being revised to reflect current testing methodology and advances in risk assessment capabilities resulting from OPP's recent experience in evaluating genetically engineered microbial pesticides. In addition, as the Agency gains risk assessment experience and assembles a larger body of risk assessment data, it may be appropriate to amend the Part 158 data requirements regulation to add to or modify the data requirements that apply to genetically engineered and nonindigenous microbial pesticides.

D. Regulatory Review of Microbial Pesticides

This unit describes EPA's data requirements and review procedures for microbial pesticides. In particular, Unit II.D.1 describes the requirements and review plan for those microbial pesticides subject to review under FIFRA before they may be used in any application in the environment (i.e., small-scale field testing). Unit II.D.2 outlines the regulatory review for those microbial pesticides subject to the FIFRA requirements for an experimental use permit or registration. In most instances, microbial pesticides subject to the provisions in Unit II.D.1 will also be subject to the provisions in Unit II.D.2 when they are to be used for larger scale or commercial purposes in the environment.

1. *Small-scale field testing.* Prior to obtaining a registration for a pesticide product, applicants generally need to conduct field studies in order to gather product performance, use, and other types of data necessary to support the registration of their product. The regulations governing field studies (40 CFR Part 172) include a generally applicable presumption that EUPs will not be required for certain small-scale uses of new pesticides (or new uses of previously registered pesticides). The Agency issued a statement of interim policy addressing small-scale field testing of microbial pesticides in 1984. The interim policy announced that the Agency should be notified before initiation of any field testing of genetically altered or nonindigenous microbial pesticides. The purpose of this policy is to provide a mechanism for the Agency to evaluate these proposed small-scale field tests for possible risk to human health or the environment and determine whether EUPs are required before the tests can be initiated.

Small-scale field studies are (1) terrestrial field studies that involve 10 acres or less of land; and (2) aquatic field studies that involve 1 surface acre or less of water.

To minimize the regulatory burden on producers of genetically engineered and nonindigenous microbial pesticides, and more closely correlate the level of Agency review with potential risk of the

microorganism, the Agency has adopted a two-level review system based on its evaluation of the potential risks posed by various types of microorganisms. The two-level system will allow the Agency to receive some basic information on small-scale testing of genetically engineered and nonindigenous microorganisms that are less likely to pose significant risks to humans or the environment (Level I reporting), while reserving full notification and review procedures for microorganisms about which there is more concern (Level II notification). The review system is designed so that producers of microbial pesticides may proceed with their small-scale field tests without Agency approval, unless they are notified within a specified time that additional information or an EUP is required. In the case of level I reporting, producers need only provide a limited amount of information, and are assured of an expedited response from the Agency if it is determined that additional information is required.

The two-level system is based on the analysis set forth at Unit I.D, in which the Agency has defined groups of microorganisms that raise more concerns about their likelihood to pose risks to humans or the environment, when released into the environment, than other microorganisms. Specifically, these include microbial pesticides formed by deliberately combining genetic material from organisms of different genera and genetically engineered or nonindigenous microbial pesticides derived from pathogenic source organisms. However, other genetically engineered and nonindigenous microbial pesticides are less likely to pose significant risks to humans or the environment when applied in small-scale field test. Accordingly, the Agency has determined that this second category of microbial pesticides will be subjected to a reporting requirement and will be reviewed as described in Unit II.D.1 a through c below. The Agency will have up to 30 days to review the reported information. The kind of information needed to fulfill the reporting requirement is typically already available to an applicant as an essential part of product research and development, and is not generally expected to require generation of new data.

All microbial pesticides formed by deliberately combining genetic material from organisms of different genera, and all genetically engineered or nonindigenous microbial pesticides derived from pathogenic source organisms will be subject to the full notification requirements (Level II) as described in Unit II.D.1.e below. The Agency has determined that these organisms should continue to be subjected to the full notification and review procedures set out in the original interim policy published on October 17, 1984. The Agency will have up to 90 days to review a Level II notification.

The scope and requirements for Level I reporting and Level II notification are detailed below. The interim policy as revised by this notice does not apply to studies conducted under enclosed, contained conditions, as defined in Unit IV.

a. *Level I reporting.* Level I reporting for small-scale field testing applies to all genetically engineered or nonindigenous microbial pesticides not otherwise covered by Level II notification as detailed in II.D.1.d below. Small-scale field tests of additional groups of genetically engineered and nonindigenous microbial pesticides now covered by Level II notification may also be determined to warrant only abbreviated review in the future. The Agency will make these determinations on a case-by-case basis.

b. *Level I information.* Each report should include the following information, or, where specific information is not submitted, documentation of why it is not practicable or necessary to provide the information.

(1) Identity of the microorganism, including characteristics, and means and limits of detection.

(2) Description of the natural habitat of the microorganism or its parental strains, including information on natural predators, parasites, and competitors.

(3) Information on the host range of the parental strain(s) or nonindigenous microorganism.

(4) Information on the relative environmental competitiveness of the microorganism, if available.

(5) If the microorganism is genetically engineered, information should be provided on the methods used to genetically engineer the microorganism(s); the identity and location of the rearranged or inserted/deleted gene segment(s) in question; a description of the new trait(s) or characteristic(s) that are expressed; information on potential for genetic transfer and exchange with other organisms, and on genetic stability of any inserted sequence.

(6) A description of the proposed testing program, including site location, crop to be treated, target pest, amount of test material to be applied, and method of application.

c. *Level I reporting process.* EPA will have up to 30 days to review the above information to make a preliminary determination of the need for an EUP. If the Agency does not notify the applicant of the need for an EUP within the 30 days, the applicant may proceed with the proposed field test. If, on preliminary assessment, the test raises sufficient concerns such that the Agency determines that additional information or monitoring is warranted, then an EUP will be required (e.g., microorganisms for which there is limited scientific information or regulatory experience, or that raise significant questions concerning genetic stability, competitiveness, or mode of action, or that warrant specific environmental monitoring during the test). In this case, the applicant has two options. First, the applicant may apply for a permit, providing the necessary data and information required to support the application. Alternatively, the applicant may provide all additional data and information required under Level II notification as outlined in Unit II.D.1.e below. If the latter option is chosen, the Agency will have an additional 60 days to review the full notification package and make a final determination as to whether an EUP is required.

d. *Level II notification.* Level II notification for small-scale field testing applies to microbial pesticides: Microbial pesticides formed by deliberately combining genetic material from organisms of different genera, genetically engineered microbial pesticides derived from source organisms that are pathogens (as defined in Unit IV), and nonindigenous pathogenic microbial pesticides (as defined in Unit IV).

e. *Level II requirements.* Notification should include adequate information to allow the Agency to evaluate the small-scale field testing program. Each notification should include the following information, or, where specific information is not submitted, documentation of why it is not practicable or necessary to provide the information.

(1) Background information on the microorganism.

(a) Identity of the microorganism, including tables of characteristics, and means and limit of detection using the most sensitive and specific methods available.

(b) Description of the natural habitat of the microorganism or its parental strains, including information on natural predators, parasites, and competitors.

(c) Information on host range, especially infectivity and pathogenicity to nontarget organisms.

(d) Information on survival and ability of the microorganism to increase in numbers (biomass) in the environment (e.g., laboratory or containment facility test data).

(e) If the microorganism is genetically altered, the following information should be provided in addition to the information listed in (a) through (d) above:

i. Information on the methods used to genetically alter the microorganism.

ii. The identity and location of the rearranged or inserted/deleted gene segment(s) in question (host source, nature, base sequence data, or restriction enzyme map of the gene(s)).

iii. Information on the control region of the gene(s), and a description of the new trait(s) or characteristic(s) that are expressed.

iv. Information on potential for genetic transfer and exchange with other organisms, and on genetic stability of any inserted sequence.

v. Information on relative environmental competitiveness compared to the parental strains.

(2) Description of proposed field test.

(a) The purpose or objectives of the proposed testing.

(b) A detailed description of the proposed testing program, including test parameters.

(c) A designation of the pest organism(s) involved (common and scientific names).

(d) A statement of composition for the formulation to be tested, giving the name and percentage by weight of each ingredient, active and inert, production methods, contamination with extraneous microorganisms, potency and amount of any toxins present, and where applicable the number of viable microorganisms per unit weight or volume of the product (or other appropriate system for designating the quantity of active ingredient).

(e) The amount of pesticide product proposed for use and the method of application.

(f) The State(s) in which the proposed program will be conducted, and specific identification of the exact location of the test site(s) (including proximity to residences and human activities, surface water, etc.).

(g) The crops, fauna, flora, geographical description of sites, modes, dosage rates, frequency, and situation of application on or in which the pesticide is to be used.

(h) A comparison of the natural habitat of the microorganism with the proposed test site.

(i) The number of acres, number of structural sites, or number of animals/plants, by State, to be treated or included in the area of experimental use, and the procedures to be used to protect the test area from intrusion by unauthorized individuals.

(j) The proposed dates or period(s) during which the testing program is to be conducted, and the manner in which supervision of the program will be accomplished.

(k) A description of procedures for monitoring the microorganism within and adjacent to the test site during the field test.

(l) The method of disposal or sanitation of plants, animals, soils, etc., that were exposed during or after the field test.

(m) Means of evaluating potential adverse effects and methods of controlling the microorganism if detected beyond the test area.

In addition, the following references should be consulted for further guidance on the kinds of data and information that may be relevant to the evaluation of genetically engineered microorganisms: "Proposed Points to Consider for Environmental Testing of Microorganisms" developed by the National Institutes of Health Recombinant DNA Advisory Committee Working Group on Release into the Environment (Ref. 11); "Subdivision M: Biorational Pesticides" (Ref. 20); a report by the Cornell Ecosystems Research Center titled "Potential Impacts of Environmental Release of Biotechnology Products: Assessment, Regulation, and Research Needs" (Ref. 9); a National Science Foundation Report titled "The Suitability for Environmental Applications of Biotechnology" (Ref. 3); and EPA "Points to Consider in the Microorganisms" (available from TSCA Assistance Office at the address given at the beginning of this notice).

f. *Level II review process.* Once the supporting data have been submitted, EPA has up to 90 days to review each notification of intent to conduct small-scale field testing and to determine whether an EUP is required. The Agency encourages prospective applicants to meet with EPA prior to submission of their notification to discuss their field test and determine what specific data would be necessary to evalaute the product.

EPA's review process will include some or all of the elements described in the following paragraphs. As the Agency builds a baseline of risk assessment data and gains more experience in evaluating these products, certain steps may no longer be necessary. In addition, an abbreviated review process may be appropriate in some situations (e.g., review of a proposal that is similar to an already reviewed case). Such a determination will be made on a case-by-case basis.

Once a notification is received, OPP reviews each proposal and assesses potential risks associated with the proposed experiment. OPP develops a written scientific position for each proposal which identifies potential problems or significant unanswered questions and sets forth a statement of the overall likelihood of significant risk from the proposed field testing. As the review process proceeds, it may be necessary for OPP to request supplemental information.

OPP obtains comments on its assessment from a workgroup within EPA and from other Federal agencies as appropriate (e.g., USDA, National Institutes of Health, Food and Drug Administration, and National Science Foundation). Their comments are incorporated into the scientific position, as appropriate.

OPP contacts the appropriate State pesticides regulatory authorities to ensure that they are aware of the proposal and to discuss EPA's assessment. These contacts ensure that the actions of EPA and the State agencies are as consistent as possible. OPP also notifies the Animal and Plant Health Inspection Service (APHIS) of the USDA so that they can determine whether any aspect of the proposed experiment falls within APHIS jurisdiction and, if so, to avoid duplicative or conflicting assessments.

Thus far, reviews of small-scale field testing proposals for genetically engineered microbial pesticides have emphasized some questions that have not been as significant in the assessments of naturally occurring microbial pesticides. For example, OPP has identified potential risks associated with the transfer of inserted genetic material to other organisms, the competitiveness of the engineered organism compared with the parental organisms in the environment, and the ability of the engineered organism to become established in a new ecological niche and thereby pose a potential adverse environmental impact.

OPP has addressed these and similar questions on a case-by-case basis in its risk assessments. In some cases, applicants have addressed questions by redesigning the proposed application or test microorganism to minimize the potential risk. In other instances, EPA has established data requirements and test methods as a baseline, and has designed specific laboratory test(s) (or

tiered series of tests) to establish whether the effect of concern is likely to materialize under field conditions.

If the notification raises complex or controversial scientific questions, OPP provides the notification package and its scientific evaluation to a group of independent scientists constituted as a subpanel of FIFRA's Scientific Advisory Panel. Separate subpanels may be formed to review each proposal since each microorganism and its proposed use may differ and raise questions that require the analysis of individuals with different expertise. The purpose of the SAP subpanel is to obtain an independent peer review of the OPP scientific position, to address specific scientific questions raised by OPP, and to identify any additional points, questions, or problems. As noted previously in Unit I.F, the Agency is forming a Science Advisory Committee which will assume these responsibilities in the future.

At the conclusion of the review, the Agency then decides whether an EUP is required. The decision document sets forth OPP's conclusions with respect to potential risks associated with the proposal, identifies any remaining questions or additional data that may be needed to complete the risk assessment, and, if an EUP is required, may recommend restrictions, limitations, or modifications of the proposal to address areas of concern. If an EUP is not required, the applicant may proceed with the proposed field test. If an EUP is required, the applicant must apply for a permit, providing the necessary data and information required to support the application. The Agency may decide to require an EUP to ensure that the experiment is conducted within certain defined limitations, the necessary data are developed to assess the proposal, or certain kinds of data are developed during the test and reported to the Agency.

2. *EUPs, large-scale testing, and registration.* Before a pesticide may be marketed as a commercial product, it must first be registered as provided for in section 3 of FIFRA. Large-scale field testing of a microbial pesticide is often necessary to evaluate a potential product and obtain data needed to support registration of the product. This testing, like small-scale field testing under an EUP, is subject to section 5 of FIFRA which authorizes EPA to approve applications for EUPs for limited use of an unregistered product or use of a registered product for an unregistered use. Data requirements for registration are specified in 40 CFR 158.170 and a subset of these requirements applies to large-scale field testing proposals to be performed under EUPs. The regulatory review process consists of the same basic elements in both situations and is described in this unit.

a. *Scope.* All microbial pesticides to be used in large-scale field tests are subject to review under FIFRA EUP regulations. The conditions under which an EUP is required are specified at 40 CFR Part 172, which also provides guidance on how to determine whether an EUP must be obtained. Likewise, all microbial pesticides are subject to the FIFRA registration requirements.

b. *General requirements for microbial pesticides.* The existing pesticide data requirements and regulations governing large-scale field testing (40 CFR Parts 158 and 172) and registration (40 CFR Parts 158 and 162) are applicable to all microbial pesticides, both naturally occurring and otherwise.

The agency believes that these requirements are adequate for the assessment of indigenous microbial pesticides, and provide a basis for evaluating genetically engineered and nonindigenous microbial pesticides as well. However, the Agency believes that additional data and information, determined on a case-by-case basis, may be necessary to evaluate some properties of genetically engineered and nonindigenous microbial pesticides. Part 158 explicitly provides the necessary flexibility to require additional data (§ 158.65) as well as the flexibility to waive data requirements that are not applicable (§ 158.45).

c. *Additional requirements for genetically engineered and nonindigenous microbial pesticides.* Any additional data requirements will be determined on a case-by-case basis depending on the particular microorganism, its parent microorganisms, its native habitat, the pesticide use pattern, and the manner and extent to which the microorganism may have been engineered. These additional requirements could include:

(1) Description of the natural habitat of the microorganism or its parental strains, including information on natural predators, parasites, and competitors.

(2) Information on relative ability to survive and increase in number or biomass as compared to the parental strains.

(3) Selected environmental fate tests from 40 CFR 158.170.

(4) Additional toxicology tests from 40 CFR 158.170.

(5) If the microorganism is genetically altered, then information on the genetic modification techniques used, the identity of inserted gene segment(s) (base sequence data or restriction enzyme map of the gene), the control region of the gene(s), a description of the new traits or characteristics that are intended to be expressed, and tests to evaluate genetic stability and exchange, may be required as specified previously at Unit II.D.1.b above.

d. *Review process for genetically engineered and nonindigenous microbial pesticides.* EUP applications will be reviewed in compliance with the EUP regulations under 40 CFR Part 172. The registration, reregistration, and classification procedures of 40 CFR Part 162 will be followed for registration applications. The review process will contain the same major elements as those outlined previously for small-scale field testing notifications (see Unit II.D.1.c). Briefly, this process involves scientific review and risk assessment by EPA scientists and, if appropriate, review and comment from other Federal agencies and independent expert consultants.

Once the supporting data have been submitted, EPA has up to 120 days to review an EUP application and determine whether to grant a permit. Past experience indicates that the registration process for a new microbial pesticide may vary from 9 months to several years depending upon the particular product, its use pattern, and the completeness of the registration package submitted to EPA.

Both the EUP and registration process may provide an opportunity for public comment. For example, § 172.11 of the EUP regulations specifies that if an application may be of regional or national significance the Agency will announce receipt of the application in the **Federal Register.** The announcement is accompanied by a description of the experimental program and public comments are solicited. Similarly, § 162.6 of the registration regulations specifies that if a registration application relates to a new active ingredient or a new use, notice of receipt of that application shall be published in the **Federal Register** with a request for public comment. Information on the submission is made available for public inspection.

EPA has several regulatory options for responding to either an EUP or registration application. For example, after completing its review, the Agency may determine that the field test or registration poses no unreasonable risks to humans or the environment and may grant the application. Alternatively, EPA may conclude that some additional information or data are needed to assess the potential risks adequately. In this

case, the application would be asked to provide the necessary data before EPA would decide whether to grant the application. In other cases, the Agency may impose additional limitations or restrictions on the field test or registration to address a potential risk. Finally, EPA will deny those applications where it has determined that it has all the necessary data to complete a risk assessment and that the field test or registration would pose an unreasonable risk to humans or the environment, even if additional limits or restrictions are imposed.

III. Applicability of the Toxic Substances Control Act (TSCA) to Microbial Products

A. Overview of This Unit

As discussed in the December 84 notice (49 FR 50886), EPA will review certain microorganisms and uses of microorganisms under TSCA. Microorganisms and their DNA molecules are "chemical substances" under section 3 of TSCA, and thus are subject to all the provisions of TSCA, except to the extent they are manufactured, processed, or distributed in commerce for use as pesticides, foods, food additives, drugs, cosmetics, and medical devices. For purposes of analysis and convenience of administering TSCA, EPA has chosen to focus on the microorganism as the "chemical substance."

This unit explains the statutory requirements of TSCA as they apply to microorganisms. It begins by describing which microorganisms are within the scope of TSCA and which are not. Following that are units describing five categories of microorganisms or uses of microorganisms that are or will be subject to reporting requirements under TSCA.

B. Scope of TSCA

Many organisms are not subject to TSCA requirements because of statutory exemptions; others will be exempt from certain TSCA requirements as a matter of regulatory policy. In general, the use of a microorganism determines whether it is subject to TSCA or to other laws.

Many of the comments received by OTS indicated misunderstandings of TSCA's scope. Therefore, those organisms which are and are not subject to TSCA are described in this Unit.

1. *Organisms not subject to TSCA*—a. *Microbes used as foods, food additives, drugs, cosmetics, medical devices, and pesticides.* Microorganisms are sometimes used directly as foods, food additives, drugs (including both human and animal vaccines), cosmetics, medical devices, and pesticides. When microorganisms are used for these purposes, they are explicitly excluded from TSCA and from the policies described in the TSCA portions of this notice (TSCA section 3(2)(B), 15 U.S.C. 2602(2)(B)).

Microorganisms that are used as foods, food additives, drugs, cosmetics, medical devices, and pesticides are regulated by the Food and Drug Administration (FDA), USDA, or the EPA Office of Pesticide Programs. Applicable requirements for pesticides are described in Unit II of this notice. Requirements for foods, food additives, drugs, cosmetics, and medical devices are described in the FDA and USDA notices in this **Federal Register.**

b. *Microbes used to produce foods, food additives, drugs, cosmetics, and medical devices.* In addition to being used themselves for food, drug, and other purposes, microorganisms are often used to produce chemicals that are in turn used for such purposes. For reasons explained in the December 84 notice, microorganisms will not be reviewed under TSCA when used to produce foods, food additives, drugs (including vaccines), cosmetics, or medical devices. Further information on these uses may be found in the FDA and USDA notices in this **Federal Register.**

Microorganisms used in the production of chemical end products other than foods, food additives, drugs (including vaccines), cosmetics, and medical devices are subject to TSCA. They are described in Unit III.B.3 below.

2. *Plants and animals not subject to these policies.* Plants and animals are not subject to the TSCA policies in this notice, either as whole organisms or as *in vitro* cultures for the reasons set forth in the December 84 Notice. (Definitions of plants and animals for regulatory purposes are provided in Unit IV of this EPA notice.) There are two exceptions to this general rule. First, if plant or animal gene segments are intentionally incorporated into microorganisms, the microorganisms that contain those plant or animal genes may be subject to TSCA, depending on how they are used (see Units III.B. 1 and 3). Second, a chemical extracted from a plant or animal may be subject to TSCA, again depending on how it is used. The USDA and FDA notices in this **Federal Register** contain information about regulations that apply to plants and animals.

3. *Organisms subject to TSCA—microorganisms used for purposes not excluded by law.* With the exceptions described above, all microorganisms produced for environmental, industrial, or consumer uses are potentially regulable under TSCA. It is not possible to list all the applications that could be subject to TSCA because many are yet to be developed. Some of the microorganisms that are expected in the near future and that would be subject to TSCA include microorganisms used in conversion of biomass for energy, pollutant degradation, enhanced oil recovery, metal extraction and concentration, and certain non-food and non-pesticidal agricultural applications, such as nitrogen fixation.

Microorganisms used in the production of a chemical end product will be subject to TSCA if the end product is any chemical substance used for a purpose other than as a food, food additive, drug, cosmetic, or medical device. For example, microorganisms are subject to TSCA if they are used in the production of pesticides, fuels, solvents, dyes, cleansing agents, etc. TSCA jurisdiction over such microorganisms, which may be used entirely in closed manufacturing systems, is consistent with TSCA coverage of conventional chemicals. For example, chemical intermediates—even those used in closed systems—fall under TSCA authority and are subject to PMN requirements if new (40 CFR Part 720). Similarly, as described in Unit III.C.1 of this notice, "new" microorganisms used in chemical production are subject to PMN requirements.

4. *Chemicals produced by microorganisms—Status under TSCA.* Although the purpose of this notice is to provide information on the applicability of TSCA to microorganisms, some readers may wish to obtain information on requirements that apply to chemicals produced by microorganisms. For example, various proteins and polysaccharide gums are produced by microorganisms and may be subject to TSCA, depending on how they are used (see Unit III.B.1). These chemicals produced by microorganisms are subject to the same requirements and procedures as chemicals produced by other means. Any special concerns pertaining to the microbial production method, such as the possibility of contaminants, will be considered during the review of the microorganisms used in producing the chemicals. This approach is explained in the December 84 notice at page 50890.

C. Specific Requirements Under TSCA

The fact that a microorganism is potentially subject to TSCA does not necessarily mean that it will be regulated under TSCA. The rest of this unit explains the specific provisions that apply or will apply to various types of

microorganisms falling within TSCA's jurisdiction.

In overview, microorganisms are (or will be) subject to TSCA requirements in the following manner:

As of the date of this notice, microorganisms that are subject to TSCA and contain genetic material from dissimilar source organisms (i.e., organisms from different genera) are subject to PMN requirements.

Microorganisms other than inter-generic combinations that are subject to TSCA and are pathogenic or contain genetic material from pathogens, will in the future, if released into the environment, be subject to "significant new use" reporting requirements under TSCA section 5(a)(2). One exception is that agricultural uses of such microorganisms will be reviewed by USDA rather than EPA. EPA expects voluntary notification to begin immediately for uses that will be subject to significant new use reporting requirements.

The research and development exemption from PMN and significant new use notification requirements will be amended so that it no longer applies to microorganisms released to the environment. EPA expects voluntary notification of such uses to begin immediately.

EPA will issue a rule requiring manufacturers and importers to submit general information on environmental uses of microorganisms that are subject to TSCA but not otherwise subject to notification requirements, so that EPA can monitor environmental releases.

All manufacturers, processors, and distributors of microorganisms subject to TSCA are reminded of the requirement to report any information on substantial risks under TSCA section 8(e).

EPA is considering initiating rulemaking that would exempt from PMN requirements inter-generic microorganisms used solely in contained systems and never intentionally released to the environment.

1. *Premanufacture notification requirements*—a. *Overview.* EPA has determined that any microorganisms that are subject to TSCA (described in Unit III.B), and that through deliberate human intervention contain genetic material from dissimilar source organisms, are "new" and therefore subject to PMN requirements of TSCA. This interpretation is effective as of the date of publication of this notice.

Organisms are considered dissimilar for the purposes of this policy if they are from different genera. In the case of chemically synthesized genes, the Agency will follow the same principle, as clarified below in Unit IV. Detailed guidance on how to determine if organisms are from different genera is also provided in Unit IV.

The agency is excluding certain inter-generic combinations from PMN requirements, i.e., those inter-generic combinations in which the genetic material added to the recipient microorganism consists only of well-characterized, non-coding regulatory regions (see Unit IV). The resulting microorganisms do not possess new combinations of traits but rather exhibit quantitative changes in preexisting traits.

EPA is leaving unanswered, for now, the question of whether microorganisms containing genetic material from other microorganisms in the same genus (i.e., products of deliberate intra-generic combinations) and those which are developed from a single source microorganism (e.g., products of undirected mutagenesis, microorganisms with deletions) should also be considered "new." In the future, it is possible that EPA will decide that such microorganisms are "new," but for now they are not subject to PMN requirements.

b. *Background.* For purposes of administering TSCA, EPA must decide what constitutes a "new" microorganism which is subject to PMN requirements. As mentioned in the introduction to the EPA portion of this notice, EPA originally proposed a "process-based" approach to determining whether a microorganism is new. This approach stated that a microorganism would be considered new if significant human intervention had been used in developing it. For example, microorganisms altered by certain techniques—such as recombinant DNA and cell fusion—were presumed to be new because they involved significant human intervention. The question of which other techniques should be considered to produced new microorganisms was left open and comments were solicited.

After reviewing the comments, EPA considered a number of alternative ways to define "new" microorganisms. These are described in the "Response to Comments" document available as background to this **Federal Register** notice. In choosing among the alternatives, EPA carefully considered the TSCA mandate to review "new" substances. The Agency also considered related issues, for example, how well the options approximated risk (there was uncertainty with all the options in this respect) and how readily they could be implemented and enforced.

c. *Rationale.* Having reviewed the TSCA section 5 PMN requirements, the PMN regulations, the public comments, and the current state of science regarding genetic engineering, EPA has concluded that microorganisms resulting from intentional, inter-generic combinations of genetic material, except those in which the transferred material is only a well-characterized, non-coding regulatory region, constitute new microorganisms for purposes of PMN reporting. The reasons for this are set forth below.

First, the Agency considered the regulatory precedents established in compiling the inventory of existing chemical substances under section 8(b) of TSCA. Any chemical substance not on this inventory is "new" under section 5(a) of TSCA and is therefore subject to PMN requirements. Naturally occurring substances and substances derived from nature with limited human intervention are not explicitly listed on the inventory but are considered implicitly to be on it, and thus are not "new" (see 40 CFR 710.4(b)). A more detailed explanation of the TSCA inventory and related issues is found in the December 84 notice at pages 50887–50888.

Second, the Agency evaluated these regulatory precedents in the light of scientific knowledge about genetic engineering and microorganisms found in nature. On this basis, EPA concluded that microorganisms found in nature and developed without any deliberate combination of genetic material are not new, because they occur naturally and are derived through limited human intervention. Furthermore, from a scientific standpoint, these microorganisms have a very low probability of exhibiting new combinations of traits. Therefore, the Agency considers that from a legal and scientific standpoint they must be considered naturally occurring (not new). Because such microorganisms are naturally occurring, they are, as explained above, implicitly listed on the TSCA chemical substances inventory and not subject to PMN requirements.

Third, where genetic material has been combined among source organisms from different genera (inter-generic), the resulting microorganisms should be considered "new" because of the degree of human intervention involved, the significant likelihood of creating new combinations of traits, and the greater uncertainty regarding the potential risks of such microorganisms. However, transfer of genetic material consisting solely of well-characterized, non-coding regulatory regions is a special case. Where only regulatory material is

transferred, no distinctly new combinations of traits are introduced; instead, existing traits in the receiving microorganisms are amplified or changed quantitatively. For this reason, EPA believes that microorganisms formed only through inter-generic transfer of well-characterized, non-coding regulatory regions should not be considered "new" under section 5 of TSCA. This is reflected in the definition of "inter-generic" found in Unit IV.A.

It is possible to argue that some microorganisms formed through intra-generic combinations are products of significant human intervention and may exhibit new combinations of traits, and therefore that they should also be considered new. However, the Agency at this time believes that it is appropriate to exclude such microorganisms form its definition of "new" because distinctly new combinations of traits are unlikely to occur through transfers of genetic material among closely related organisms, because transfers among closely related organisms are more likely to occur in nature, and because the current state of taxonomy with regard to species designations is sufficiently unstable that it makes it difficult to include such microorganisms in a definition of "new" (the rationale is found in Unit I.D.3.a). As explained previously, however, the Agency will continue to review the status of such microorganisms and may, in the future, determine that certain combinations among similar organisms should be considered new.

In summary, EPA considers microorganisms deliberately formed to contain genetic material from different genera to be new, except where only well-characterized, non-coding regulatory regions are transferred. Conversely, intra-generic and non-engineered microbes are considered naturally occurring. These conclusions are based on the TSCA section 5 mandate to review "new" substances, and they also reflect a number of scientific considerations. Among these are (1) the Agency's concern that microorganisms formed with genetic material from different genera warrant regulatory review, because of the inherent uncertainty about the characteristics and behavior of such microorganisms, (2) the observation that microorganisms from different genera are less likely to exchange genetic material in nature than microorganisms that are more closely related, (3) the regulatory precedent that significant human intervention creates new substances for purposes of PMN under TSCA section 5, and (4) the necessity of having a definition of "new" that can be readily interpreted and enforced given the current state of science. These scientific and legal issues are more fully described in Unit IV.A.

d. *How to comply with the PMN requirements for new microorganisms.* The following requirements apply to "new" microorganisms produced for uses subject to TSCA authority (see Unit III.B.1 and 3). Detailed criteria for determining whether a microbe meets the definition of "new" microorganism (i.e., whether it contains genetic material from organisms from different genera) may be found in Unit IV.A.

Certain PMN policies in this notice are immediately effective. As of the date of publication of this notice, microorganisms that are being manufactured or imported for any TSCA commercial purposes other than research and development (R&D) are subject to PMN requirements 90 days prior to manufacture or import. This requirement applies to both contained and environmental uses that have gone beyond R&D. The requirement is based on the current provisions of 40 CFR Part 720. The definition of R&D under these regulations is clarified in the **Federal Register** of April 22, 1986 (51 FR 15096).

In addition, new microorganisms that are being manufactured or imported for R&D that involves environmental release will have to be reported to EPA at least 90 days before such activities begin. This policy will be implemented through amendments to 40 CFR 720 (explained fully in Unit III.C.3); in the meantime, persons manufacturing or importing new microorganisms for R&D activities involving environmental release are expected to comply with this policy voluntarily.

EPA believes that there are no manufacturers who are presently beyond the research and development stage with new microorganisms subject to TSCA. However, if any companies are now engaged in such activities, they should contact EPA and determine whether a PMN is necessary. If a company in this position contacts EPA promptly, it will not be considered out of compliance with policy. Further information on TSCA PMN requirements may be obtained from the TSCA Assistance Office (address provided at the beginning of the EPA portion of this notice).

(1) *How to know if a microorganism is subject to PMN.* As stated above, all microorganisms containing deliberate combinations of genetic material from organisms from different genera are new and subject to PMN. An exception to this policy is an inter-generic combination in which the genetic material added to the recipient microorganism consists only of well-characterized, non-coding regulatory regions. Unit IV.A of this notice contains detailed guidance that manufacturers should use to determine if their microorganisms meet this definition.

Submitters should consult the Agency if they have any questions about how to determine if a microorganism contains genetic material from different genera.

(2) *PMN exemptions.* EPA considers it a priority to exempt from PMN requirements new microorganisms that can be shown to meet the findings for exemption under TSCA section 5(h)(4). Further information on exemptions the Agency is considering may be found in Unit III.C.6 of this notice.

(3) *Submitting the PMN.* EPA expects manufacturers and importers to contact EPA well in advance of PMN submission, to allow sufficient time for prenotice consultation. These consultations will help the Agency and the submitter anticipate potential problems and expedite the review.

Information regarding new microorganisms should not be submitted on the standard PMN form, as this form is not applicable to microbial products. Instead, EPA and the submitter will discuss the level and types of information appropriate for the notice during prenotice consultations. The general kinds of information EPA expects to see in most submissions for microorganisms are described in the next unit below.

(4) *What information to submit.* Section 5(d)(1)(A) of TSCA specifies the information PMN submitters must provide in their notices, including information on production, workplace exposure, and release. In addition, under section 5(d)(1)(B) submitters must provide all test data related to the health and environmental effects of the new chemical substance in their possession or control. For more information on PMN requirements, persons should consult EPA's PMN rule (40 CFR Part 720).

In general, information to assess a substance's potential risk should be developed in a step-wise fashion. PMN submitters should begin with published literature on the source organisms, then move through laboratory, microcosm, growth chamber, and/or greenhouse studies that simulate as closely as possible the conditions of the eventual use or environmental application.

The remainder of this unit describes the types of information EPA expects

submitters to provide in PMNs on new microorganisms.

(a) *Identifying the microorganism.* PMN submitters must provide information that identifies microorganisms well enough to be listed on the TSCA chemical substance inventory. If the identity and/or use of the microorganism are claimed as confidential business information by the submitter, the PMN must also include a generic description of these items so that the information can be published in the **Federal Register.** Confidential submissions will be considered incomplete unless this generic information is included (see 40 CFR 720.65, 720.85, and 720.87).

Once a new microorganism is actually manufactured or imported, it will be listed on the inventory and will be no longer subject to PMN requirements. (See 40 CFR 720.102 concerning submission of a Notice of Commencement of Manufacture or Import.) EPA proposed an approach to inventory listings in a background document to the December 84 notice. The Agency received very few comments on this document, but those who commented stated that a general method for listing all microbes does not seem possible at this time. The Agency agrees and therefore intends to list microorganisms on the inventory on a case-by-case basis while developing more general procedures for different classes of microorganisms, and gaining experience that will help in developing standard listings. For now, the inventory definition will usually include the genus and species designations of source organisms and of the microorganism being reported, and other relevant phenotypic information such as nutritional and substrate requirements, proteins expressed, primary characteristics for which the microbe was engineered, and characteristics that are a typical for the species.

To identify the microorganism, EPA is likely to require information on:

i. Source organisms (e.g., taxonomy, source, reproductive cycle, and capacity for genetic transfer).

ii. Methods used to manipulate source organisms genetically to obtain the resulting product (e.g., source and function of genetic material to be combined; description of methods for vector construction and introduction, fusion of cells, injection of DNA, etc.).

iii. The special functions obtained (e.g., new traits intended to be expressed; selection method; nature and amount of source genetic material remaining in the product microorganism; genetic stability of new trait).

(b) *Risk assessment information.* Data required for conducting the risk assessment will vary according to the specifics of each case, but in general will fall into several major categories: Information on exposure, environmental fate, and human health and environmental effects.

If the microorganisms will be produced in enclosed, commercial-scale facilities, or used solely in physically contained systems, the notice should include the following information:

i. Production processes (e.g., culture conditions and requirements; sites, methods, and amounts of manufacture, processing, storage, and shipment; volume, composition, and disposal of wastes).

ii. Workplace exposure and worker practices (e.g., potential for exposure, worker protection practices, and equipment).

iii. Containment and possible releases (e.g., potential sources and characteristics of releases, physical containment methods, emergency back-up systems, monitoring, and detection methods in event of a release).

In the case of small-scale field tests and other environmental releases, EPA expects that the submitter will provide information on:

(A) Purpose and intended effect of application.

(B) Site of application and surroundings, including geographic, physical, chemical, and biological features.

(C) Numbers of microorganisms and methods of application.

(D) Containment and mitigation measures (e.g., procedures in event of accidental release, for emergency termination of the application, and to reduce dispersal beyond the site).

(E) Monitoring (e.g., detection procedures including their limits, sampling procedures).

For field tests and other environmental releases, data on environmental fate and effects will be essential. In such cases, manufacturers should assume, in the absence of data to the contrary, that the microorganisms may present a risk because of their potential to reproduce and exhibit new traits. Therefore, EPA will expect manufacturers to provide test and other data demonstrating the microorganisms' safety. These data should include:

(i) General background information on the source organism (e.g., habitat and geographic distribution, interactions with other organisms, involvement in biological cycling processes, potential for genetic exchange in nature).

(ii) Test data on the new microorganism itself, indicating its potential for survival, replication, dissemination, and genetic exchange with other organisms.

For further guidance, manufacturers should refer to the "Proposed Points to Consider for Environmental Testing of Microorganisms" developed by the National Institutes of Health Recombinant DNA Advisory Committee Working Group on Release into the Environment (Ref. 11). This document is particularly useful in developing data and information for submissions on small-scale field tests. While some points in this document relate solely to recombinant DNA techniques, most of the considerations are relevant to environmental tests of microorganisms regardless of the techniques involved in their production.

In addition, the Agency has prepared a more detailed guidance document entitled "Points to Consider in the Preparation and Submission of PMNs for Microorganisms." This document provides guidance on both environmental and industrial applications of microorganisms and is available from the TSCA Assistance Office (see address at the beginning of this notice).

At least three other documents will be useful to submitters. These are the "EPA Pesticide Assessment Guidelines: Subdivision M—Biorational Pesticides" (Ref. 20), a National Science Foundation report titled "The Suitability and Applicability of Risk Assessment Methods for Environmental Applications of Biotechnology" (Ref. 3), and a report by the Cornell Ecosystems Research Center titled "Potential Impacts of Environmental Release of Biotechnology Products: Assessment, Regulation, and Research Needs (Ref. 9).

e. *The PMN review.* All reviews of microorganisms will follow established administrative steps that are the same for all substances subject to PMN review. First, within 5 days of receiving the PMN, EPA will issue an announcement in the **Federal Register** describing the submission. The anouncement will include information on the identity of the new microorganism, the type of use, occupational exposure, production volume, a summary of test data submitted in the notice, and the submitter's identity. It will have confidential business information deleted according to the manufacturer's instructions, although EPA will strongly encourage manufacturers to release as much information as possible. If identity and use are claimed confidential, the Agency will include a generic description provided by the submitter.

EPA will have 90 days to review the PMN (extendable to 180 days), during which time the microorganism cannot be manufactured or processed for purposes other than research and development. Within the review period, the Agency may take action under section 5(e) of TSCA to prohibit or limit the activities, pending receipt of more data, or under section 5(f) or 6 to prohibit or limit the activities if there is sufficient information to make an unreasonable risk finding. Alternatively, EPA may take no action. In this case, manufacture and use may begin without restriction.

(1) *Case-by-case assessments.* Because of the very recent development of genetically engineered microorganisms for environmental use, there is little direct experience for conducting risk assessments on environmental releases of engineered microorganisms. In the absence of such experience, the Agency will conduct case-by-case reviews by using information from various scientific disciplines and by directly considering the features of specific genetically engineered microorganisms and their uses.

Many existing risk assessment approaches that are used for non-engineered microorganisms will contribute to the analysis of risks of engineered microbes in the environment. Some of these will be adopted with few if any changes, while others will require modifications to address special problems.

EPA believes that standardized protocols and procedures should be gradually blended with the case-by-case approach. As experience is gained, increasingly detailed guidance on routine testing and procedures can and will be developed.

(2) *Use of experts.* Expert judgment will be critical in determining information needs, evaluating protocols for testing, and reviewing potential risks. Because of the range of expertise that may be required in any given case, EPA intends to supplement its staff expertise by using experts from other government agencies, academia, and other independent sources. Persons will be specifically chosen for their knowledge and experience with organisms and uses related to the PMN under review.

As announced in the December 84 notice (and further described in Unit I of this notice), EPA is forming a biotechnology Science Advisory Committee to provide scientific advice and promote consistent review procedures.

Many academic experts may have financial or contractual relationships with biotechnology companies. Using non-Agency experts to assist in PMN reviews may therefore raise two potentially sensitive issues: Conflicts of interest and access by non-Agency experts to confidential business information. To address these issues, the EPA Office of Toxic Substances has developed special procedures to ensure that scientists contributing to biotechnology PMN reviews will not have conflicts of interest, and will have the necessary access to CBI to review the PMN without compromising trade secrets or violating TSCA CBI procedures. A document describing these procedures will be placed in the public record for this policy statement.

(3) *Major parts of the review process.* As stated earlier, EPA expects persons developing biotechnology products to engage in prenotice consultations with the Agency. During these discussions, EPA and the consulting company can identify preliminary concerns by considering the source organisms and intended uses of the microorganism subject to PMN. Significant time may be saved later in the PMN process if these concerns are addressed before the PMN is submitted.

Once the PMN is submitted, EPA will develop hazard and exposure assessments based on information submitted in the PMN, other available information, and consultation with non-Agency experts. Reviewers will consider the types of issues and questions described here and in the various guidance documents on risk assessments for microorganisms. As appropriate, they may also consult with external scientific experts, and their analyses may be peer reviewed by the Agency's biotechnology Science Advisory Committee.

As a risk/benefit statute, TSCA requires that benefits be estimated and considered in judging whether the risk may be unreasonable. While the risk assessments are being developed, Agency economists will estimate the benefits of the product based on information from the submitter, independent economic research, and consultation with non-Agency experts.

Finally, EPA staff will prepare a summary of the risks and benefits to use in reaching regulatory decisions.

(4) *Public involvement in the review.* EPA will issue for publication a section 5(d)(2) notice after receipt of a PMN for a new microorganism. EPA will also maintain a copy of the PMN, from which CBI has been deleted, in the OTS Public Information Office at the address listed in Unit VI of the EPA notice. EPA will welcome comments from interested members of the public on the PMN. The public is generally given 30 days to comment on a PMN after publication of the section 5(d)(2) notice.

In addition to the normal procedures for public comment on PMNs, EPA intends that meetings of its biotechnology Science Advisory Committee will be open to the public, although certain portions of meetings may have to be closed to discuss CBI. EPA also intends to charter its committee to include representatives from the lay public. These features will help to ensure that the public has access to information about EPA biotechnology policies and decisions.

(5) *Possible regulatory decisions.* The Agency may come to one of three decisions at the conclusion of a particular PMN review: (a) There is sufficient information to determine that the risks are reasonable, (b) there is sufficient information to determine that the risks are unreasonable, or (c) there is insufficient information to make a reasoned evaluation of risk, and the substance may present an unreasonable risk or there may be significant or substantial exposure to it.

Where the first decision is made, the Agency will notify the PMN submitter that the manufacture and use may proceed without restriction. In any event, unless the Agency notifies the company to the contrary before the end of the 90-day review period (with a possible 90-day extension), the submitter may begin to manufacture and use the organism.

A decision that risks will be unreasonable leads to two regulatory options. The Agency may require measures to reduce the risks to an acceptable level as a condition of manufacture and use. Alternatively, the Agency may prohibit manufacture or use of the microorganism if there are no alternatives available or practical to reduce the risk sufficiently. Such actions can be taken under TSCA section 5(f).

If the information submitted with the PMN is insufficient for a reasoned evaluation, and EPA finds that the microorganism may present an unreasonable risk or that there may be significant or substantial human exposure to it, or substantial environmental release, EPA may, under TSCA section 5(e), limit or prohibit the manufacture or use of the microorganism until sufficient data are submitted to the Agency to evaluate the risks.

2. *Significant new uses of microorganisms*—a. *Overview.* EPA intends to supplement its PMN requirements by requiring persons to notify the Agency before they introduce

pathogenic microorganisms (including microorganisms containing genetic material from pathogens) into the environment. Notification will be required for new environmental applications of genetically engineered pathogens prior to their release in any amounts into the environment, while notification for nonengineered pathogens will be required at a somewhat later stage, prior to their introduction on more than 10 acres of land (or some equivalent measurement standard in cases where acreage is not applicable, e.g. aquatic uses). If a pathogen used for agricultural purposes is subject to USDA review, it will not be subject to this policy. Applicable definitions may be found in Unit IV.

EPA intends to implement these notification requirements through a significant new use rule (SNUR) under TSCA section 5(a)(2). The public will have the opportunity to comment on the proposed rule, including its scope and possible categories that could be excluded from coverage.

Until the rule is final, EPA expects persons introducing pathogens into the environment for non-agricultural new uses to report to EPA voluntarily. In the unlikely event that an imminent hazard would arise during this interim period, the Agency could use its authority under section 7 of TSCA to immediately limit or prohibit the manufacture, processing, distribution in commerce, use, or disposal of the hazardous product.

b. *SNUR background.* Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a significant new use. The Agency must make this determination by rule, after consideration of all relevant factors, including those listed in section 5(a)(2). Once EPA determines that a use of a chemical substance is a significant new use, section 5(a)(1)(B) of TSCA requires persons to submit a notice to EPA at least 90 days before they manufacture, import, or process the substance for that use.

Persons subject to a SNUR must comply with most of the same notice requirements and regulatory procedures as submitters of PMNs under section 5(a) of TSCA. EPA's review procedures and regulatory authority are the same for SNUR notices as for PMNs. However, if EPA does not take action on a SNUR notice, section 5(g) of TSCA requires the Agency to explain in the **Federal Register** its reasons for not taking action. Procedures and requirements for PMN review are described above in Unit III.C.1.

c. *SNUR rationale.* As explained in the December 84 notice, EPA recognizes that any approach to defining "new" microorganisms, including the one described in Unit III.C.1, excludes some types of microorganisms from PMN review and therefore may not address some significant potential risks. EPA believes there is one currently identifiable category of microorganisms that is not being treated as "new" under TSCA at this time but that should be reviewed before environmental release. That category includes pathogens and microorganisms that contain genetic material from pathogens (henceforth, both are referred to collectively as "pathogens"). As explained in more detail in Unit I, the Agency believes it is necessary to review pathogens released to the environment because of their ability to cause disease in microbes, plants, animals, and humans.

EPA intends to take a slightly different regulatory approach with nonengineered pathogens. The Agency will not require SNUR reporting on the use of nonengineered pathogens until they are to be used on more than 10 acres of land, or some equivalent standard (to be determined) for uses where acreage is an inappropriate standard (e.g. aquatic or subterranean uses). The reason for this exception is explained in Unit I.D., "Rationale for Approach."

To avoid duplicative requirements with USDA, EPA will exclude pathogens used solely for agricultural purposes from the scope of its SNUR. USDA permits to use such microorganisms are mandatory, while EPA review would be discretionary because these are not "new" microorganisms. However, new environmental applications of pathogens for non-agricultural purposes will be subject to EPA review as significant new uses, and will in some cases also be subject to USDA oversight (if they are plant or animal pests under the USDA definition). In such cases, USDA's review will primarily be for the purpose of detecting potential adverse agricultural effects, while EPA's review will focus on the potential non-agricultural impacts. See Unit I.E for an explanation of how the agencies will work together to coordinate their review.

EPA is considering whether it should also include provisions in the SNUR requiring notification prior to small-scale releases or commercial uses of other categories of microorganisms besides pathogens. For example, some people have expressed concern over nonindigenous microorganisms, and others have expressed concern over microorganisms that degrade structural components of nature such as lignin and cellulose. Members of neither category are subject to PMN when the microorganisms involved are naturally occurring or intra-generic (not new), and they would not be subject to the provisions for pathogens described above. However, they may present certain risks because they are new to the environment in which they are used or because of their degradative capabilities. The literature contains much documentation of the adverse effects that have occasionally been caused by nonindigenous microorganisms such as the chestnut blight fungus and Dutch Elm disease fungus. There is, on the other hand, very little known about many degradative microorganisms and their potential for adverse effects. The Agency will request comments on these concerns when it issues its proposed SNUR.

d. *Guidelines for voluntary compliance.* The SNUR that EPA will propose will describe, in detail, the persons who will be subject to the rule and the microorganisms and activities for which significant new use reporting will be required. In the meantime, EPA strongly encourages persons who are planning to manufacture, import, or process pathogenic microorganisms for non-agricultural, new environmental uses, except those used solely for agricultural purposes, to report their activities to the Agency and to provide information similar to that required for a PMN for a new microorganism.

For purposes of voluntary reporting, persons may use the following definitions and assumptions. These guidelines may be changed in the proposed and final forms of the SNUR.

(1) *How to know if a use would be considered a significant new use.* For purposes of voluntary reporting, the Agency encourages people to be as comprehensive as possible and to consider that any new, non-agricultural release of a pathogen to the environment is appropriate to report. "Environmental release" is defined in Unit IV.D, this definition should be used in the interim until the SNUR is final. Cases that may not be entirely clear, e.g., use in waste water treatment plants and use in mines or oil wells, should be reported until the Agency provides further guidance.

Many microorganisms that are pathogens or that contain genetic material from pathogens are being used in the environment already. For example, specific naturally occurring pathogens are used for waste treatment purposes and are tested in non-contained experiments. These applications of these specific microorganisms cannot be considered

significant "new" uses because they are ongoing. Therefore, persons now using pathogens in environmental applications will not be expected to notify the Agency of such uses of these pathogens, except for informational purposes (see Unit III.C.4).

In developing the proposed and final rule, the Agency will have to determine exactly which types of uses should be considered significant new uses, taking into account that the purpose of the rule is to ensure the Agency has the opportunity to review releases of pathogens that could entail significant exposure or risk to the environment or the public. Considerations relating to the appropriate scope of the rule will be discussed in the proposed SNUR, and the public will be invited to comment.

(2) *How to know if a microorganism is a pathogen.* Unit IV.B of this notice contains the definition of "pathogen" that the Agency will use for purposes of administering TSCA and FIFRA, and provides guidance on how to determine if a microorganism is a pathogen.

(3) *How to know if a microorganism is genetically engineered.* As discussed in Unit III.C.2.c, EPA will not require nonengineered pathogens to be reported until they are used on more than 10 acres of land (or some equivalent standard, not yet determined, for uses where acreage is an inappropriate standard). For now, a pathogen should be considered nonengineered if there has been no deliberate attempt to promote genetic changes. Any human intervention beyond removal from the environment and selection for the desired variant populations should be considered to result in an engineered microorganism.

(4) *Submitting the significant new use notice.* Persons subject to the SNUR will have to notify the Agency at least 90 days prior to any new, non-agricultural use involving environmental release of engineered pathogens. The Agency will treat nonengineered pathogens slightly differently; producers of nonengineered pathogens will be subject to significant new use notification 90 days prior to new uses involving environmental applications on more than 10 acres of land. Significant new use notifications for microorganisms should contain the same general types of information as PMN submissions for microorganisms. In all cases, SNUR notice submitters should initiate prenotice consultations with EPA well in advance of the actual submission, to expedite the Agency's review of the notice.

e. *Significant new use notice review.* EPA reviews of significant new uses of microorganisms will be conducted in a fashion similar to PMN reviews of microorganisms. The review must be completed in 90 days, extendable for good cause to 180 days. In conducting the review, EPA will use Agency and non-Agency scientists selected for their expertise on issues relevant to the specific case.

The Agency recognizes that various environmental uses of different types of pathogens pose very different levels of potential risk to human health and the environment. For example, risks should generally be lower when pathogens are applied in areas distant from host organisms; the manufacturer has used nonpathogenic strains of a pathogenic species; transferred genes are for a trait not directly involved in pathogenicity; the pathogenic source organisms have very narrow host ranges; and pathogenic genes have been deleted.

Because it recognizes these variations in risk, the Agency expects to subject some pathogenic microorganisms to more rigorous regulatory oversight than others.

3. *Research and development (R&D) exemption*—a. *Overview.* TSCA section 5(h)(3) exempts from PMN and SNUR notification requirements chemical substances manufactured in small quantities solely for R&D. However, to ensure adequate review prior to environmental release, EPA intends to require persons developing "new" microorganisms and certain engineered pathogens to notify EPA prior to any research involving environmental release. This will be accomplished by amending the PMN rule (and possibly the general SNUR rules in 40 CFR Part 721) to specify that field testing of microorganisms does not fall within the definition of "small quantities" for R&D. Until the necessary rule changes implementing this policy are final, EPA expects submitters to comply with this policy voluntarily. Notice submitters are advised to consult the Agency if they are unsure whether a particular test is subject.

b. *Background.* As explained in the December 84 notice (at page 50891), section 5(h)(3) of TSCA exempts from PMN requirements new chemical substances produced "only in small quantities solely for purposes of research and development." ("Small quantities" must be defined by rule.) The same exemption applies to substances produced for significant new uses. if this exemption as now defined were applied to living microorganisms, many microorganisms would go unreviewed by EPA until perhaps years after their initial testing in the environment. Because microorganisms can reproduce in the environment and have the potential to exhibit new traits, this has raised the question of whether these field tests for R&D purposes could present significant risks that would go unreviewed.

Because of this concern, an important issue for EPA in implementing the biotechnology program has been whether to alter the R&D exemption of TSCA section 5 notice requirements in the case of living microorganisms. EPA requested and received substantial public comments on this issue, which it considered carefully in developing this policy. The comments and EPA's response to them are described in the EPA "Response to Comments" document, available as part of the public record of this EPA notice.

c. *Rationale.* The PMN rule definition of "small quantities" for R&D has been appropriate for most chemicals subject to TSCA because of the assumption that chemical R&D generally involves limited exposure and therefore limited risk. In the case of field tests involving living microorganisms, this assumption will not always apply. Microorganisms that survive may reproduce, potentially leading to significant exposure and risks. Because of their ability to reproduce and therefore increase beyond the amount originally released, living microorganisms used in the environment cannot be considered to meet the commonly understood meaning of "small quantities" for research and development, and thus do not qualify for the exemption.

d. *Implementation.* To implement the change in the R&D exemption, EPA intends to amend the PMN rule (40 CFR 720.3(cc) and 720.36) and possibly the SNUR general provisions in 40 CFR Part 720. The amendments will specify when a microorganism is considered not to qualify for the R&D exemption, and will provide enforceable standards for that determination.

Until the R&D rule amendments are final, EPA expects commercial researchers intending to release new, living microorganisms and engineered pathogens into the environment to report their activities to the Agency as explained in the units on PMN and SNUR notification (Units III.C.1 and 2). In addition, EPA strongly encourages researchers, prior to the time of reporting, to maintain records regarding containment procedures used in their experiments. Researchers should use the definition of "environmental release" provided in Unit IV.D as a guide, ask EPA for further guidance if questions arise, and in general be as inclusive as possible in their estimation of what should be reported.

e. *Noncommercial R&D.* Noncommerical R&D is exempt from section 5 of TSCA under section 5(g) and would therefore be exempt from PMN and SNUR requirements even under the proposed amendments. EPA has defined "noncommercial" for all chemical substances subject to TSCA section 5 in a final rule published in the **Federal Register** of April 22, 1986 (51 FR 15096). As a general guide, R&D done by a commercial company should be considered commercial, and purely academic R&D should be considered noncommercial. For more specific guidance, the reader should examine the definition of "noncommercial" in the final rule and the discussion of "noncommercial" in the proposed PMN rule revisions published in the **Federal Register** of December 27, 1984 (49 CFR 50208). Readers should also note that the NIH Recombinant DNA Advisory Committee (RAC) and USDA Agriculture Biotechnology Recombinant DNA Advisory Committee (ABRAC) have jurisdiction over many noncommercial R&D activities, specifically recombinant DNA experimentation at institutions that receive funds from NIH and USDA. Both of these committees encourage submission of experiments from other sources as well.

4. *General information reporting requirements*—a. *Overview.* EPA intends to collect general information prior to the environmental use of microorganisms that are subject to TSCA, but that are not the subject of premanufacture or significant new use notification requirements. EPA will gather such information by means of a section 8(a) reporting rule. The information EPA collects will primarily be used to monitor environmental uses of microorganisms, thus making the Agency aware of cases that may require special regulatory action under other TSCA authorities. It will also be used to help the Agency evaluate and modify the scope of its biotechnology programs over time.

b. *Section 8(a) background.* Section 8(a) of TSCA authorizes EPA to issue rules requiring manufacturers, importers and processors of specified chemical substances to submit information to the Agency. TSCA section 8(a)(2) authorizes the Agency to obtain a broad range of data, including information on chemical identity and structure, production, use, exposure, disposal, and health and environmental effects. Small manufacturers, importers, and processors, as defined by EPA, are exempt from section 8(a) reporting and recordkeeping requirements, with certain statutory exceptions.

c. *Rationale for section 8(a) rule.* As explained in the overview to the EPA portion of this notice, the biotechnology review procedures described in this notice are intended to focus on the current areas of highest priority based on considerations of risk and on determinations about what makes a microorganism "new." However, there is a relatively high degree of scientific uncertainty involved in establishing these priorities at this early stage in the development of the biotechnology industry. The Agency cannot say definitively that all the microorganisms and uses that are not at this time subject to notification requirements will never need to be regulated or should never be subject to notification requirements in the future.

EPA believes that TSCA section 8(a) is the best mechanism available for determining whether specific microorganisms or categories of microorganisms not subject to PMN or SNUR notice requirements may need to be regulated. The Agency must be aware of how microorganisms are being used in the environment to fulfill its responsibility to identify and prevent important or immediate hazards that might unexpectedly arise with specific uses. The section 8(a) reporting will also provide EPA with necessary information to assess whether its overall priorities with regard to biotechnology regulation have been, in fact, appropriately set and whether they should change over time. As was pointed out by many comments on the Agency's first proposed statement on biotechnology, flexibility and incorporation of new information should be major components of any regulatory scheme.

d. *Implementation*—(1) *Who will have to report under section 8(a)?* When promulgated, EPA intends for this rule to apply to manufacturers, importers, and processors of microorganisms that are subject to TSCA and to be released in the environment, but are not otherwise reviewed under the PMN and SNUR policies described earlier. In other words, general information will be required prior to environmental releases of all microorganisms that are subject to TSCA and that are non-engineered pathogens, or that are intra-generic or naturally occurring non-pathogens.

Although the rule will apply in general to the above groups, small manufacturers, importers, and processors are usually exempt from section 8(a) reporting and recordkeeping requirements. EPA has established general exemption standards for small manufacturers (40 CFR Part 704). The Agency will consider whether these standards should be retained or altered in some way to reflect considerations particular to the biotechnology industry.

When EPA issues its notice of proposed rulemaking, the public will have an opportunity to comment on the question of who will have to report under the rule.

(2) *What information will have to be reported under section 8(a)?* EPA is in the process of considering exactly what information it will propose to require on microbial products and uses under the section 8(a) reporting rule. In deciding what information should be reported on microorganisms, EPA will consider what information is necessary for the Agency to assess the safety of planned environmental releases, to evaluate its biotechnology regulations over time, and to consider necessary and appropriate improvements. The Agency will also consider the economic impact of special information and whether the information is generally "known to or reasonably ascertainable by" potential respondents to the rule.

5. *Reporting of information on substantial risks.* All manufacturers, processors, and distributors of microbial products subject to TSCA, including those involved in research and development, are reminded of their responsibility to notify EPA immediately of any new information which "reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment" (TSCA section 8(e)).

Guidance on the section 8(e) requirement was published in the **Federal Register** of March 16, 1978 (43 FR 11110). Manufacturers, processors, and distributors will find that this policy statement provides general guidance on TSCA section 8(e) reporting, but it should not be considered exhaustive in terms of the types of information that would reasonably support a conclusion of substantial risk. Specifically with regard to microorganisms, the types of information that should be reported include but are not limited to (1) pathogenicity to humans, plants, animals, or microbes, (2) significant ability to displace other organisms in the intended use area, (3) significant potential to transfer genetic material to other organisms, and (4) any other significant potential to cause harm to human health or the environment.

Manufacturers, processors, and distributors should be vigilant and immediately report substantial risk information concerning microorganisms subject to TSCA.

6. *Exemptions from premanufacture notification requirements.* Section 5(h)(4) of TSCA allows EPA, by rule, to exempt from PMN requirements chemical substances that it finds will not present unreasonable risks. EPA expects to use this authority, where appropriate, to reduce the burden of PMN reporting requirements.

In its December 84 notice (at page 50891), EPA asked for comment on the issue of whether certain microorganisms or categories of microorganisms should be exempt from PMN requirements under the authority of section 5(h)(4) of TSCA. Ten respondents stated that microorganisms used in closed systems should be exempt under the 5(h)(4) provision, although several specifically remarked that appropriate biological and physical containment conditions should first be determined and met. Others suggested modifications to this approach, such as expedited reviews or reduced information requirements rather than outright exemption, or application of the exemption only to specific microorganisms or substances (e.g., *E. coli.* used in contained systems). One commenter stated that an exemption was not appropriate because there is no current Federal authority to determine safety in the event of accidental release.

Under TSCA, the PMN policy described in Unit III.C.1 extends to commercial-scale, closed system uses of microorganisms as well as environmental releases. The statute requires that all manufacturers of "new" substances must submit PMNs, regardless of whether they are used in contained facilities or open environments. Nonetheless, EPA believes that closed-system uses of new microorganisms will often present lower risks than environmental releases of the same organisms. The contained uses may therefore warrant a section 5(h)(4) exemption, and EPA is hereby announcing its intent to pursue that possibility.

Since the Agency does not yet have sufficient information to make the necessary finding under section 5(h)(4) that such activities "will not present an unreasonable risk of injury to human health or the environment," it is soliciting more data to support that finding in the case of closed system uses. The Agency would appreciate receiving data that would support an exemption either for all inter-generic microorganisms used in closed systems, or for specific categories of such microbes. For example, a category that has been suggested for exemption is inter-generic combinations involving microorganisms that exchange DNA by known physiologic processes, and that are on the NIH RAC exchanger list. This possible exclusion is mentioned in the OSTP preamble published in this **Federal Register.**

Information and data relevant to this issue should be sent to EPA at the address listed at the beginning of this notice.

In addition to supporting the use of section 5(h)(4) exemptions, the Agency will try to identify categories of microorganisms that pose lower risk even though they may not meet the necessary findings for exemption. In such cases, the Agency will consider reducing the burden of PMN reporting by lowering the information requirements associated with the PMN, and by conducting expedited reviews. The Agency requests any data or information that could be used to support exemptions or expedited reviews.

IV. Definitions of Terms for Regulatory Purposes

As explained in the previous units of this notice, EPA intends at this time to focus its regulatory programs on microorganisms containing genetic material from dissimilar source organisms (defined as organisms from different genera), pathogenic microorganisms, microorganisms containing genetic material from pathogens, nonindigenous microorganisms, and TSCA nonagricultural environmental applications. Applicable requirements are described in Units II and III of this notice. The purpose of this unit is to provide detailed information on how a person should determine whether a specific product is a pathogen, contains genetic material from a pathogen, contains genetic material from organisms of different genera (inter-generic combination), is nonindigenous, is released to the environment, or is used for nonagricultural TSCA purposes.

A. How To Determine if a Product Is an Inter-Generic Combination

For purposes of implementing its concept of "new" microorganisms, the Agency is defining "new" microorganisms as those formed by deliberate combinations of genetic material from organisms of different genera.

This standard is purposely based on the taxonomic designations of microorganisms. While imperfect in many ways, taxonomy appears to provide the best available standard for "dissimilarity" among organisms, for the following reasons:

1. Although subject to periodic revision within the scientific community, taxonomy is a common language used by scientists to describe how organisms are similar and dissimilar (Refs. 4, 18).

2. Taxonomy reflects the most recent scientific observations about phenotypic and genotypic differences between organisms.

3. Taxonomy provides a universally available point of reference that can be understood by industry and enforced by the Agency.

4. EPA expects microorganisms being used in biotechnology research and development will have or can be assigned clear taxonomic designations; therefore, the use of taxonomic standards imposes few if and additional requirements on industry.

5. There is a significant adminstrative advantage to independently established criteria such as taxonomic standards, because EPA will not have to create and maintain a separate set of criteria for regulatory purposes.

The Agency expects all manufacturers to know or determine the currently accepted designations (genus, species) of the source organisms they have used in producing microbial products subject to FIFRA and TSCA. In addition, EPA expects submitters to use taxonomic literature and taxonomic experts, if necessary, to determine the correct identity of their microorganisms. A number of commenters on the December 84 notice stated that organisms manipulated by modern genetic engineering will in most cases already be well characterized. This fact should make implementation of this policy relatively easy in most cases.

Excluded from this policy on inter-generic combinations are microorganisms that have resulted from the addition of inter-generic material that is well-characterized and contains only non-coding regulatory regions such as operators, promoters, origins of replication, terminators, and ribosome-binding regions.

"Well-characterized, non-coding regulatory regions" means that the producer of the microorganism can document the following:

a. The exact nucleotide base sequences of the regulatory region and any inserted flanking nucleotides.

b. The regulatory region and any inserted flanking nucleotides do not code for protein, peptide, or functional RNA molecules.

c. The regulatory region solely controls the activity of other regions that code for protein or peptide molecules or act as recognition sites for the initiation of nucleic acid or protein synthesis.

EPA emphasizes that this policy excludes only inter-generic combinations that have resulted solely from the addition of well-characterized, non-coding regulatory regions. If the final microorganism contains any regions from organisms of other genera that do not meet this restriction, such as coding regulatory regions or any poorly characterized regions, the microorganisms is considered new and does not come under the exclusion for regulatory regions discussed above.

To document these features, EPA expects that companies will use sources such as citations to published scientific literature, copies of unpublished studies relied upon, or data from tests performed to determine the above characteristics.

If persons do not know the genera of particular organisms, they should consult standard sources such as the following:

i. Bacteria

(1) Skerman, V.B.D., V. McGowan, and P.H.A. Sneath. 1980. Approved list of bacterial names. International Journal of Systematic Bacteriology 30:225–420.

(2) Moore, W.E.C., E.P. Cato, and L.V.H. Moore. 1985. Index of the bacterial and yeast nomenclature changes published in the International Journal of Systematic Bacteriology since the 1980 approved list of bacterial names (1 January 1980 to 1 January 1985). International Journal of Systematic Bacteriology 35:382–407.

Manufacturers should consult issues of the International Journal of Systematic Bacteriology for validly published names and for names placed on Validation Lists since January 1985.

ii. Algae

(1) DeToni, 1889. Sylloge Algarum.

(2) Index Kewensis. 1895-present. (Royal Botanical Gardens, Kew.)

iii. Protozoa

(1) Nomenclator Zoologicus. 1758-present. Published in four volumes and two supplements from 1939 onwards. Edited by S.A. Neave. Zoological Society, London.

(2) Index Zoologicus. 1800–1900. Charles Owen Waterhouse. (Published 1902.) Edited by David Sharpe. Zoological Society, London.

(3) Index Zoologicus. 1902-present. (Zoological Society, London.)

iv. Fungi

(1) Saccardo, P.A. 1882–1921. Sylloge Fungorum. (Pavia, 25 vol.)

(2) Clements, F.E. and C.L. Shear. 1931. The Genera of Fungi (H.W. Wilson and Co., N.Y.)

(3) Index to Fungi. 1940-present. Commonwealth Mycological Institute, Kew, Surrey, England.

(4) Petrak's List of Fungal Names. 1922–1940. Commonwealth Mycological Institute, Kew, Surrey, England.

(5) Hawksworth, D.L., B.C. Sutton, and G.C. Ainsworth. 1983. Ainsworth and Bisby's Dictionary of the Fungi. Commonwealth Mycological Institute, Kew, Surrey, England.

v. Viruses

(1) Mathews, R.E.F. 1979. Classification and nomenclature of viruses, 3rd report of the International Committee on Taxonomy of Viruses. Intervirology 12(3–5):1–199.

If the taxonomic positions of source organisms are ambiguous or if the boundaries of a genus are in dispute, the Agency expects the submitter to be aware of these controversies. Ambiguities at the species level or lower will not affect the FIFRA and TSCA policies. However, if the taxonomy at the genus level is controversial, such that organisms may be considered by some to belong to the same genus and by others to belong to different genera, the submitter must comply with the applicable requirements of FIFRA or TSCA, or come to EPA for a case-specific determination (address provided at the beginning of this notice). In general, submitters should expect that microorganisms will be considered inter-generic if the taxonomy of either source organism, at the genus level, is controversial.

In the case of chemically synthesized genes, the Agency will follow a similar principle. The genetic sequence of the synthesized gene may be identical to a sequence known to occur in an organism in the same genus as the recipient microorganism. If so, the resulting microorganism will be considered intra-generic. However, the producer should be prepared to document how it made this determination. Conversely, the sequence of the synthesized gene may be different or not known to be identical to a sequence in the genus of the recipient microorganism. In this case, the resulting product will be considered inter-generic.

EPA's definition of inter-generic combinations contains a standard of intent on the part of the manufacturer or producer. Inter-generic combinations that occur as unintentional byproducts of microorganisms coming in contact with one another will not be considered subject to the provisions of TSCA and FIFRA that apply to inter-generic combinations. For example, inter-generic combinations may occur at very low frequencies if microorganisms from different genera are applied to the same plot of land, or are sold together as mixtures. Similarly, if manufacturers develop microorganisms that are naturally infected with viruses, and if the developer did not intend to promote and did not provide conditions actively promoting the infection of the microorganisms with the naturally occurring viruses, then the microorganisms containing naturally occurring inter-generic combinations would not be considerd inter-generic under the FIFRA and TSCA policies.

On the other hand, if the manufacturer or producer intentionally provides conditions to promote genetic transfer, or if inter-generic microorganisms are primary components of a product or mixture, then the microorganisms will be considered inter-generic and subject to the applicable provisions of FIFRA and TSCA.

Submitters should consult the Agency if they have any questions about these distinctions.

B. How to Determine if a Product Is a Pathogen

For the purposes of this policy, a pathogen is defined as a virus or organism (including its viruses and plasmids, if any) that has the ability to cause disease in other living organisms (i.e., humans, animals, plants, or microorganisms). A disease is an abnormal physiological function in an organism, occurring as a consequence of the activity of proliferating microorganisms directly associated with or infecting the host organism, or due to biologically active substances such as toxins, antibiotics, or growth regulators produced by a microorganism (Refs. 5, 6, 7, 8, 14, 19).

This policy is not meant to include such organisms as competitors or colonizers of the same substrates, commensalistic or mutualistic microorganisms, or opportunistic pathogens. However, if a microorganism has more than one mechanism for affecting other organisms and one of these is pathogenicity, then the microorganism is considered to be a pathogen.

A microorganism will be subject to EPA policies regarding pathogens if:

1. The organism belongs to a pathogenic species or to a species containing pathogenic strains, according to sources identified by EPA below, or from information known to the producer that suggests that the organism is a pathogen; excepted are organisms belonging to a strain used for laboratory research or commercial purposes and generally recognized as non-pathogenic according to sources identified by EPA, or information known to the producer and EPA; an example of a nonpathogenic strain of a pathogenic species is *Escherichia coli* K–12; examples of nonpathogenic species are *Bacillus subtilis, Lactobacillus acidophilus,* and *Saccharomyces* species; or,

2. The organism has been derived from a pathogen or has been deliberately engineered such that it contains genetic material from a pathogenic organism as defined in item 1, above. An exception to this requirement is a genetically engineered organism developed by transferring well-characterized, non-coding regulatory regions from a pathogenic donor to a nonpathogenic recipient.

"Well-characterized, non-coding regulatory region" means that the producer of the microorganism can document the following:

a. The exact nucleotide base sequences of the regulatory region and any inserted flanking nucleotides.

b. The regulatory region and any inserted flanking nucleotides do not code for protein, peptide, or functional RNA molecules.

c. The regulatory region solely controls the activity of other regions that code for protein or peptide molecules or act as recognition sites for the initiation of nucleic acid or protein synthesis.

To document these items, EPA expects that companies will use sources such as citations to published scientific literature, copies of unpublished studies, or data from tests performed to determine the above characteristics.

The Agency is excluding genetically engineered organisms containing material from pathogens if the material transferred is from a pathogenic donor to a nonpathogenic recipient, and consists solely of well-characterized, non-coding regulatory regions. In this case, the transferred material does not code for traits directly associated with pathogenicity. The Agency believes that these organisms do not pose significant risks because they do not possess new combinations of traits or pathogenic traits, but instead exhibit quantitative changes in preexisting traits in a nonpathogenic recipient.

The Agency is excluding opportunistic pathogens for two reasons. First, in terms of risk priorities, outright pathogens are of significantly greater concern than organisms that would not act as pathogens except under unusual circumstances. Second, because of the very large number of microorganisms that could be considered to be opportunistic, their inclusion would result in an inappropriately restrictive policy.

There are a number of standard sources that can be used to determine whether a microorganism belongs to a pathogenic species. EPA is compiling a list of such sources, and is considering developing a list of pathogenic species, as part of future rulemaking activities. As interim guidance, persons should consider sources such as the following:

(1) Anne, W., ed. 1980. Fish Diseases. Springer-Verlag, New York.

(2) Anver, M.R. and C. Pond. 1984. Biology and Diseases of Amphibians. In Laboratory Animal Medicine, J.G. Fox, B.J. Cohen, F.M. Loew, eds. Academic Press, Orlando, FL.

(3) Bliss, D.E., ed. 1982–1985. Biology of Crustaceans (Volume 6 Pathobiology). Academic Press, New York.

(4) Blood, D.C., J.A. Henderson, and O.M. Radostits. 1979. Veterinary Medicine: A Textbook of the Diseases of Cattle, Sheep, Pigs, and Horses. 5th edition. Lea & Febiger, Philadelphia, PA.

(5) Braude, A. 1986. Medical Microbiology and Infectious Diseases. 2nd edition. W.B. Saunders, Philadelphia, PA.

(6) Buchanan, A.M. 1982. Veterinary Microbiology. Elsevier Scientific, Amsterdam.

(7) Buchanan, R.E. and N.E. Gibbons, eds. 1974. Bergey's Manual of Determinative Bacteriology. 8th edition. Williams and Wilkins Co., Baltimore.

(8) Cantwell, G.E., ed. Insect Diseases, M. Dekker, New York.

(9) Commonwealth Mycological Institute. Descriptions of Plant Pathogenic Bacteria, Fungi, and Viruses. Commonwealth Agricultural Bureaux, Kew, Surrey, England.

(10) Davidson, E., ed. 1981. Pathogenesis of Invertebrate Microbial Diseases. Allanheld, Osmum, Totowa, NJ.

(11) Ellis, A.E., ed. 1985. Fish and Shellfish Pathology. Academic Press, London.

(12) Gherna, R., W. Nierman, and P. Pienta, eds. 1985. Catalogue of Bacteria, Phages, rDNA Vectors. 16th edition. American Type Culture Collection, Rockville, Maryland.

(13) Hagan, W.A. and D.W. Bruner. 1981. Hagan and Bruner's Infectious Diseases of Domestic Animals: With Reference to Etiology, Pathogenicity, Immunity Epidemiology, Diagnosis and Bilogic Therapy. 7th edition. Comstock Publishing Associates, New York.

(14) Hitchner, S.B., ed. 1980. Isolation and Identification of Avian Pathogens. 2nd edition. American Association of Avian Pathologists, College Station TX.

(15) Jacobson, E. 1984. Biology and Diseases of Reptiles. In Laboratory Animal Medicine, J.G. Fox, B.J. Cohen, F.M. Loew, eds, Academic Press, Orlando, Fl.

(16) Jong, S.C. and M.J. Gantt, eds. 1985. Catalogue of Fungi/Yeasts. 16th edition. American Type Culture Collection, Rockville, Maryland.

(17) Kinne, O. 1980–1983. Diseases of Marine Animals. Vol. I. General Aspects, Protozoa to Gastropoda, published by John Wiley, Vol. II Bivalvia to Arthropoda, Vol. III, Echinodermata to Vertebrata, Vol. IV, Pisces Applied Aspects, Volumes II–IV published by Biologische Anstalt, Helgoland, Germany.

(18) Krieg, N.R. and J.G. Holt, eds. 1984. Bergey's Manual of Systematic Bacteriology, Vol. I, Williams and Wilkins Co., Baltimore, MD.

(19) Marcus, L.C. 1981. Veterinary Biology and Medicine of Capitve Amphibians and Reptiles. Lea and Febiger, Philadelphia, PA.

(20) Padhye, A.A. 1978. Fungi pathogenic to Man and Animals. In A.I. Laskin and H.A. Lechevalier, eds. Chemical Rubber Company. Handbook of Microbiology, 2nd edition, Volume II, pp. 319–340.

(21) Sparks, A.K. 1985. Synopsis of Invertebrate Pathology Exclusive of Insects. Elsevier, Holland.

(22) Starr, M.P., H. Stolp, H.G. Truper, A. Balows, and H.G. Schlegel, eds. 1981. The Prokaryotes—A Handbook on Habitats, Isolation, and Identification of Bacteria. Vols. 1 and 2. Springer-Verlag.

(23) Steinhaus, E.A., ed. 1963. Insect Pathology: An Advanced Treatise, Academic Press, New York.

(24) U.S. Department of Agriculture. 1960. Index of Plant Diseases in the United States. Crops Research Division, Agriculture Research Service. Agriculture Handbook No. 165.

(25) U.S. Department of Health, Education, and Welfare. 1977. Classification of Etiologic Agents on the Basis of Hazard. In A.I. Laskin and H.A. Lechevalier, eds. Chemical Rubber Company Handbook of Microbiology, 2nd edition, Volume I, pp. 559–573.

(26) U.S. Department of Health and Human Services. 1984. Biosafety in Microbiological and Biomedical Laboratories. Public Health Service, Centers for Disease Control, Atlanta, GA.

(27) Whiteman, C.E., and A.A. Bickford. 1983. Avian Diseases Manual. 2nd edition. American Association of Avian Pathologists. Kennett Square, PA.

The Agency expects that producers will be sufficiently familiar with the relevant literature and the species of the microorganisms under development that the pathogenicity or lack of it will already be known. Therefore, the Agency does not believe that determining whether a microorganism belongs to a pathogenic species based on published sources will be burdensome.

Where there is disagreement among sources about whether a strain belongs to a pathogenic species, the submitter must assume that it belongs to a pathogenic species, or come to EPA for a case-specific determination (address provided at the beginning of this notice).

As part of further rulemaking, the Agency plans to develop a list of nonpathogenic strains of pathogenic species, in addition to *E. coli* K–12, that will be exempt from Agency policies for pathogenic microorganisms. In the interim, if a submitter is using a strain that belongs to a pathogenic species, except *E. coli* K–12, the submitter should assume that it is pathogenic.

Because of the pathogenic potential of most, if not all, viruses, and because the species concept does not generally apply in virus taxonomy, the Agency will consider any product that is or contains genetic material from a virus to be a pathogen.

The Agency intends to update this guidance periodically, particularly the list of publications.

C. How To Determine if a Product Is a Nonindigenous Microorganism

A microorganism will be considered nonindigenous to any one of the geographic areas listed below if it is isolated from outside that area:

1. The continental United States, including Alaska, and the immediately adjoining countries (i.e., Canada and Mexico).
2. The Hawaiian Islands.
3. The Caribbean Islands including Puerto Rico and the U.S. Virgin Islands.

For example, a microorganism from Hawaii, developed for use as a microbial pesticide in the continental U.S., will be considered to be nonindigenous to the continental United States. Under FIFRA, the Agency would therefore be notified before initiation of small-scale field testing of the microbial pesticide in the continental U.S.

In normal usage, nonindigenous organisms are generally considered to be naturally occurring organisms placed in environments where they are not native or have not evolved. This concept means that a microorganism could be considered nonindigenous to an ecosystem that is adjacent to the one in which it evolved, nonindigenous to ecosystems far removed, or even indigenous to nearby or far-removed ecosystems. This happens for a number of reasons such as the widely varying effects of geographic barriers as isolating mechanisms; microbial dispersal mechanisms; and the biological, chemical, and physical features shaping different environments. Given the complexity and impracticality of determining whether a particular microorganism is indigenous to a wide range of habitats that may exist within regions and states, the Agency has selected continental boundaries to describe geographic regions that are clearly isolated and are easily used for administrative purposes. These boundaries will be used to determine whether a microorganism is nonindigenous and hence subject to particular provisions under FIFRA (see Unit II).

D. How To Determine if a Product Is Released to the Environment

In the future, it is likely that a definition of environmental release will be developed. In the interim, the Agency's approach will focus on when a microorganism is considered to be contained rather than when it is released.

A microorganism will be considered environmentally contained if the microorganism is used in a laboratory that complies with NIH RAC guidelines; or the microorganism is used in a contained greenhouse, fermenter, or other contained structure. In general, "contained greenhouse, fermenter, or other contained structure" means a building or structure that has a roof and walls. It should also have a ventilation system to minimize microbial release to the outdoors, a system for sterilizing water runoff and wastes, and a system for restricting insects, if any of these are plausible routes for dissemination of microorganisms. Experimenters should control pests, sterilize soil or other material containing microorganisms before disposal or reuse, and generally limit access only to those persons who must have access for research purposes.

E. How to Determine if a Product Is Used for Nonagricultural Purposes

An agricultural use of a microorganism is any use or application, the primary purpose of which is to produce, enhance, or cultivate plants or animals. The definition is not meant to include pesticides.

F. Definition of Plants and Animals

For the purposes of this EPA notice, plants are defined as multicellular organisms characterized by eukaryotic cell walls, photosynthetic ability, and embryonic development. Members include mosses, liverworts, and vascular plants (including most terrestrial crop plants). Animals are defined as multicellular organisms composed of eukaryotic cells with ingestive nutrition and lacking rigid cell walls and photosynthetic ability. Members include coelenterates, flatworms, molluscs, segmented worms, arthropods, echinoderms, and vertebrates.

V. References

The following books, articles, and reports were used in preparing this notice:

(1) Agrios, G.N. 1978. Plant pathology. Academic Press, New York, NY.

(2) Campbell, A. 1978. Tests for gene flow between eucaryotes and procaryotes. Journal of Infectious Diseases 137: 681–685.

(3) Covello, V.T. and Fiksel, J.R., eds. 1985. The suitability and applicability of risk assessment methods for environmental applications of biotechnology. National Science Foundation, Report #NSF/PRA 8502286, Washington, DC.

(4) Curtis, H. 1983. Biology. Worth Publishers, Inc., New York, NY.

(5) Cruickshank, R., J.P. Duguid, B.P. Marmion, and R.H.A. Swain. 1973. Medical microbiology, Vol. 1: Microbial infections. Churchill Livingstone, Edinburgh.

(6) Davis, B.D., R. Dulbecco, H.N. Eisen, H.S. Ginsberg, W.B. Wood, Jr., M. McCarty. 1980. Microbiology, Harper and Row, New York, NY.

(7) Freeman, B.A. 1979. Burrows textbook of microbiology. W.B. Saunders Co., Philadelphia, PA.

(8) Fuerst, R. 1983. Microbiology in health and disease. W.B. Saunders Co., Philadelphia, PA.

(9) Gillett, J., Levin, S., and Stern, A. 1985. Potential impacts of environmental release of biotechnology products: Assessment, regulation, and research needs. Cornell Ecosystems Research Center, ERC–075, Ithaca, NY.

(10) Lewin, B. 1983. Genes. John Wiley and Sons, New York, NY.

(11) Milewski, E.A. 1985. Field testing of microorganisms modified by recombinant DNA techniques: applications, issues, and development of "Points to Consider" document. Recombinant DNA Technical Bulletin 8: 102–108.

(12) Reanney, D.C., P.C. Gowland, and J.H. Slater. 1983. Genetic interactions among microbial communities. Pages 379–421 in J.H. Slater, R. Whittenbury, and J.W.T. Wimpenny, eds. Microbes in their natural environments. 34th Symposium of Society of General Microbiology. Cambridge University Press, Cambridge.

(13) Sanderson, K.E. 1976. Genetic relatedness in the family Enterobacteriaceae. Annual Review of Microbiology 30:327–349.

(14) Schuhardt, V.T. 1978. Pathogenic microbiology. J.B. Lippincott Co., Philadelphia, PA.

(15) Sharples, F.E. 1983. Spread of organisms with novel genotypes: Thoughts from an ecological perspective. Recombinant DNA Technical Bulletin 6: 43–56.

(16) Simberloff, D. 1981. Community effects of introduced species. Pages 79–107 in M.H. Nitecki, Biotic crises in ecological and evolutionary time. Academic Press, New York, NY.

(17) Simberloff, D. 1984. Potential ecological effects of releasing genetically engineered organisms. Testimony before the Subcommittee on Toxic Substances and Environmental Oversight, of the Senate Committee on Environment and Public Works, Washington, DC, September 27, 1984.

(18) Staley, J.T. and N.R. Krieg. 1984. Classification of procaryotic organisms: an overview. Pages 1–4 in N.R. Krieg and J.G. Holt, eds., Bergey's manual of systematic bacteriology, Vol. 1. Williams and Wilkins, Baltimore, MD.

(19) Stedman's Medical Dictionary. 1976. Williams and Wilkins Co. Baltimore, MD.

(20) U.S. Environmental Protection Agency. 1982. Pesticide Assessment Guidelines: Subdivision M—Biorational Pesticides. #PB 83–153965, National Technical Information Service, Springfield, VA.

VI. Public Record

EPA has established a public record for this statement of policy (docket number OPTS–00049A) which is available to the public in the OTS Public Information Office, 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

The Public Information Office is located in Rm E–107, 401 M St. S.W.,

Washington, D.C. 20460. The record includes all information considered by EPA in formulating this policy. The record includes the following categories of information:

1. **Federal Register** notices.
2. Support documents and reports.
3. Public comments, summaries of comments, and EPA's responses to comments on the EPA December 1984 Notice on biotechnology (49 FR 50860).
4. Communications.

The record also includes, by reference, published literature cited in this policy statement and generally available.

The docket of the record detailing its specific contents is available in the OTS Reading Room.

VII. Regulatory Assessment Requirements

A. Regulatory Flexibility Act

As required by the Regulatory Flexibility Act (5 U.S.C. 605(b)), EPA has assessed the impact of the immediately effective aspects of this policy on small businesses. EPA has determined that the immediately effective requirements will not create additional impacts on small businesses over those already identified in the final PMN rule, 40 CFR Part 720, and the Interim Policy for small-scale field testing of microbial pesticides (49 FR 40659).

B. Paperwork Reduction Act

The information collection requirements contained in this policy have been approved by the Office of Management and Budget (OMB) under provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 et seq. and have been assigned OMB control numbers 2070-0012 and 2070-0069.

DEPARTMENT OF AGRICULTURE

Final Policy Statement for Research and Regulation of Biotechnology Processes and Products

AGENCY: Department of Agriculture.

ACTION: Final policy statement.

SUMMARY: This statement presents, in final form, an explanation of the U.S. Department of Agriculture (USDA) policy for research and regulation of biotechnology applications in agrilculture and forestry. New Information is provided about policy for agricultural biotechnology research, proposed regulations, and scientific review mechanisms. The document also contains responses to comments and clarifications of the USDA policy statement published in the **Federal Register** on December 31, 1984 (49 FR 50897-50904).

FOR FURTHER INFORMATION CONTACT: For regulatory activities, contact Dr. James W. Glosser, Associate Administrator, Animal and Plant Health Inspection Service (APHIS), USDA, Room 313-E Administration Building, 12th and Independence Avenue, SW., Washington, DC 20250, telephone Area Code (202) 447-3580. For research activities, contact Dr. John Patrick Jordan, Administrator, Cooperative State Research Service (CSRS) USDA, Room 304-A, Administration Building, 12th and Independence Avenue, SW., Washington, DC 20250, telephone Area Code (202) 447-4423.

All written documents received by USDA on this notice are available for public inspection in Room 313-E Administration Building, 12th and Independence Avenue, SW., Washington, DC, weekdays between 8:00 a.m. and 4:00 p.m.

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I. Introduction

The USDA portion of the "Proposal for a Coordinated Framework for Regulation of Biotechnology" (hereafter referred to as the December 31, 1984 Notice) appeared at 49 FR 50897-50904. As a part of its policy perspective, USDA stated that agriculture and forestry products developed by biotechnology will not differ fundamentally from conventional products and that the existing regulatory framework is adequate to regulate biotechnology.

USDA has both research and regulatory responsibilities for biotechnology activities. This document provides significant new information in both areas. Section II describes 1985 **Federal Register** notices concerning USDA policies and responsibilities for biotechnology. Included in this discussion is an explanation of the assignment of responsibilities within USDA for the oversight of USDA funded research and for the regulation of the products of biotechnology. An understanding of the way in which USDA has divided these responsibilities should prove helpful to those in the private sector seeking review and/or approval of biotechnology applications.

A new section III has been added describing USDA's policy for agricultural biotechnology research. USDA is publishing as a companion document, USDA Guidelines for Biotechnology Research that will closely parallel the NIH Guidelines. The USDA guidelines will be issued under the authority of the Food Security Act of 1985 (Pub. L. 99-198). This Act amended section 1404(2) of the National Agriculture Research, Extension, and Teaching Policy Act (NARETPA). The Amendment gave the Secretary of Agriculture responsibility for establishing "appropriate controls with respect to the development and use of the application of biotechnology to agriculture." All USDA funded agriculture biotechnology research or research conducted at an entity receiving USDA funds would be subject to the USDA Guidelines for Biotechnology Research unless the specific research project is supported by and subject to the guidelines or regulations of another Federal agency. These Guidelines would encompass all phases of agricultural biotechnology research, i.e. (1) Contained laboratory experiments; (2) specialized isolation research (e.g., greenhouse, biotron); and (3) environmental research release (e.g., controlled and segregated field plots). USDA hopes that entities not required to comply with the Guidelines would voluntarily adhere to the requirements. To encourage compliance, USDA proposes to adopt the NIH policy of providing the researchers not required to comply with these Guidelines the opportunity to have their new biotechnology research proposals reviewed by USDA.

Those entities covered by the USDA Guidelines for Biotechnology Research would also be required to comply with any applicable statutes such as those set forth in section IV of this document, and any regulatory issues thereunder.

The Secretary of Agriculture has established an Office of Agriculture Biotechnology (OAB), which will have primary responsibility for implementing and coordinating the Department's policies and procedures pertaining to all facets of biotechnology. This includes the conduct of laboratory and field research, exprimentation on biotechnology products prior to their commercialization, and all matters of oversight of biotechnology in agriculture. The new office will report to the Assistant Secretary for Science and Education through the authority provided in the amendment to the Food Security Act of 1985. The Assistant Secretary for Science and Education will seek to establish an Agriculture Biotechnology Recombinant DNA

Advisory Committee (ABRAC) and shall continue the responsibilities for agriculture formerly handled by the NIH-RAC during the last 10 years. The OAB shall operate in a close parallel manner to the Office of Recombinant DNA Activities (ORDA) of the National Institutes of Health. This includes the responsibility of the ABRAC and the implementation of the USDA Guidelines for Biotechnology Research. The NIH system is well respected both domestically and worldwide, and has achieved a high degree of efficiency in achieving broad confidence in the safety of new biological research conducted under its requirements.

The OAB also will serve as a focal point for coordinating a National Biological Impact Assessment Program, which is to evaluate and monitor the potential impacts of biotechnological processes and products on safety and the environment.

Section IV contains USDA's regulatory policy statements for veterinary biological products, plants and plant products, meat and poultry products, and seeds. USDA stated in the December 31, 1984 Notice that while its existing regulatory framework is adequate, it would constantly reevaluate its regulatory position and should additional regulatory measures become necessary, amend its regulations (49 FR 50904). For veterinary biologicals regulated under the Virus-Serum-Toxin Act (VSTA), USDA has identified three categories which may be derived by recombinant DNA techniques or developed from hybridomas. The categories are based on biological characteristics and safety concerns, and are described fully in section IV(A). The first category consists of inactivated recombinant DNA-derived vaccines, bacterins, bacterin-toxoids, virus subunits, or bacterial subunits, as well as monoclonal products. This category presents no new or unusual safety or environmental concerns. The second category includes those products containing live microorganisms that have been modified by the addition or deletion of one or more genes. Such products will be evaluated under current regulatory policies and procedures to assure that the addition or deletion of specific genetic information does not impart increased virulence, pathogenicity, or survival advantages. The third category includes products using live vectors to carry recombinant derived foreign genes for immunizing antigens and/or other immune stimulants. Characteristics of safety and transmission must be established fully before questions and concerns dealing with safety to humans, animals, and release into the environment can be answered and before such products can be considered for licensing. Section IV(A) also includes new information about revised USDA review procedures for the importation of cell cultures and hybridomas. A brief discussion is included about the proposed regulations implementing the provisions of the amendments to the VSTA contained in the Food Security Act of 1985.

For organisms and products derived by the techniques of genetic engineering, USDA is proposing new rules to regulate organisms which are plant pests or which there is reason to believe are plant pests. It is USDA's policy to regulate certain genetically engineered organisms if the donor, vector/vector agent, or recipient organism is a member of a group of organisms that are known to contain plant pests, or if based on experience, USDA determines that a genetically engineered organism or product is a plant pest or if USDA has reason to believe that a genetically engineered organism or product is a plant pest. The proposed regulations are summarized in section IV(B).

The USDA policy for regulating meat and poultry products and seeds derived through biotechnology remains substantially as stated in the December 31, 1984 Notice, and appears in section IV (C) and (D).

A new section (V) has been added describing the scientific review mechanisms to be established by USDA to assist USDA Agencies in biotechnology research and regulatory decision-making. USDA has established a Committee on Biotechnology in Agriculture (CBA) chaired by the Assistant Secretary for Science and Education and the Assistant Secretary for Marketing and Inspection Services.

A detailed summary of comments on the December 31, 1984 Notice and USDA responses appears as section VI. The comments are organized to conform to the form of the December 31, 1984 Notice, with general comments and responses on the USDA regulatory philosophy followed by comments and responses on specific aspects of USDA's regulatory structure.

II. Notices

Three **Federal Register** notices concerning the Department's biotechnology related activities have been published subsequent to publication of the December 31, 1984 Notice.

On July 19, 1985, a document amending the delegations of authority of USDA to assign responsibility for these research and regulatory activities (7 CFR Part 2) was published in the **Federal Register** (50 FR 29367-29368).

In this document, the Secretary of Agriculture delegated responsibility to the Assistant Secretary for Marketing and Inspection Services to coordinate the development and carrying out of all matters and functions pertaining to the Department's regulation of biotechnology and to act as liaison on all matters and functions pertaining to the regulation of biotechnology between agencies within the Department and between the Department and governmental and private organizations. These responsibilities were further delegated from the Assistant Secretary for Marketing and Inspection Services to the Administrator of the Animal and Plant Health Inspection Service (APHIS).

Also in this document, the Secretary of Agriculture delegated responsibility to the Assistant Secretary for Science and Education to coordinate the development and carrying out of all matters and functions pertaining to agricultural research involving biotechnology conducted or funded by the Department including the development and implementation of guidelines for oversight of research activities, and to act as liaison on all matters and functions pertaining to agricultural research in biotechnology between agencies within the Department and between the Department and other governmental, educational and private organizations.[1]

On September 23, 1985, USDA's APHIS published a notice which contained its policy statement and requirements for the control and protection of documents that contain confidential business information concerning biotechnology and the veterinary biologics program (50 FR 38561-38563).

On November 14, 1985, the Office of Science and Technology Policy published a notice in the **Federal Register** announcing the establishment of the Biotechnology Science

[1] The Assistant Secretary for Science and Education oversees the research activities of the Agricultural Research Service (ARS), the Cooperative State Research Service (CSRS), the Extension Service (ES), and the Office of Grants and Program Systems (OGPS). The Assistant Secretary for Marketing and Inspection Services oversees the regulatory activities of the Animal and Plant Health Inspection Service (APHIS), which includes Veterinary Services (VS) and Plant Protection and Quarantine (PPQ); the Agricultural Marketing Service (AMS); and the Food Safety and Inspection Service (FSIS). The policies and procedures of these agencies for biotechnology were described in the USDA portion of the coordinated policy statement at 49 FR 50899-50904

Coordinating Committee (BSCC) (50 FR 47174–47195). This Committee is to serve as an interagency forum for coordinating science issues related to research and commercial applications of biotechnology. The notice also stated that USDA will establish a Committee on Biotechnology in Agriculture (CBA) to assist in assuring that research and regulatory decisions are based on the best science available.

III. USDA Research Policy Statement

USDA supports research to promote and protect the general health and welfare of the people of the United States.[2] Research program include: Studies on production of food and agricultural processing and marketing; identity and development of new crop and animal sources of food, fiber, and energy; increased agricultural efficiency and reduction of dependence on petroleum-based products; development of improved management and conservation of soil, water, forest, and range resources. The programs are fulfilled through State, Federal, and private industry cooperative efforts.

In the areas of agricultural research relevant to biotechnology, many plant, animal, and microbial alterations have been developed for release through traditional genetic approaches such as mutagenesis and hybridization. In a complementary vein, beneficial introduction of organisms from abroad have established a sound base for research and regulatory oversight. The experience with these bases provide a substantial knowledge base for conducting evaluations of the safety and efficacy of biotechnology processes and products.

USDA will evaluate the environmental impacts in the context of individual experiments that encompass the entire range of experimentation from contained facilities to open field testing. As knowledge and experience are gained, broadly applicable procedures and guidelines will be developed. Particular consideration will be given to the stability of engineered changes and the possibility that genetic elements might be transferred from one organism to another. Also important will be the development of data that will enable predictions of which organisms may become established in new ecosystems, and resulting environmental consequences.

USDA considers products developed through biotechnological techniques as no different from those products resulting from research using conventional techniques providing appropriate research review is conducted with established protocols. Agricultural biotechnology research activities require appropriate review to avoid untoward effects on human health and the environment.

USDA expects to rely on the existing network of scientific expertise in the agriculture research community. Thousands of plant selections, animal breeding lines, and microorganisms are tested annually at sites under varying climatic conditions through the Nation. This network of scientific expertise permits continual, open assessment of agricultural research and products of that research in the field. USDA has broad statutory authority to conduct and support research in wide ranging areas of agriculture. In addition to the authorities described in the matrix of Federal Laws related to biotechnology found in the **Federal Register** Notice of November 14, 1985 (50 FR 47174–47195) the Food Security Act of 1985 (Section 1404(2) of the National Agriculture Research, Extension, and Teaching Policy Act Amendments of 1985, Pub. L. No. 99–198), made the Secretary of Agriculture responsible for establishing "appropriate controls with respect to the development and use of the application of biotechnology to agriculture." Through this authority, and pursuant to the Delegation of Authority Pertaining to Biotechnology published in the **Federal Register** on July 19, 1985 (50 FR 29367–68), the Assistant Secretary for Science and Education will complete development of a national system of agricultural biotechnology research oversight in much the same manner that agriculture has been a part for the last 10 years through the NIH-RAC.

The Assistant Secretary for Science and Education has initiated the establishment of the Agriculture Biotechnology and Recombinant DNA Advisory Committee (ABRAC), to be managed through an Office of Agriculture Biotechnology (OAB) which is a parallel to the National Institutes of Health Recombinant DNA Advisory Committee (NIT-RAC) and Office of Recombinant DNA Activities (ORDA). The OAB will serve as the focal point for developing and coordinating USDA policies and activities pertaining to biotechnology research and will perform related interagency and public liaison functions. OAB will also assist in carrying out the responsibilities assigned to the Assistant Secretary for Science and Education, including the development and implementation of policies and procedures, and guidelines for the conduct of laboratory and field research.

All federally-funded agriculture biotechnology research or reseach conducted at an entity receiving USDA funds will be subject to the USDA Guidelines for Biotechnology Research, which are published as a companion document to this policy statement, unless the specific research project is supported by and subject to the guidelines or regulations of another Federal agency. These Guidelines encompass the entire spectrum of degrees of containment in agricultural biotechnology research i.e.: (1) Contained laboratory experiments; (2) specialized isolation research (e.g., greenhouse, biotron); and (3) environmental research agricultural biotechnology release (e.g., controlled and segregated field plots). Research investigators not required to comply with USDA Guidelines will be encouraged to follow these Guidelines. To assure consistency, USDA adopted the model established by the NIH of providing such researchers with the opportunity to have their biotechnology research proposals reviewed as required by the Guidelines.

The USDA Guidelines for Biotechnology Research require that research organization use the Institutional Biosafety Committee (IBC) concept as established by NIH. This requirement assures that each research organization and its investigators employ a multidisciplinary team to assist in carrying out their responsibilities under the Guidelines. The IBC's, as described in the Guidelines, would consist of persons with relevant agricultural expertise in areas such as recombinant DNA technology, biological safety, physical containment, and ecology. Requests for review beyond IBC should be sent to the Office of Agriculture Biotechnology (OAB) through the Assistant Secretary of Science and Education, Room 324–A, Administration Bldg., Washington, D.C. 20250.

These Guidelines also would require compliance with existing statutes of the USDA involving the movement of regulated organisms that require the issuance of a permit. The movement of microorganism injurious to plants and animals as well as the movement of certain non-indigenous plants and animals would continue to follow long-established procedures for USDA approval. After review, a permit, if needed, may be issued that allows movement. It is the responsibility of the research scientists to obtain that permit.

[2] See Addendum for Research Legislative Authorities.

The Assistant Secretary for Science and Education will complete establishment of a National Biological Impact Assessment Program (NBIAP) as indicated in the USDA Guidelines for Biotechnology Research. NBIAP would serve to assist USDA in the evaluation and monitoring of biotechnology research and impact over time. Coordination of NBIAP will be provided through OAB.

IV. USDA Regulatory Policy Statements

The existing USDA regulatory authority for biotechnology was listed in the matrix of the December 31, 1984 Notice at 49 FR 50860–50874 and described in brief at 49 FR 50898–50899. The statutes considered most applicable to biotechnology applications are the Virus-Serum-Toxin Act (VSTA) of 1913 (21 U.S.C. 151–158), the Federal Plant Pest Act (FPPA) of May 23, 1957 (7 U.S.C. 150aa–150jj), the Plant Quarantine Act (PQA) of August 20, 1912 (7 U.S.C. 151–164, 166, 167), the Organic Act of September 21, 1944 (7 U.S.C. 147a), the Federal Noxious Weed Act (FNWA) of 1974 (7 U.S.C. 2801 *et seq.*), the Federal Seed Act (FSA) (7 U.S.C. 551 *et seq.*), the Plant Variety Protection Act (PVPA) (7 U.S.C. 2321 *et seq.*), the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*), and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*).

A. Veterinary Biological Products

Under the Virus-Serum-Toxin Act of 1913, 21 U.S.C. 151–158, the USDA exercises regulatory authority over all veterinary biologics imported into the United States or shipped or delivered for shipment interstate. Recent amendments contained in the Food Security Act of 1985 have extended this authority to products which are shipped intrastate or exported, and have given the Department additional enforcement mechanisms such as the power to detain and seize products. Under the VSTA, veterinary biologics may not be shipped or delivered for shipment if they are worthless, contaminated, dangerous, or harmful. Veterinary biological products must be prepared in a USDA-licensed establishment under regulations promulgated by the Secretary of Agriculture. Those products which are imported into the United States must be imported under a permit issued by the Secretary. The pertinent regulations for veterinary biologics are found in Title 9 of the Code of Federal Regulations, Parts 101 through 117. New regulations will be drafted to implement the provisions of the amendments to the VSTA. Such regulations will provide for a more comprehensive regulatory scheme, including seizure and condemnation and detention procedures. They also will establish procedures to be used in the issuance of special licenses and exemptions provided for by the legislative amendments.

Veterinary biological products are defined in the governing regulations, 9 CFR 101.2(w) as "all viruses, serums, toxins, and analogous products of natural or synthetic origin, such as diagnostics, antitoxins, vaccines, live microorganisms, killed microorganisms, and the antigenic or immunizing components of microorganisms intended for use in the diagnosis, treatment, or prevention of diseases of animals."

Licensing provisions for veterinary biological products and establishments are found in Part 102 of the USDA regulations (9 CFR Part 102). A product license requires the satisfactory completion of various requirements to assure purity, safety, potency, and efficacy of the products. The specific requirements were discussed in the December 31, 1984 Notice at 49 FR 50899.

Pursuant to § 103.3 (a) through (g) of the USDA regulations, a person may be authorized to ship unlicensed biological products for the purpose of evaluating experimental products by treating limited numbers of domestic animals if USDA determines that the conditions under which the experiment is to be conducted are adequate to prevent spread of disease and approves the procedures set forth in the request for such authorization (9 CFR 103.3 (a)–(g)).

Upon satisfactory completion of all requirements, including review and acceptance of labels, a U.S. Veterinary Biological Product License may be issued.

The application of new biotechnological procedures for the production of veterinary biological products is expanding constantly. For the purposes of licensing, biologics derived by recombinant DNA-techniques or developed from hybridomas, may be classified into three broad categories. This division is based upon the biological characteristics of the new products and the safety concerns they present, and is wholly analogous to the approach used in other veterinary biologics.

The first category includes inactivated recombinant DNA-derived vaccines, bacterins, bacterin-toxoids, virus subunits, or bacterial subunits. These nonviable or killed products pose no risk to the environment and present no new or unusual safety concerns. Monoclonal antibody (hybridoma) products used prophylactically, therapeutically, or as components of diagnostic kits also are included in this category.

The second category includes those products containing live microorganisms that have been modified by the addition or deletion of one or more genes. Deleted genes may code for virulence, oncogenicity, enzyme activity, or other biochemical functions. Added genes may result in the expression of new immunizing antigens or the production of novel biochemical byproducts such as beta-galactosidase. Precautions must be exercised to assure that this addition or deletion of specific genetic information does not impart increased virulence, pathogenicity, or survival advantages in these organisms which are greater than those found in natural or wild-type forms.

Modifications also must not impart undesirable new or increased adherence or invasion factors, colonization properties, or intrahost survival factors. It is important that genes added or deleted do not compromise the safety characteristics of the organisms. In most cases it is expected that they will be improved, and would therefore not pose any new threat to humans, other animal species, or to the environment.

The genetic information to be added or deleted must consist of well-characterized DNA segments. Required licensing data may include base pair analysis, sequence information, restriction endonuclease sites, as well as phenotypic characterization of the altered organism. A comparison is also required to be made between the genetically engineered organism and the wild-type form with respect to biochemical pathways, virulence traits, or other factors affecting pathogenicity.

The third category includes products using live vectors to carry recombinant-derived foreign genes that code for immunizing antigens and/or other immune stimulants. Live vectors may carry multiple recombinant-derived foreign genes since they can carry large quantities of new genetic information. They also are efficient at infecting and immunizing target animal species. These properties, for example, make vaccinia virus recombinants very popular subjects for vaccine development programs.

Live vectors currently being evaluated by licensees, applicants, and other research organizations include vaccinia, bovine papilloma virus, adenoviruses, Simian Virus–40, and yeasts. Characteristics of safety and transmission must be examined before questions and concerns dealing with

safety to humans, animals, and release into the environment can be answered and before such products can be considered for licensing.

USDA will continue to avail itself of additional expertise from the Public Health Service "Interagency Group to Monitor Vaccine Development, Production, and Usage." This interagency committee will be utilized to consider potential human health hazards from the use of veterinary biological products and to review issues such as those arising from the potential effect of organisms potentially pathogenic to people or animals.

Veterinary biological products prepared using modern biotechnological procedures such as recombinant DNA, chemical synthesis, or hybridoma technology will be treated similarly to products prepared by conventional techniques. The unlimited number and kind of products that may result from these modern biotechnology procedures make it impossible to define all requirements in specific terms. Each product is evaluated individually to determine what will be necessary to establish its purity, safety, potency, and efficacy. Scientific considerations may dictate generic areas of concerns or the use of certain tests for specific situations. Special assays, preferably using in vitro methods, may be required for potency and stability determinations. Additional tests may be required to assure safety, especially when live microorganisms are present in the biological products.

USDA is authorized to issue three types of permits for importing biological products into the United States (9 CFR 104.2). A separate United States Veterinary Biological Product permit is required for each shipment of biological product to be imported.

Permits are required for imported biological products used for research and evaluation, distribution and sale, or transit shipment only. Requests for application (U.S. Form 14–5) should be submitted to the Veterinary Biologics Staff, Veterinary Services, Animal and Plant Health Inspection Service, 6505 Belcrest Road, Hyattsville, Maryland 20782.

To provide guidance to current or prospective manufacturers employing modern biotechnological methods, the following points are presented:

1. *Recombinant DNA-Derived Products.* Genetic information coding for a product of interest and other sequences not indigenous to the host are referred to as foreign DNA. Recombinant DNA technology encompasses the isolation, characterization, and expression of foreign DNA in organisms or vectors. The specific cloned nucleotide segment coding for the desired product or other foreign DNA segments must be defined in data supporting each license application. These data must also include a description of the source of the DNA and the nucleotide sequence.

A vector is a cloning vehicle which provides a suitable origin of replication necessary for production of foreign DNA. Such replicons may be derived from plasmids, bacteriophages or viruses such as vaccina, bovine papillomavirus, adenoviruses, or SV–40.

Production of functional gene products depends on the efficient expression of cloned DNA-vector complexes in suitable host organisms. Tissue culture cells, bacteria, yeasts, and virus cells may be used as hosts for replication of vectors. The mechanisms of transfer, the copy number, and the physical state of the constructed vector inside the host cell, integrated or extrachromosomal, must be described.

USDA's licensing procedure for veterinary biological products derived from recombinant DNA involves a careful evaluation of each product on an individual basis to assure purity, safety, potency, and efficacy. Scientific and safety considerations may require specific safeguards and procedures in some situations. The USDA strongly recommends that all applicants establish Institutional Biosafety Committees which follow applicable provisions of the NIH Guidelines for Research Involving Recombinant DNA Molecules. USDA intends to propose guidelines which specifically relate to veterinary biological products. Amendments of the regulations and standards dealing with veterinary biologics will also be considered.

2. *Chemically Synthesized Antigens.* When the product consists of chemically synthesized polypetides, the appropriate amino acid sequences will mimic the antigenic site or epitope found in the native antigen where one exists. Procedures used to increase or prolong an immune response, such as coupling to carrier proteins or addition of adjuvants, must also be described. Immunological data derived from chemically synthesized peptides must be as definitive as those from natural antigens.

3. *Monoclonal Antibody Products.* The specificity and potency of monoclonal antibody will be compared with those of similar polyclonal antibody products where appropriate. The sensitivity and specificity of monoclonal antibody products used in diagnostic test kits and their potency characteristics when used therapeutically must be similar to conventional antibody. Monoclonal antibody must be derived from Master Cell Stocks which meet the applicable requirements of 9 CFR 113.52. In addition, as is currently required, a description of cell cloning procedures, preparation, and characterization of cell passages must also be provided.

The Outline of Production must describe all processes including scale-up, ascites fluid or cell culture supernatant preparation, purification, concentration, and inactivation. Mouse colonies must be screened to demonstrate freedom from adventitious agents, especially those detected by the mouse antibody production (MAP) test. If the MAP test discloses the presence of adventitious agents, the product shall not be released unless inactivation procedures approved by Veterinary Services have been performed and tests conducted to ensure proper application of the procedures.

4. *Master Seeds.* Bacterial or viral seed stocks used to prepare veterinary biological products must meet established procedures used to certify Master Seeds for biological products.

The Master Seed for recombinant DNA-derived products may consist of a plasmid or virus carrying the inserted gene. This constructed plasmid is then introduced into the appropriate eukaryotic or prokaryotic expression system selected for vaccine production. Genomic DNA may also be transfected directly into a variety of mammalian cells. Alternatively, in such cases, the stable transfected cell could be considered as the Master Seed.

The establishment of Master Seeds consisting of constructed plasmids or transfected cells requires submission of background information concerning the recombinant DNA procedures used to isolate, purify, and identify genetic material from one source and the modification used for inserting of this material into a new host. Data from cloning, isolation, proliferation, and selection of genetically unique cells would be retained by licensed applicants. In order to characterize adequately the foreign DNA used to code for a particular antigen, the manufacturer must provide a nucleotide sequence analysis.

Tissue culture-propagated cells from vertebrate animals used for vector propagation and antigen production must meet the requirements of 9 CFR 113.51 or 113.52.

If a Master Seed has been accepted by Veterinary Services for use in a licensed product, further genetic modifications may be approved with reduced

requirements for additional host animal efficacy studies.

Each Outline of Production must be prepared in accordance with 9 CFR 114.9. Outlines must include procedures to ensure consistency in production and recovery of specific antigenic material. Recovery procedures must include removal of excessive antibiotic levels (9 CFR 114.10) and undesirable fermentation byproducts such as excessive levels of bacterial endotoxins. Serial release tests for purity, safety, and potency will be required. In addition product characterization tests may be required to demonstrate consistent gene expression.

Organisms and Vectors

Pursuant to the Act of February 2, 1903, (21 U.S.C. 111), and the VSTA, USDA has authority to issue such regulations and take such measures as may be deemed proper to prevent the introduction or dissemination into the United States of the contagion of any contagious, infectious, or communicable disease of animals and/or live poultry from a foreign country into the United States or from one State or territory of the United States or the District of Columbia to another. The importation into the United States or interstate shipment of organisms and vectors is regulated under 9 CFR Part 122. Organisms and vectors are defined in 9 CFR 122.1 as entities which may introduce or disseminate any contagious or infectious disease of animals. Such substances may not be shipped interstate or imported without a permit. Permit applications must completely describe the substances, intended use, location of the permittee, and safeguards.

A number of revised administrative and technical provisions have been instituted to expedite the USDA review and issuance of permits for importation or organisms and vectors which include cell cultures and hybridomas. No animal-origin biological materials, such as cell cultures, monoclonal antibodies, organisms, vectors, or related material, may be imported into the United States without a Veterinary Services (VS) Permit (VS Form 16–3A). To obtain a permit, an application (VS Form 16–3) should be submitted to: Import-Export Staff, Organisms and Vectors, VS, APHIS, USDA, 6505 Belcrest Road, Hyattsville, MD 20782. This is different from the permit required to import veterinary biologics pursuant to Part 104 of the USDA regulations governing such products (VS Form 14–5 and 14–6).

Applicants must also complete the questionnaire entitled "Importation Information" and submit it with their application. Based upon the information submitted by the applicant, a determination will be made if the material to be imported requires safety testing to ensure it is free from livestock pathogens. Safety testing is conducted at the Foreign Animal Disease Diagnostic Laboratory (FADDL), Plum Island, New York.

Applicants will be advised if a safety test is required and will be given an estimate of the cost for conducting the test. Applicants desiring to have material safety tested must enter into a Cooperative Trust Fund Agreement with APHIS, VS, and deposit in advance sufficient funds to cover the estimated cost. The Import-Export Animals and Products Staff will initiate the Cooperative Trust Fund Agreement. In order to expedite the procedure, VS may issue a permit for the material to be shipped to FADDL pending receipt of the funds and Cooperative Trust Fund Agreement. However, the signed Cooperative Agreement, plus the necessary funds, must be received by VS before testing can be scheduled at FADDL.

Usually 60 to 90 days is needed for issuing a permit for importing material to Plum Island, New York, the completion of safety tests, and the transfer of the imported material to the applicant. A minimum of four vials, each containing at least 1 million cells from a uniform lot, is required for the safety testing.

When the test is completed and a determination made that the imported material is free from livestock pathogens, the remainder of the imported material is released directly to the importer under conditions specified in the permit.

If an importer wishes to import cell cultures and/or hybridoma cells on a regular basis, the applicant may enter into a continuous Cooperative Trust Fund Agreement with VS and establish an escrow account to ensure that unnecessary delays will not occur due to insufficent funds.

Each safety test utilizing susceptible host animals usually cost approximately $2,000 to $3,000. Sometimes it is possible to reduce the cost by pooling samples in one host animal test. Scientists at FADDL developed in vitro safety tests to detect certain livestock pathogens resulting in substantial cost savings for importers. The current cost of each in vitro test is approximately $500, depending upon the type of animal disease present in the country of origin as well as the intended use of the imported material.

Safety testing may not be required for some cell cultures imported for human diagnostic purposes and research. Examples of material which could enter without safety testing include cultured human bone marrow cells, amniocentesis samples, and cells imported for karyotype analysis. Applications for such cell cultures will be considered individually.

Permit applications are evaluated by a new classification scheme that correlates intended use of imported cell cultures with the level of safety testing conducted at FADDL.

The following classification of cell cultures is based on intended use and generally indicates the level of safety testing required.

Class I Cell cultures to be used for the production of products such as vaccines, hormones, or other biologicals to be used in livestock, poultry, or for commercial distribution.

Requirement: These cell cultures must be safety tested at FADDL using susceptible host animals, approved in vitro test, and/or laboratory animals.

Class II Cell cultures to be used only for in vitro studies and not to be used in animals other than primates.

Requirement: These cultures may not require safety testing. The material may be sent directly to the importer when no safety testing is required. The permit (VS Form 16–3A) will specify restrictions such as "FOR IN VITRO LABORATORY TESTS: DO NOT INOCULATE INTO LIVESTOCK, BIRDS, OR LABORATORY ANIMALS."

Cell cultures imported under permit which do not require a safety test may not be distributed to other laboratories without prior approval from USDA, APHIS, VS. Applications for the distribution of imported material should be submitted to the USDA, APHIS, VS, Import-Export Staff, Organisms and Vectors.

When appropriate, a review is conducted by the Administrator's Parent Committee on Organisms and Vectors. Members of this committee have wide expertise in evaluating safety. Clearance may also require testing in high security facilities at the Veterinary Services, FADDL, Plum Island, New York.

B. Plants and Plant Products

Pursuant to the authority granted by the Federal Plant Pest Act (FPPA) of May 23, 1957, as amended (7 U.S.C. 150 aa through 150 jj), and the Plant Quarantine Act (PQA) of August 20, 1912, as amended (7 U.S.C. 151 through 164, 166, and 167), USDA has regulatory authority over the movement into or within and through the United States of

plants, plant products, plant pests, and any product or article which may contain a plant pest at the time of movement. These articles are regulated in order to prevent the introduction, spread, or establishment of plant pests new to or not widely prevalent in the United States. The regulations implementing this statutory authority are found in 7 CFR Parts 300 through 399.

"Plant Pest," as defined by statute, means any living stage of any insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi, or parasitic plants or reproductive parts thereof, viruses, or any organisms similar to or allied with any of the foregoing, or any infectious substances, which can directly or indirectly injure or cause disease or damage in any plants or parts thereof, or any processed, manufactured, or other products of plants (7 U.S.C. 150aa(c)).

"Movement," as defined by statute, means to ship, deposit for transmission in the mail, otherwise offer for shipment, offer for entry, import, receive for transportation, carry, or otherwise transport or move, or allow to be moved, by mail or otherwise (7 U.S.C. 150aa(g)).

The current permit system requirements for the movement into or within and through the United States of plants, plant products, plant pests, and other articles regulated by FPPA and PQA were fully described in the December 31, 1984 Notice at 49 FR 50900–01. The procedures for issuing permits for the movement of plant pests were discussed separately from plants, plant products and other articles which may contain plant pests at 49 FR 50901–02. USDA regulates the importation of noxious weeds through a permit system similar to that established for plant pests. The existing regulations in 7 CFR Part 360 which designate plants as noxious weeds and establish procedures for obtaining an import permit were described at 49 FR 50902.

Regulation of the Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are or Which There Is Reason to Believe Are Plant Pests

The FPPA and PQA are applicable to the movement of plants, plant products, and other articles and plant pests developed through genetic engineering if such plants, plant products, other articles, or plant pests present a risk of plant pest introduction, spread, or establishment.

Under the authority granted by the FPPA and PQA, USDA is proposing new regulations which would impose restrictions on the introduction of organisms and products altered or produced through genetic engineering which are plant pests or which there is reason to believe are plant pests.

In accordance with the provisions of the FPPA and PQA, USDA must determine the plant pest status of plants, plant products or articles to be moved into or within or through the United States. The evaluation process for determining what safeguards, if any, can be imposed which would allow the movement of the plant pest without risk that the plant pest would be disseminated were described in the December 31, 1984 Notice at 49 FR 50901–02. For genetically engineered material from dissimilar source organisms (inter-generic combinations), the determination may be complex. Information about genetically engineered organisms produced through the use of donor, vector/vector agent and recipient organisms that are from a list of known plant pests is needed in order that such organisms be properly regulated.

During the past year, USDA has received permit applications to move genetically engineered organisms into or through the United States. USDA is confident that organisms altered through genetic engineering will play a major role in increased plant yield and improved plant quality. However, a genetically engineered organism derived from organisms that are plant pests also presents a risk of plant pest introduction. The organisms themselves, the cultures in which they are transported, or their packaging may be contaminated with plant pathogens. Genetic alteration may create a plant pest new to and not widespread in the United States. It is necessary, therefore, to establish appropriate safeguards to prevent the introduction of genetically engineered organisms that pose a threat to agriculture. Other genetically engineered organisms that are not plant pests or where there is no reason to believe such organisms are plant pests would not be regulated.

New data have to be required in order to properly evaluate permit applications for those organisms which are plant pests or which there is reason to believe are plant pests. A determination was made that additional data requirements would be incorporated into proposed regulations for those genetically engineered organisms which are of concern under the provisions of the FPPA and PQA.

USDA is publishing as a companion document in the "proposed rules section" of this issue of the **Federal Register** its proposed regulations pertaining to organisms and products altered or produced through genetic engineering which are on plant pests or which there is reason to believe are plant pests.

The proposed regulations would establish a new part entitled, "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There is Reason to Believe are Plant Pests", in Title 7 of the Code of Regulations (7 CFR), pursuant to the authority of the FFPA, as amended (7 U.S.C. 150aa–150jj) and the PQA, as amended, (7 U.S.C. 151–164, 166, 167). Such proposed regulations would regulate the importation into and movement within and through the United States as well as prevent the release into the environment of certain organisms, or products altered or produced through genetic engineering, which are plant pests or which there is reason to believe are plant pests.

The proposed regulations would restrict the "introduction" of certain organisms and products altered or produced through genetic engineering, referred to as "regulated articles." In this context, "introduction" means to move into the United States, to release into the environment, or to move interstate, or any attempt thereat." "Release into the environment" means "use of a regulated article outside the constraints of physical confinement that are found in a laboratory, contained greenhouse, or fermenter or other contained structure."

USDA's proposed regulations, which are designed to prevent the release into the environment of genetically engineered organisms which are plant pests or which there is reason to believe are plant pests are consistent with the legislative intent of the FPPA. The FPPA was enacted in 1957 and was intended as "gap filling" legislation for the purpose of protecting American agriculture against invasion by plant pests and diseases which are new to or not theretofore known to be widely prevalent or distributed within and throughout the United States. The FPPA also provides USDA with authority to regulate insects or pests that might later be found to be injurious to cultivated crops. The release into the environment of a genetically engineered plant pest is tantamount to the introduction of a plant pest which is new to and not theretofore known to be widely prevalent within and throughout the United States and subject to regulation under the FPPA.

It should be noted that "regulated article" would be defined as any organism or product altered or produced through genetic engineering, if the donor

organism, recipient organism, or vector or vector agent belongs to a group of organisms designated by the proposed regulations as having plant pests or any organism or product which USDA determines is a plant pest or which there is reason to believe is a plant pest. Under USDA's proposed definition, certain microorganisms would be excluded if the recipient microorganism is non-pathogenic, is non-infectious, and otherwise not a plant pest, and resulted from the addition of genetic material that is well characterized and contains only non-coding regulatory regions. Restrictions would be required for regulated articles because they are plant pests, or because USDA has reason to believe they are plant pests. The proposed regulations would require that a person obtain a permit prior to the introduction of a regulated article and would list specific conditions required for the introduction of a regulated article. The regulated article could be introduced only if all conditions in the proposed regulations as well as all conditions specified on the permit were met. It is important to note that in considering whether a permit can be issued for the introduction of a genetically engineered organism, USDA will perform the same comprehensive analysis that is used in determining whether a permit can be issued for the movement of a "conventional" plant pest. Such asessment shall include an examination of the factors that were discussed in the December 31, 1984, Notice at 49 FR 50901–02 as part of the evaluation process for determining what safeguards can be imposed which would allow the movement of a plant pest without risk of dissemination. These factors are oriented toward an examination of the ecological and environmental effects of a release of the genetically engineered organism or product into the environment.

The proposed regulations also contain provisions for a certificate of exemption for those organisms or products altered or produced through genetic engineering that are not subject to the proposed regulations. A person seeking to introduce an exempt article could voluntarily request a certificate of exemption to facilitate the introduction of the organism or product.

The proposed regulations provide a list of groups of organisms which are plant pests or contain plant pests. If the donor, vector/vector agent, or recipient of the genetically engineered organism is derived from an organism on the list of organisms containing plant pests, such genetically engineered organism would be deemed a "regulated article".

As defined in the proposed regulations, a plant pest includes microorganisms such as bacteria and viruses, and thus a "regulated article" may be a microorganism unless it meets the provisions for exclusion. It is important to note that in some instances certain microorganisms will be subject to joint regulation by USDA and EPA. USDA has jurisdication over certain microorganisms under the FPPA and PQA if the microorganisms are a plant pest. EPA would have jurisdiction under the Toxic Substances Control Act (TSCA) if the microorganism is deemed to be a "new" microorganism or under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (FIFRA) if the microorginism is to be used as a pesticide. Because each Agency has a different statutory mandate, certain jurisdictional overlaps cannot be avoided. However, EPA and USDA will work cooperatively and simultaneously in the evaluation of genetically engineered microorganisms that fall under the jurisdication of both Agencies. To expedite the review of these microorganisms each Agency will appoint contact persons to coordinate the review to ensure data requests are not duplicated.

The specifics of which microorganisms will be subject to dual Agency review, or primarily single Agency review, is set forth in the preamble of USDA's proposed regulations being published as a companion document to this policy statement. That document should be consulted for further information.

A key to determining whether a genetically engineered organism will be regulated by USDA is the list of organisms containing plant pests that appears in § 340.2 in proposed Part 340. USDA acknowledges that this is not an exhaustive list, and that it does not attempt to list every pest species. Comments are welcome on the list as well as on other parts of the proposed regulations.

In order to solicit as many comments as possible on the list and all other parts of the proposed regulations, USDA has scheduled public hearings in Washington, DC and Sacramento, California, during the 60-day comment period. The time and place of the public hearings as well as the address to send written comments is specified in the preamble to the proposed regulations.

USDA believes that through the submission of detailed comments and full participation by public and private interests, USDA will be able to promulgate a final regulation that will prevent the introduction and dissemination of genetically engineered organisms which are plant pests or which there is reason to believe are plant pests, yet not impede the development of biotechnology.

C. Meat and Poultry Products

The Food and Safety Inspection Service (FSIS) is responsible for assuring the safety, wholesomeness, and proper labeling of food products prepared from domestic livestock and poultry. The Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) require FSIS to inspect cattle, sheep, swine, goats, equines, poultry, and food products prepared from them which are intended for use as human food to assure that they are wholesome, not adulterated, and properly labeled, marked, and packaged. Inspection under these statutes is mandatory. The cost of inspection, except for overtime and holiday inspection work, is required to be borne by the USDA. Food, animals and animal products, other than those required to be inspected under the FMIA and PPIA, may be inspected under a voluntary, reimbursable inspection program established under the Agricultural Marketing Act of 1946.

Within the framework of food safety statutes, FSIS has developed regulations for research on animals that are administered experimental animal drugs, biologics, and pesticides (9 CFR 309.17 and 381.75). These regulations state that no animal used in any research investigation involving an experimental biological product, drug, or chemical shall be eligible for slaughter at an official establishment unless certain conditions are met. These conditions include any of several different ways of demonstrating that the use of such biological product, drug, or chemical will not result in the products of such animals being adulterated.

Products Subject to Review. FSIS anticipates that many food animals which are subject to the new techniques of modern biotechnology will not differ substantially in appearance, behavior, or general health from currently inspected cattle, sheep, swine, goats, equines, and poultry. They would be subject to the same inspection procedures and regulations as tradionally inspected food animals. FSIS is aware that some genetically engineered animals, such as mosaics, chimeras, and some hybrids, may differ substantially from animals that are inspected currently under the FMIA and PPIA. If such animals are ever intended for use as human food and are presented for inspection at an official

establishment, a decision would have to be made as to whether such animals were covered under the FMIA or PPIA, and if not, whether the FMIA and PPIA should be amended to require inspection of such animals and their products.

Implementation of Review Authority. FSIS's approach toward the review of food animals resulting from the techniques of moderm biotechnology consists, in general, of two phases. The first, an experimental phase, focuses on the experimental aspects of vector administration, gene transfer and gene expression. Since artificial vectors used in animal gene transfer may be considered as either animals drugs or animal biologics, their administration to food animals would be covered under the current regulations on animals used for research (9 CFR 309.17 and 381.75). The requirement that an animal carcass intended for use as human food not be adulterated may require that certain phenotypic, biochemical, and microbiological parameters not be exceeded before the animal can be slaughered for human food. Depending on future developments, FSIS may amend the regulations (9 CFR 309.17 and 381.75) to provide further assurance that the products of animals genetically engineered by certain techniques are not adulterated. The second phase would be carried out under existing regulations (9 CFR Parts 301 through 381) and would focus on the commercial development, production, inspection and labeling of food animals and food animal products.

D. Seeds

The Federal Seed Act (FSA) (7 U.S.C. 1551 *et seq.*) defines USDA regulatory authority over the importation and interstate shipment of agricultural and vegetable seeds. It does not apply to the production or intrastate distribution of seeds or to seeds other than agricultural or vegetable seeds ("agricultrual seeds" are grass, forage, and field crop seeds).

The FSA prohibits interstate shipment of seed that contains noxious weed seeds at levels in violation of the laws of the State of destination or in excess of levels allowed by the Secretary of Agriculture. This provision applies primarily to seed adulterated with noxious weed seed. In a few instances, however, States have determined that a particular variety of agricultural or vegetable seed is itself a noxious weed. In these instances, FSA prohibits the interstate shipment of the seed into those States. The FSA also allows the Secretary to prohibit the importation of agricultural and vegetable seed which is adulterated with noxious weed seed or which is unfit for seeding purposes.

The authority granted to the Secretary by the FSA to prohibit the interstate shipment or importation of seeds which are found to be detrimental to the agricutural interests of the United States applies to seeds genetically engineered with the modern biotechnology to the same extent as any other seeds.

V. Scientific Review Mechanisms

The manner in which both regulation and oversight of research in agriculture-related biotechnology evolves and is implemented in the United States will have a direct impact on the competitiveness of U.S. industry in both domestic and world markets. Inconsistent or unnecessary procedures for regulation and research will place the U.S. scientific effort and U.S. producers at a substantial disadvantage. It also is important that safeguards be built into biotechnological research processes, and that releases be based on careful evaluations while further experience is being gained. Therefore, USDA feels that such regulatory and research decisions must be based on the best science available.

While the responsibilities within USDA for biotechnology reside with the Assistant Secretary for Science and Education and the Assistant Secretary for Marketing and Inspection Services as the delegates of the Secretary of Agriculture, in carrying out their respective responsibilities based on the best science available, they would be able to take advantage of the expertise and perspectives within the Federal Government through a committee to be called the Committee on Biotechnology in Agriculture (CBA). The CBA, to be chaired by these two Assistant Secretaries, will function both as a policy body in the USDA and a bridge between its research and regulating structures.

Committee on Biotechnology in Agriculture

The objectives of the CBA will include:

—To provide advice, when requested, on initiatives, proposals, and policy for agriculture-related regulation and research, and assist in the coordination of these activities;
—To review scientific issues submitted by agencies within the Department;
—To assist in identifying data gaps for basic research in agricultural biotechnology;
—To foster public awareness of the scientific issues in biotechnology;
—To provide Departmental support for participation in the FCCSET BSCC.

USDA expects that the CBA also will utilize existing cooperative entities (e.g., other Federal agencies, universities, State regulatory officials, the public sector, and industry) to acquire, when necessary, information for addressing those issues submitted to it. Such entities, when requested, can provide technical support for sound regulatory and research decisions regarding the use of biotechnology in agriculture and foresty. These entities offer a vast scientific resource upon which USDA can draw.

VI. Summary of Comments

USDA received the comments of one hundred-two (102) respondents, one-half of whom commented specifically on the USDA policy statement. Although USDA agencies considered all comments on the coordinated policy proposal, this response is confined to comments on the USDA portion of the notice.

The two largest categories of respondents were business and academic, followed closely by associations representing these interests. Comments came in lesser numbers from environmental and public interest groups, individuals, law firms, and foreign governments, as well as the National Institutes of Health Recombinant DNA Advisory Committee (NIH-RAC) and a member of the U.S. Congress

The USDA response to the comments follows the form of the original notice, with a discussion of comments on regulatory philosophy followed by a response to comments on the regulatory framework.

Comments on the Nature of Products of Modern Biotechnology: Fourteen respondents stressed their agreement with the USDA statement that "agriculture and forestry products developed by modern biotechnology will not differ fundamentally from conventional products," while six commenters dissented. Three respondents felt that genetic engineering across species barriers did create a potentially different product and the possiblity of unique ecological effects. Concern about the "need for public trust" and public assurance on safety and ethical issues was stressed by three commenters. Seven respondents agreed with USDA that "to date, no unique or safety problems have been associated with products of genetic engineering," but four of the same commenters who view biotechnology products as fundamentally different from conventional products stressed that the potential exists for safety problems with biotechnology applications.

Response: USDA recognizes the importance of ecological effects and the need for developing procedures responsive to public concerns about safety.

Although USDA's regulatory philosophy remains as stated, additions to regulatory procedures are being proposed for genetically engineered plants and plant products and veterinary biologics produced by biotechnology (see section IV). The previously discussed delegations of authority within USDA for biotechnology increase the effectiveness of the administration of current and proposed regulatory procedures affecting the products of modern biotechnology.

For veterinary biological products, USDA is currently developing additional procedures pursuant to the VSTA, as amended, for evaluating requests to conduct experimental field trials with live vectors containing genetically engineered organisms or to support product license applications. The procedures being developed consider the parental organism and the effect of the gene alteration on the genetic properties of the recipient, especially the survival, reproduction, and dispersal characteristics. A careful analysis of the genetics, biology, and ecology of the wild-type and modified microorganisms will provide as reasonable prediction of the risks which might be associated with use of the altered organisms.

USDA is proposing regulations pursuant to the Federal Plant Pest Act (FPPA) and the Plant Quarantine Act (PQA) for regulating the introduction of certain organisms of products thereof altered or produced through biotechnology which are plant pests or may become plant pests. This proposed rule should assist USDA in assessing the ecological effects of the release of such genetically engineered organisms into the environment.

Guidelines for oversight of agricultural biotechnology research funded by USDA will be issued under the authority of the Food Security Act of 1985.

USDA also is establishing scientific review mechanisms to assist in research and regulatory decisions (see section V).

These proposed modifications in the procedural framework are described as a part of the final policy statement for veterinary biologics, plants and plant products, research, and scientific review mechanisms.

Comments of the Adequacy of Existing Authority: Thirteen commenters agreed with USDA that its existing regulatory framework is adequate for biotechnology applications, and nine favor the case-by-case approach under existing authority. Five commenters felt that new legislation is or may be needed; two of the five oppose the case-by-case approach.

Response: USDA has examined its statutory authority for regulating biotechnology products and processes, and USDA agencies have processed licensing and permit applications under the existing statutes. The existing authority is considered adequate at this time. Established procedures, with the proposed modifications, can be adapted effectively to handle biotechnology applications. USDA is currently considering genetic engineering applications on a case-by-case basis using existing authority.

Comments on Need for Procedures and Guidelines: Sixteen respondents commented that USDA had not outlined procedures for the review and approval of genetically engineered products. Twelve respondents stressed the need for flexibility, and six requested sunset provisions in USDA biotechnology regulations.

Response: The USDA policy statement of December 31, 1984, did outline procedures currently used for the review and approval of certain genetically engineered products. In considering license applications for genetically engineered veterinary biologics, USDA follows the standards and procedures applicable to all such products found in §§ 101–117 of the applicable regulations and standards (9 CFR 101–117). In the December 31, 1984 Notice, USDA offered supplementary guidelines for licensing such products. New procedures are being developed to evaluate production and testing of veterinary biologics derived through use of genetic engineering techniques. The information needed for proper evaluation will depend on the parent organism and the effect of the gene alteration on the genetic properties of the recipient. A paper describing the USDA licensing policy for biologics produced by recombinant DNA technology was presented at the Joint International Association of Biological Standardization/World Health Organization Symposium on "Standardization and Control of Biologics Produced by Recombinant DNA Technology," Geneva, Switzerland, 1983 (published in *Developments in Biological Standardization*, V. 59, pp. 167–173, S. Korgel, Basel, 1985). The paper describes requirements for plasmid/vector characterization and stability, and correlation to conventional Master Seed concepts, as well as methodology which can be used to monitor antigenic expression, concentration, purification, and stability testing during production and recovery.

The movement of genetically engineered products which are plant pests and present a risk of plant pest introduction or spread is regulated by 7 CFR 330.200 implemented pursuant to the FPPA and PQA. The movement of organisms and vectors which may cause desease in animals is regulated under 9 CFR Part 122.

USDA realized that the statement left unanswered some questions about the means for review and approval of various genetically engineered products. The proposed regulations described in section IV(B), implemented under the authority of the FPPA establish permit requirements for the "introduction" of organisms altered or produced by genetic engineering which are or may become plant pests. The regulations would be flexible because organisms determined not to be plant pests would be exempt, and this category could be expanded in the future to include organisms whose plant pest status is currently uncertain and therefore restricted. It is hoped that the discussion in section IV(B) of this policy statement answers any remaining questions about the review and approval procedures for such genetically engineered products.

Comments on Confidential Business Information (CBI): Six commenters representing business and scientific interests expressed concern about the protection of "confidential business information" in the USDA regulatory process while two public interest groups stressed the "public's right to know."

Response: The USDA regulations implementing the Freedom of Information Act (FOIA) (5 U.S.C. 552) are found in 7 CFR 1.1–1.16. The FOIA provides that Federal agencies must make available to the public all records not specifically exempt from disclosure. Exemptions include "trade secrets and commercial or financial information," (5 U.S.C. 552(b)(4)). On September 23, 1985, USDA's APHIS issued a policy statement on the protection of privileged or confidential information (50 FR 38561–38563). This policy statement establishes requirements for the control and protection of documents received by APHIS that contain privileged or confidential business information concerning biotechnology and the veterinary biologics program. The procedures established conform to the FOIA requirements for both protection and disclosure.

Comments on Use of NIH Guidelines: Four respondents questioned the USDA requirements that manufacturers of

veterinary biological products using recombinant DNA technology follow the National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines). One respondent thought USDA implied that all people "who work with recombinant DNA plants" would be required to comply with the NIH Guidelines, and requested procedural guidelines for industry.

Response: The USDA does not require that the manufacturers of veterinary biological products or plant products of recombinant DNA technology follow the NIH Guidelines. However, USDA strongly recommends that all license applicants for veterinary biologics follow appropriate provisions of the NIH Guidelines, such as those regarding the establishment of an institutional biosafety committee. USDA intends to propose guidelines that will parallel closely the NIH Guidelines, and it intends to recommend strongly that entities not required to follow the USDA guidelines do so voluntarily.

Comments on Importation of Cell-Lines: Three associations representing biotechnology companies requested that USDA take steps to reduce delays in the clearance and testing procedures required for the importation of biotechnology-derived products and cell-lines. On February 12, 1985, the Association of Biotechnology Companies (ABC) delivered a report on USDA importation guarantine issues to the APHIS Parent Committee for Foreign Pathogens and Vectors. This report was an attachment to the ABC comment letter.

Response: The USDA has instituted a number of revised administrative and technical provisions to expedite the issuance of permits for importation of organisms and vectors which include cell cultures and hybridomas. A supplementary questionnaire, designed to insure adequate information on cell cultures and products from recombinant DNA or hybridoma technologies, now accompanies each permit application. Applicants are advised whether or not a safety test is required and a cost estimate is given. Safety testing may be conducted concurrently with the administrative review of the permit application, but only at APHIS' Foreign Animal Disease Diagnostic Laboratory (FADDL) at Plum Island, New York. New test procedures have reduced the cost of safety testing, and the cost per sample can be further reduced by conducting a safety test with pooled samples. Permit applications are evaluated using a new classification scheme that equates intended use of imported cell cultures with the level of safety testing required at FADDL. Class I cell cultures, employed in the preparation of products such as enzymes, vaccines, or hormones for commercial use, are subject to complete safety testing. Class II cell cultures, used only for in vitro studies and not to be used in animals other than primates, are subject to a lesser degree of testing.

Comments on Risk Analysis: Seven respondents discussed the issue of risk assessment or risk/benefit analysis of biotechnology applications. Comments varied from a recommendation that "standard risk assessment methodologies" be adopted by all agencies to a warning against attempting to regulate the "hypothetical and imaginary "potential' dangers" of recombinant DNA techniques.

Response: The National Environmental Policy Act (NEPA) applies to USDA actions. The "APHIS Guidelines Concerning Implementation of NEPA Procedures" (44 FR 50381, August 28, 1979) would be used to make an environmental assessment or environmental impact statement of the effects of a proposed release of a genetically engineered organism regulated pursuant to the VSTA, the FPPA and PQA, and related statutes. A formal risk management procedure based on a wide variety of safety concepts will be used to evaluate systematically proposed releases. The information required by any new regulations promulgated under the FPPA and PQA would be used to prepare the environmental assessment for release of a genetically engineered product which is a plant pest or may become a plant pest.

In normal husbandry and laboratory practices, veterinary biological products normally are not considered to be released into the environment. In the event that a conventionally prepared or recombinant derived product would be considered to be released into the environment, the issuance of a license or import permit would require compliance with procedures being developed and interagency approval. The procedures under development consider the parental organism and the effect on the gene alteration on the genetic properties of the recipient, especially the survival, reproduction and dispersal characteristics.

Safety, ethics, and policy issues in agricultural biotechnology research will be overseen by the Committee on Biotechnology in Agriculture (CBA) and such supporting technical advisory groups as may be established by the USDA agencies. Currently, all USDA and USDA-sponsored research involving recombinant DNA must be cleared prior to initiation for compliance with the NIH Guidelines.

Comments on Jurisdiction: The potential for overlapping jurisdiction in the policy notice drew the largest number of comments. Eighteen respondents pointed out that both USDA and EPA propose to regulate agricultural microorganisms. Respondents representing the interests of the veterinary biologics industry contended that a jurisdictional dispute between USDA and FDA delayed the approval of bovine interferon. While generally supporting the concept of the memorandum of understanding (MOU) between USDA and FDA to resolve jurisdictional disputes, one respondent challenged the legality of the MOU, noting that it contains the statement that "animal biological products generally act through a specific immune process," while USDA's current regulations do not restrict its jurisdiction to products operating through such a mechanism of action. Industry respondents also pointed out that the intrastate producer of veterinary biologics is not regulated by USDA. Two firms and one industry association urged prompt Federal oversight action so that States do not act independently to regulate biotechnology products.

Response: USDA agrees that there is the potential for overlapping jurisdiction among the Federal agencies involved in regulating biotechnology products. USDA and EPA representatives have discussed jurisdiction over genetic engineering applications since 1983. USDA and EPA have begun to establish a regulatory procedure for reviewing certain submissions of genetically engineered microorganism applications, a procedure which has resulted in joint consultation on several proposals for release into the environment of organisms altered by genetic engineering.

For veterinary biologics regulated under the VSTA, use of procedures currently under development will increase USDA effectiveness in evaluating biotechnology license and product applications. The MOU between USDA and FDA was published on June 8, 1982, in an attempt to resolve the issue of new products which fall into the questionable definitional area between animal drugs regulated by FDA and animal biologics regulated by USDA. An interpretation by some that the term animal biologics only includes substances that act through a specific immune process has resulted in some confusion. There is nothing in USDA's

current regulations or law which restricts its jurisdiction to products acting solely through this mechanism of action, and because of this fact, the memorandum qualifies its reference to specific immune process by the word "generally." Although efforts will be made to clarify the issue further, it should be noted that there appears to be little uncertainty about whether a particular product is a veterinary drug or biologic.

The Food Security Act of 1985 contains amendments to the VSTA that extend USDA's jurisdiction to veterinary biologics which are shipped intrastate or exported. The provisions of the amendments are discussed more fully in Section IV.

Comments on the National Biological Impact Assessment Program (NBIAP): Seven respondents commented on the NBIAP, the proposal by the National Association of State Universities and Land Grant Colleges (NASULGC) for establishing a program to assess genetically engineered organisms before they are released into the environment. Three commenters—a member of Congress, a spokesperson for a biotechnology firm, and an officer of an environmental organization—posed questions about the proposal. The questions concerned the NBIAP's statutory or regulatory status; its relation to other USDA agency operations and other Federal agency operations; the processes of risk assessment to be used; its adequacy to review an increasing volume of products; and the appropriateness of biohazard committees as vehicles for review of commercial processes and products. Four respondents representing NASULGC institutions endorsed the proposal stating the view that the agricultural research community has the capability to develop guidelines and assess impacts of biotechnology research and commercial products. The major goal of the program was thought to be insuring the safety of society and the environment.

Response: NBIAP is a scientific advisory system that would be available to the Assistant Secretary for Science and Education. By this system the USDA can draw upon the best experience available from scientists in universities, Federal laboratories, and industry to help assess the risks involved in the processes and products from RDNA work in biotechnology.

NBIAP shall act in an advisory capacity and is in no direct way a part of the formal approval process. It is available to provide assessment, but is not a mandatory process.

Comments on Definitions, Terms, and Data Requirements: Five respondents recommended changes in the definitions, terms, data requirements or classification used by USDA in the notice. Each recommendation is discussed below.

Two respondents commented on the USDA statement of licensing policy for veterinary biologics produced by modern biotechnical methods at 49 FR 50899–50900. Under the heading "1. Recombinant DNA-Derived Products," a manufacturer of veterinary biologics questioned the need to provide the entire nucleotide sequence of a foreign DNA being cloned into a vector.

It is USDA's position that in order to characterize adequately the foreign DNA used to code a particular antigen, the manufacturer should provide a nucleotide sequence analysis. The construction of the vector used for expression of the cloned nucleotide sequence also should include source and function of the component parts of the vector, i.e., origin of replication, antibiotic resistance genes, promotor, enhancers, etc. The manufacturer also questioned the data requirement under the heading "2. Chemically Synthesized Antigens" concerning the persistence of the immune response following administration of the synthetic peptide. The USDA feels that a major concern with the use of synthetic peptides is the development persistence of the immune response. USDA does not intend to require more stringent efficacy data than that necessary to support a veterinary biologic license application employing natural antigens. However, immunological data derived from chemically synthesized peptides must be as definitive as the serological response from natural or nonsynthetic antigens. With respect to the next sentence in the policy statement, an individual respondent proposed a change from the term "antibody response" to "immune response." It is true that the term used in the sentence "Procedures used to increase or prolong an antibody response . . ." is somewhat limiting and can create confusion between B-cell and T-cell response. Therefore, the recommendation to replace "antibody response" with the term "immune response" is accepted, since both T-cell responses as well as T-cell/B-cell interactions would be included in the statement.

On the subject of plants and plant pests, a plant pathologist commented on the references to *Pseudomonas syringae* as plant pathogens under the heading "ice nucleation negative bacteria" at 49 FR 50902. The respondent noted that none of the strains of *Pseudomonas syringae* currently proposed for use are plant pathogens and that it would be more correct to call *P. syringae* plant-associated bacteria, some of which are pathogens. USDA will clarify future references to these organisms as the respondent suggests. According to current practice, and under the proposed FPPA regulations, an applicant for a USDA permit to import or move *Pseudomonas syringae* would be required to submit data to show whether or not the strain was a plant pest.

Addendum—Research Legislative Authorities

The USDA is authorized under its Organic Act (7 U.S.C. 2201 et seq.) and other legislation to conduct and support research in wide ranging areas of agriculture. Examples of such other laws include:

The Alcohol Fuels Research (7 U.S.C. 3154); the National Latex Commercialization and and Economic Development Act (7 U.S.C. 178–178n); the Animal Health and Disease Research Act (7 U.S.C. 3195); Special Research Grants (7 U.S.C. 450i(c)); The National Aquaculture Act (16 U.S.C. 2801 et seq.); the Cotton Research and Promotion Act (7 U.S.C. 2101 et seq.); the Potato Research Information Act (7 U.S.C. 2611–2627); the Egg Research and Consumer Information Act (7 U.S.C. 701 et seq.); the Beef Research and Information Act (7 U.S.C. 2901 et seq.); the Wheat and Wheat Foods Research and Nutrition Education Act (7 U.S.C. 3401 et seq.); the Animal Cancer Research Act (7 U.S.C. 3901 et seq.); the Floral Research and Consumer Information Act (7 U.S.C. 4301 et seq.); and the Forest Research Assistance Act (16 U.S.C. 582a–582a–7).

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

Agency Guidelines on Biotechnology

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Announcement of guidelines on occupational safety and health in the field of biotechnology.

SUMMARY: OSHA has reviewed its responsibilities under the Occupational Safety and Health Act of 1970 (29 U.S.C. 651 et seq.) as they relate to the protection of the safety and health of workers in the rapidly developing field of biotechnology. Section 8 of the Act authorizes OSHA to inspect workplaces including laboratories and places of employment relating to biotechnology.

Section 5(a)(1) of the Act requires that each employer furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm.

OSHA has determined that this general duty clause, together with several specific standards, currently provides an adequate and enforceable basis for protection of the safety and health of employees in the field of biotechnology. No additional regulation of workplaces using biotechnology appears to be needed at this time, or since no hazards from biotechnology per se have been identified. However, if any of the new biotechnology processes cause hazardous working conditions that result in a significant risk of death or serious harm to workers, OSHA will consider regulating unless the worker exposure is effectively controlled under current OSHA standards or another agency has exercised its authority over health and safety matters for those working conditions. Guidelines contained in this notice are provided to: (1) Clarify the relationship of the existing statute to the field of biotechnology, and (2) reiterate commonly employed laboratory safety practices.

FOR FURTHER INFORMATION CONTACT: James F. Foster, Director, Office of Information and Consumer Affairs, Occupational Safety and Health Administration, Room N-3637, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210. Telephone (202) 523-8151.

A. Background

The Occupational Safety and Health Administration (OSHA) published an announcement of guidelines on occupational safety and health in the **Federal Register**, Volume 50, Number 71, page 14483, April 12, 1985 with a request for public comment. All comments received supported the statement although the National Institute for Occupational Safety and Health (NIOSH) recommended increased surveillance because their research indicated gaps in current knowledge.

Biotechnology is the application of biological systems and organisms to technical and industrial processes. The technologies employed in this area include, but are not limited to:

(1) Classical genetic selection and/or breeding for purposes such as developing bakers yeast, conventional fermentation and vaccine development;

(2) The direct in vitro modification of genetic material, e.g., recombinant DA or gene splicing; and,

(3) Other novel techniques for modifying genetic material of living organisms, e.g., cell fusion and hybridoma technology.

Modern biotechnology is analogous to other conventional industrial processes and has great potential benefit to society and wide application to numerous industries. It is considered by some to have economic potential comparable to the microprocessor industry. Genetic engineering has a wide spectrum of applications of commercial importance, but many such applications are in the early stages of development or have been expressed only as concepts.

The Occupational Safety and Health Act of 1970 (OSH Act) grants the Secretary of Labor broad power to require employers to provide a safe and healthful workplace for their employees. Where other Federal agencies exercise their statutory authority to prescribe or enforce standards or regulations affecting occupational safety or health, OSHA is preempted by section 4(b)(1) of the Act.

Section 5(a)(1) of the Act requires employers to furnish their employees with a workplace "free from recognized hazards that are causing or are likely to cause death or serious physical harm." Section 5(a)(2) requires employers to comply with safety and health standards set by the Secretary. The Secretary in establishing standards to deal with toxic materials and harmful physical agents is required by the OSH Act to "set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life" (section 8(b)(5)). Under a recent Supreme Court decision permanent standards can be promulgated only upon a finding by the Secretary that the standard is reasonably necessary to remedy a significant risk of material health impairment. Finally, emergency temporary standards may be promulgated only upon a finding that employees are "exposed to grave danger." (section 8(c)(1).)

In view of the statutory criteria briefly outlined above and the currently known hazards from biotechnology processes there does not appear to be a need for new OSHA regulations. Furthermore, the biotechnology processes, whether present in laboratories, pilot projects or industrial plants, usually involve conventional chemicals and processes that are already covered by OSHA regulations. These conventional processes use solvents or products, some of which may be toxic or dangerous to employee health in certain dosages over certain periods of time. The potentially hazardous character of some aspects of biotechnology is primarily from the chemicals used and not the biotechnology products. Therefore, the regulations that effectively regulate chemical exposures will usually ensure that biohazards too will be controlled. However, when a process employing biotechnology alone or in combination with conventional chemicals and technology presents a significant hazard to employees which cannot be dealt with by existing standards or the general duty clause, OSHA will consider regulating in order to protect employees health. Increased industrial hygiene monitoring and medical surveillance will help to assure worker protection. At this time, no new regulations that would specifically cover biohazards are warranted.

OSHA endorses the BSCC definitions of "intergeneric (new) organism" and "pathogen" found in the preamble, believing they describe the microorganism appropriate for review when environmental or agricultural applications of microorganisms are contemplated. For contained commercial manufacturing processes, these definitions may also properly exclude from review certain microorganisms of known low risk.

OSHA is committed to the policy described in the section entitled "International Aspects" in the Office of Science and Technology Policy General Preamble, published in today's **Federal Register.**

B. Guidelines

As stated above, section 5(a) of the OSH Act requires that each employer:

(1) Shall furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees;

(2) Shall comply with occupational safety and health standards under this Act.

Specific standards which may be applicable include:

- Specific air contaminants (29 CFR Part 1910, Subpart Z).
- Access to employee exposure and medical records (29 CFR 1910.20).
- Hazard communication (29 CFR 1910.1200).

• Exposure to toxic chemicals in laboratories (currently in draft and under development).

• Respiratory protection (29 CFR 1910.134) (currently being updated).

• Safety standards of a general nature, for example, general environmental, walking and working surfaces, fire protection, compressed gases, electrical safety, and material handling and storage contained in 29 CFR Part 1910 Subparts J, D, E and L, H, S and N).

Effective biological safety and health programs have been operative in a variety of laboratories for many years. Motivation and critical judgment are necessary in addition to specific safety and health knowledge to ensure protection of personnel, the public and the environment. All personnel directly involved in biotechnological projects should receive adequate instruction so that the potential biohazards can be understood and appreciated. Emergency plans should be formulated for each project where the chemicals used or biotechnical product produced pose a potential safety or health hazard. The plans should describe the procedures to be followed if an accident contaminates personnel or workplaces. If a research group is working with a known pathogen for which an effective vaccine is available, employees should be immunized, as appropriate.

Before biotechnological work is undertaken, it is imporant that management determine the potential hazards involved and the precautions to be taken. Program and support staff should then be advised of the real and potential hazards. Staff should be instructed and trained in the protection and techniques required to ensure safety and in the procedures for dealing with accidentally created hazards.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Statement of Policy

AGENCY: National Institutes of Health, PHS, DHHS.

ACTION: Notice.

SUMMARY: This notice describes the role of NIH in relation to biotechnology.

FOR FURTHER INFORMATION CONTACT: Additional information can be obtained from Dr. William J. Gartland, Office of Recombinant DNA Activities, Building 31, Room 3B10, National Institutes of Health, Bethesda, Maryland 20892, (301) 496-6051.

SUPPLEMENTARY INFORMATION: The primary role of the National Institutes of Health (NIH) in relation to biotechnology has been the funding of basic biomedical research. This is discussed in a February, 1985, NIH Report on Biotechnology prepared for the Committee on Appropriations, U.S. House of Representatives, which describes NIH-supported basic research both "directly related to or utilizing the new biotechnology" and "underlying the new biotechnology." The NIH will continue its extensive support of basic biomedical research which can be expected to lead both to many future advances in biotechnology, and to uses of biotechnology towards the better understanding, diagnosis, prevention, and treatment of human diseases.

In addition, the NIH was the first Federal agency involved in the oversight of the safety of recombinant DNA research; NIH's role is described in detail in the NIH Guidelines for Research Involving Recombinant DNA Molecules (Guidelines). The Guidelines were first published in 1976 and have been revised many times since then. A complete revision of the Guidelines appeared in the **Federal Register** of November 23, 1984 (49 FR 46266-46291). A complete new republication appears in the **Federal Register** of May 7, 1986 (51 FR 16958). A summary of the contents of the Guidelines is given below. It is NIH's intention to continue to revise and oversee the Guidelines, and to continue the NIH Recombinant DNA Advisory Committee (RAC) and the NIH Office of Recombinant DNA Activities (ORDA), described below.

Summary of Contents of Guidelines

Section I of the Guidelines includes: The purpose of the Guidelines; definitions of terms used; and the statement that "the Guidelines are applicable to all recombinant DNA research within the United States or its territories which is conducted at or sponsored by an Institution that receives any support for recombinant DNA research from the National Institutes of Health."

Section II of the Guidelines gives a general discussion of "physical containment" and "biological containment."

Section III of the Guidelines divides recombinant DNA experiments into four classes, i.e. "III-A. Experiments which require specific RAC review and NIH and IBC [institutional biosafety committee] approval before initiation of the experiment; III-B Experiments which require IBC approval before initiation of the experiment; III-C. Experiments which require IBC notification at the time of initiation of the experiment; [and] III-D. Experiments which are exempt from the procedures of the Guidelines." For class III-A, it is specified that "Experiments in this category cannot be initiated without submission of relevant information on the proposed experiment to NIH, the publication of the proposal in the **Federal Register** for thirty days of comment, review by the RAC, and specific approval by NIH." Four types of experiments are placed within Class III-A, i.e.: "III-A-1. Deliberate formation of recombinant DNAs containing genes for the biosynthesis of toxic molecules lethal for vertebrates at an LD_{50} of less than 100 nanograms per kilogram body weight. . . .; III-A-2. Deliberate release into the environment of any organisms containing recombinant DNA. . . .; III-A-3. Deliberate transfer of a drug resistance trait to microorganisms. . . .; [and] III-A-4. Deliberate transfer of recombinant DNA or DNA derived from recombinant DNA into human subjects. . . ."

Section IV of the Guidelines specifies the roles and responsibilities of "each institution conducting or sponsoring recombinant DNA research covered by these Guidelines" including the Institutional Biosafety Committee, Biological Safety Officer, and Principal Investigator. Noncompliance with the Guidelines may result in "suspension, limitation or termination of financial assistance for such projects and of NIH funds for other recombinant DNA research at the Institution. . . ." Section IV of the Guidelines also discusses the roles and responsibilities of the NIH, including the Director, NIH, the NIH Recombinant DNA Advisory Committee (RAC), and the NIH Office of Recombinant DNA Activities (ORDA). The RAC "shall consist of 25 members . . . appointed by the [HHS] Secretary or designée, at least fourteen of whom shall be selected from authorities knowledgeable in . . . scientific fields . . . and at least six of whom shall be persons knowledgeable in applicable law, standards of professional conduct and practice, public attitudes, the environment, public health, occupational health, or related fields. Representatives from Federal agencies shall serve as non-voting members." No changes in the Guidelines shall be made without publication of the proposed change for public comment in the **Federal Register** at least 30 days prior to a RAC meeting, and consideration by the RAC.

Section V of the Guidelines contains footnotes and references for Sections I-IV.

Section VI of the Guidelines, entitled "Voluntary Compliance," states that "individuals, corporations, and

institutions not otherwise covered by the Guidelines are encouraged to do so. . . . Since commercial organizations have special concerns, such as protection of proprietary data, some modifications and explanations of the procedures . . . are provided."

Appendix A and Appendix C of the Guidelines list certain types of experiments which are exempt from the Guidelines. Appendix B classifies disease-causing microorganisms. Appendix D describes certain action taken under the Guidelines. Appendix E describes certified host-vector systems. Appendix F gives containment conditions of cloning of genes coding for the biosynthesis of molecules toxic for vertebrates. Appendix G describes physical containment and defines four Biosafety Levels (BL1, BL2, BL3, and BL4). Appendix H covers shipment of organisms containing recombinant DNA molecules. Appendix I discusses biological containment. Appendix J describes the Biotechnology Science Coordinating Committee. Appendix K gives physical containment for large-scale uses of organisms containing recombinant DNA molecules. Appendix L specifies conditions under which certain plants may be approved for release into the environment.

November 22, 1985, Revision of the Guidelines

On November 22, 1985, a number of revisions of the Guidelines were promulgated in the **Federal Register** (50 FR 48344). One of these changes added a new sentence at the end of Section III-A of the Guidelines which specifies that if experiments in the category that require RAC review and NIH and IBC approval before initiation "are submitted for review to another Federal agency, the submitter shall notify ORDA; ORDA may then determine that such review serves the same purpose, and based on that determination, notify the submitter that no RAC review will take place, no NIH approval is necessary, and the experiment may proceed upon approval from the other Federal Agency." It is NIH's intention to consider such experiments (including "deliberate release") on a case-by-case basis. In many such cases, including submissions to the Environmental Protection Agency or the Department of Agriculture, the NIH may well decide "that no RAC review will take place, no NIH approval is necessary, the experiment may proceed upon approval from the other Federal Agency."

[FR Doc. 86-14126 Filed 6-9-86; 4:55 pm]

BILLING CODE 3410-34-M

federal register

Thursday,
June 26, 1986

Part III

Department of Agriculture

Animal and Plant Health Inspection Service

7 CFR Parts 330 and 340

Plant Pests; Introduction of Organisms and Products Altered or Produced Through Genetic Engineering; Proposed Rule and Notice of Public Hearings

Advanced Notice of Proposed Guidelines for Biotechnology Research

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. 85-351]

7 CFR Parts 330 and 340

Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There is Reason to Believe Are Plant Pests

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule and notice of public hearings.

SUMMARY: This document proposes to establish regulations for the introduction (importation, interstate movement, or release into the environment) of genetically engineered organisms or products which are plant pests or which there is reason to believe are plant pests (regulated articles). The proposed regulations set forth the procedures for obtaining a permit which would be required prior to a regulated article being moved into or through the United States, moved interstate, or released into the environment. These regulations are necessary to prevent the introduction into and dissemination and establishment of plant pests in the United States.

This document also gives notice of public hearings concerning this proposal.

DATES: Written comments concerning this proposed rule must be received on or before August 25, 1986. Public hearings will be held on July 29, 1986, in Sacramento, California; and on August 5, 1986, in Washington DC.

ADDRESSES: Written comments should be submitted to Dr. James W. Glosser, Associate Administrator, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Room 313E, Administration Building, 14th and Independence Avenue SW., Washington, DC 20250. Comments should state that they are in response to Docket Number 85-351. Written comments received may be inspected in Room 313-E of the Administration Building between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. The public hearings will be held at the following locations: (1) On July 29, 1986, at Sacramento Convention Center, Yuba Room, 1100 14th St., Sacramento, California 95814, and (2) on August 5, 1986, at Jefferson Auditorium, South Agriculture Building, 14th and Independence Ave. SW., Washington, DC 20250.

FOR FURTHER INFORMATION CONTACT: John R. Wood, Director, Biotechnology and Environmental Coordination Staff, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Room 600, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, 301-436-8896.

SUPPLEMENTARY INFORMATION:

Public Hearings

A representative of the Animal and Plant Health Inspection Service will present a statement concerning the proposed regulations at each of the public hearings described under "**ADDRESSES.**" Any interested person may appear and be heard in person, by attorney, or by other representative.

Each hearing will begin at 9:30 a.m. and is scheduled to end at 5 p.m., local time. However, a hearing may be terminated at any time after it begins if all of those persons at the hearing who desire an opportunity to speak have been heard. Persons who wish to speak are requested to register with the presiding officer prior to the hearing at the location of the hearing from 8:30 a.m. to 9:30 a.m. Those persons registered will be heard in the order of their registration. However, any other person who wishes to speak at the hearing will be afforded such opportunity after the registered persons have been heard. It is requested that two copies of any written statements that are presented be provided to the presiding officer at the hearing. If the number of preregistered persons and other participants in attendance at the hearing warrants it, the presiding officer may limit the time for each presentation in order to allow everyone wishing to speak the opportunity to be heard.

Background

On December 31, 1984, as a part of the Office of Science and Technology Policy's Proposal for a "Coordinated Framework for Regulation of Biotechnology" (49 FR 50856-50907), the U.S. Department of Agriculture (USDA) published a statement of policy for the regulation of biotechnology processes and products (49 FR 50897-50904). USDA's policy statement was not an exhaustive set of application requirements, but a document intended to inform the public, scientists, and industry of USDA's perspective on the regulation of biotechnology processes and products. That perspective, simply stated, was that USDA anticipates that agriculture and forestry products developed by modern biotechnology will not differ fundamentally from conventional products.

USDA indicated in the policy statement that while its existing regulatory framework is adequate, it would constantly reevaluate its regulatory position as the state of the art of biotechnology evolves. The policy statement also indicated that "USDA will use a formal and logical process to ensure the continual integration of safety concepts and other principles for the evaluation of biotechnological processes and products in agriculture and forestry for licensing and granting of permits. Should any new processes or products be shown to require additional regulatory measures, USDA will amend regulations or will request additional authority." (49 FR 50904).

USDA's mandate is to protect and enhance agriculture and forestry in the United States. USDA is confident that organisms altered or produced through genetic engineering will play a major role in increased plant yield and improved plant quality. However, such organisms may also present a risk of plant pest introduction.

During the last 10 years, there has been a dramatic increase in biotechnological research and product development throughout the world. For example, the manipulation or movement of genetic material by recombinant DNA technology has made its possible to perform genetic engineering procedures with an increasing number of applications in agriculture and forestry (see 49 FR 50899-50900). There is also a growing domestic and international trade in genetically engineered organisms. Such trade may introduce exotic plant diseases and pests into the United States and pose a threat to U.S. agriculture if the introduction and dissemination of certain genetically engineered organisms is not regulated. Certain organisms themselves, the cultures in which they are transported, or their packaging may be contaminated with plant pests. It is necessary, therefore, to establish regulatory control over genetically engineered organisms which are plant pests or which there is reason to believe are plant pests. Other genetically engineered organisms, which are engineered from certain organisms which are not plant pests or classified in taxa which do not contain plant pests, need not be regulated.

Regulation of the Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There is Reason to Believe Are Plant Pests

This document proposes to establish a new part entitled, "Introduction of Organisms and Products Altered or

Produced Through Genetic Engineering Which Are or Which There is Reason to Believe Are Plant Pests" in Title 7 of the Code of Federal Regulations (7 CFR) (hereinafter referred to as the proposed regulations), pursuant to the authority of the Federal Plant Pest Act of May 23, 1957, as amended, (FPPA), (7 U.S.C. 150aa–150jj) and the Plant Quarantine Act of August 20, 1912, as amended (PQA), (7 U.S.C. 151, 164, 166, 167). The regulations propose to regulate the introduction (importation, interstate movement, and release into the environment) of certain organisms or products altered or produced through genetic engineering which are plant pests or which there is reason to believe are plant pests. These articles would be regulated in order to prevent the introduction, spread, or establishment of plant pests that are new to or not known to be widely prevalent or distributed within and throughout the United States. (See 7 U.S.C. 150dd(a)).

The PQA and the FPPA provide authority for regulating plant pests and other articles. Specifically, the PQA provides authority to regulate the importation and interstate movement of plants and plant products that may result in the entry into the United States of injurious plant diseases or insect pests. The FPPA authorizes the issuance of regulations to prevent the dissemination into the United States or interstate of plant pests, in any situation in which such regulations are not authorized under the Plant Quarantine Act. These provisions include authority for regulating the "release into the environment" in the United States of certain genetically engineered organisms.

"Release into the environment" would be defined to mean "the use of a regulated article outside the constraints of physical confinement that are found in a laboratory, contained greenhouse, or a fermenter or other contained structure."

The proposed regulations which are designed to prevent the release into the environment of genetically engineered organisms which are plant pests or for which there is reason to believe are plant pests are consistent with the legislative intent of the FPPA which gave USDA the authority to regulate plant pests and other articles in order to prevent injury and damage to plants, plant products, and crops.

The FPPA was enacted in 1957 and was intended as gap filling legislation, for the purpose of protecting American agriculture against invasion by foreign plant pests and diseases, which are "new to or not theretofore known to be widely prevalent or distributed within and throughout the United States". The FPPA was enacted because of deficiencies in such acts as the Insect Pest Act (repealed), the Plant Quarantine Act (7 U.S.C. 151 *et seq.*) the Mexican Border Act (7 U.S.C. 149) and the Mollusk Act (repealed), (See Report No. 289 to accompany H.R. 3476, 85th Congress, 1st Session, pp. 2–3).

USDA believes that when a regulated article is released into the environment from a contained greenhouse, a laboratory, or any other containment facility, such release is tantamount to the introduction of an organism which is "new to and not theretofore known to be widely prevalent or distributed within and throughout the United States" and which there is reason to believe is a plant pest. Such exotic organisms are subject to regulation under the FPPA.

Restrictions on the introduction of regulated articles (§ 340.0)

The proposed regulations restrict the "introduction" of those organisms and products altered or produced through genetic engineering which are a plant pest or for which there is reason to believe are plant pests. Such organisms are referred to as "regulated articles".

Modern genetic engineering techniques permit genetic material to be intentionally combined in organisms in combinations that occur only at low frequency in nature. These traits may be new to the organism, or new to the environment in which the organism is released. Some of these genetically engineered organisms may exhibit new or altered traits affecting, for example, their survivability, host range, substrate utilization, or competition. Such organisms may be plant pests.

The most significant concern to USDA from a regulatory viewpoint is when an organism or product is altered or produced by genetic engineering and one or more of its constituents (donor, vector/vector agent or recipient) comes from a family or genus of organisms known to contain plant pests. USDA believes that such a genetically engineered organism needs to be regulated. This is because when an organism whose constituents come from a group of organisms that are plant pests, there is a risk that certain undesirable traits may be transferred to the new organism and may survive when the organism is released into the environment. The introduction of such organisms would be prohibited unless authorized by a permit.

Section 340.0(a) prohibits any person from introducing a regulated article unless the introduction is authorized by a permit and such introduction is in conformance with all of the applicable restrictions contained in Part 340.

Section 340.0(b) provides that if any regulated article is not in compliance with the requirements of Part 340 when introduced, that such regulated article shall be subject to the immediate application of remedial measures or safeguards against escape of the article as the inspector determines is necessary to prevent the introduction of plant pests.

For informational purposes footnote 1 has been included to inform persons that the introduction into the United States of organisms that have been altered or produced through genetic engineering may be subject to other regulations that have been promulgated under the Federal Plant Pest Act (7 U.S.C. 150aa *et seq.*), the Plant Quarantine Act (7 U.S.C. 151 *et seq.*), and the Federal Noxious Weed Act U.S.C. 2801 *et seq.*) which are found in 7 CFR Parts 319, 321, 330, and 360.

Proposed Part 340 would be applicable to the introduction of organisms or products altered or produced through genetic engineering whose plant pest status is uncertain and would not affect the Department's existing regulations in 7 CFR 330.200 entitled, "Subpart—Movement of Plant Pests." The regulations in 7 CFR 330.200 specify permit requirements for the importation and interstate movement of "known" plant pests which are naturally occurring and have not been genetically engineered, where there is no uncertainty as to their plant pest status.

Thus, a person seeking to import or move interstate the fungal organism *Puccinia horiana*, the cause of Chrysantheum white rust disease, would be subject to the regulations in 7 CFR 330.200. However, if the fungus *P. horiana* was used as either the donor or recipient organism to genetically engineer a new type of organism, the genetically engineered organism would be subject to regulation under proposed Part 340.

In order to reflect the distinctions between the plant pest regulations in §§ 330.200–330.212 and the proposed regulations, USDA is amending the definition of "plant pest" in 7 CFR 330.100 to indicate that the regulations in §§ 330.200–330.212 are not applicable to plant pests that have been genetically engineered.

Footnote 2 has also been included for informational purposes. This footnote explains the authority available to USDA to take emergency action against a regulated article by seizing, destroying, quarantining, or disposing of any regulated article which is a plant

pest or is believed to be infested or infected by or otherwise believed to contain a plant pest.

Definitions (§ 340.1)

In addition to the definitions of "introduction" and "release into the environment" the proposed regulations in § 340.1 present definitions of the following terms: "Certificate of exemption", "Classical genetics", "Deputy Administrator", "Donor organism", "Environment", "Genetic engineering", "Genetic manipulation", "Inspector", "Interstate", "Move", "Mutagen", "Organism", "Pathogen", "Permit", "Person", "Plant", "Plant pest", "Plant Protection and Quarantine", "Product", "Recipient organism", "Regulated article", "Responsible person", "Secretary", "State", "United States", and "Vector or vector agent", "Well-characterized and contains only non-coding regulatory regions".

Genetic engineering is defined as "genetic manipulation of organisms by procedures other than those used in classical genetics, including, but not limited to, protoplasts, cell, and embryo fusions; recombinant DNA engineering, and directed mutagenesis."

In order to explain the meaning of certain terms in the definition of genetic engineering in the proposed regulations, the following words are defined further in the proposed regulations:

Organism is defined to mean "any active, infective, or dormant stage or life form of an entity characterized as living, including vertebrate and invertebrate animals, plants, bacteria, fungi, mycoplasmas, mycoplasma like organisms, as well as viroids, viruses, and prions, or any entity related to the foregoing and any part, copy, or analog thereof, including deoxyribonucleic acid (DNA) and ribonucleic acid (RNA) which is infectious."

The meaning of the term "organism(s)" encompasses not only whole organisms, but also portions of organisms (e.g., organs, organelles or portions of organelles, segments of DNA or RNA, etc.), analogs of organisms (functionally similar to the organism but not necessarily an exact copy of the organism or part of the organism), and natural or synthetic copies of organisms or portions of organisms if any confer infectivity. An organism may be in a stage or form ordinarily known of as "living." Such a living organism may be "dormant" or it may be "active." Some organisms, such as viruses, viroids, and prions, are considered by some people to be living (as in "active"), and by other people not to be alive. For the purposes of the proposed regulations, these organisms, portions of natural or synthetic DNA and RNA, and similar organisms, are considered to be active or infectious (capable of entering into functioning, or integrating themselves into other organisms and affecting the functioning of the other organism). Inactivated or dead organisms, or portions of these organisms, are covered under this definition because they may be active or infectious in that they are capable of functioning or affecting the functioning of another organism.

Classical genetics is defined as "genetic manipulation of organisms by procedures which occur in nature or in conventional breeding, including but not restricted to such methods as natural and hand pollination, and natural and artificial insemination and undirected mutagenesis."

Genetic manipulation is defined as "the process of causing hereditary variation in an organism through the introduction of change in its DNA and RNA structure or function."

Mutagens are defined as "agents such as colchicine, radioactive elements, lasers, and ultraviolet light that cause mutations without the exchange of genetic material between organisms."

The proposed regulations define a plant as "any living stage or form of any organism of the plant kindgom including, but not limited to, bacteria, prokaryotic algae, eukaryotic algae, fungi, mosses, club mosses, ferns, horsetails, liverworts, angiosperms, gymnosperms, and lichens (which contain algae) including any parts (e.g., pollen, seeds, cells, tubers, stems) thereof, and any cellular components (e.g., plasmids, ribosomes, etc.) thereof."

Plant pest is defined as "any living stage (including active and dormant forms) of insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals; bacteria, fungi, other parasitic plants or reproductive parts thereof viruses or any organisms similar to or allied with any of the foregoing; or any infectious agents or substances, which can directly or indirectly injure or cause disease or damage in or to any plant or parts thereof, or any processed, manufactured, or other products of plants."

The proposed regulations also present a definition of the term "Responsible person." Responsible person is defined as the person who has control and will maintain control over the introduction of the regulated article and assure that all conditions contained in the permit and requirements in this part are complied with. A responsible person shall be a resident of the United States or shall designate an agent who is a resident of the United States.

Under the proposed regulations a regulated article is defined as "any organism or any product which has been altered or produced through genetic engineering, if the donor organism, recipient organism, or vector or vector agent belongs to a group designated in § 340.2 of this part, or any organism or product altered or produced through genetic engineering which the Deputy Administrator determines is a plant pest or has reason to believe is a plant pest.

Excluded are microorganisms that are non-pathogenic, non-infectious, and otherwise not a plant pest, that have resulted from the addition of genetic material that is well characterized and contains only non-coding regulatory regions such as operators, promoters, origins of replication, terminators, and ribosome binding regions."

Under the proposed definitions the term "well characterized and contains only non coding regulatory regions" (i.e. operators, promoters, origins of replication, terminators, and ribosome binding regions) means the genetic material added to a microorganism in which the following can be documented about such genetic material:

a. The exact nucleotide base sequence of the regulatory region and any inserted flanking nucleotides;

b. The regulatory region and any inserted flanking nucleotides do not code for protein or peptide; and

c. The regulatory region solely controls the activity of other sequences that code for protein or peptide molecules or act as recognition sites for the initiation of nucleic acid or protein synthesis."

The definition of regulated article excludes recipient microorganisms that are non-pathogenic, non-infectious, and otherwise not a plant pest, that have resulted from the addition of genetic material that is well characterized and contains only non-coding regulatory regions.

The addition of the genetic material that is well characterized and which contains only non-coding regulatory regions has no coding capacity for the production of any gene product (proteins or peptides) and does not promote the production of any new material. These regulatory regions (operators, promoters, origins of replication, terminators, and ribosome binding sites) are responsible for the initiation and modulation of nucleic acid synthesis at the specific region where they appear in the chromosome. Thus, if the recipient microorganism is non-pathogenic, non-infectious, and otherwise not a plant pest, then the resulting genetically engineered microorganism would be

non-pathogenic, non-infectious, and otherwise not a plant pest.

The exclusion from regulation of certain genetically engineered microorganisms that have resulted from the addition of genetic material that is well-characterized and contains only noncoding regulatory regions such as operators, promoters, origins of replication, terminators and ribosome binding regions was adopted by the Biotechnology Science Coordinating Committee of the Office of Science and Technology Policy.

In view of the above, USDA does not have reason to believe that such microorganisms are plant pests nor will they become plant pests.

The proposed regulations also contain a definition of pathogen. As used in the term "regulated article" pathogen means "a virus or microorganism (including its viruses and plasmids, if any) that has the ability to cause disease in other living organisms. Excluded are those microorganisms for which it can be documented that the microorganisms come from nonpathogenic species, (e.g. *Bacillus subtilis, Lactobacillus acidophilus,* and *Saccharomyces* species) or come from a nonpathogenic strain of a pathogenic species (e.g., *Escherichia coli* K-12)."

Like the definition of regulated article, the definition of pathogen references certain exclusions. A microorganism will not be deemed a pathogen if it can be documented that it comes from a nonpathogenic species (e.g., *Bacillus subtilis, Lactobacillus acidophilus,* or *Saccharomyces* species) or from a nonpathogenic strain of a pathogenic species (e.g. *Escherichia coli,* K-12).

Groups of organisms which are or contain plant pests (§ 340.2)

Proposed § 340.2 entitled, "Groups of organisms which are or contain plant pests" in a key provision in determining whether a genetically engineered organism is subject to regulation under this part. A person who has genetically engineered an organism intended for introduction should consult § 340.2 of the proposed regulations in order to determine if such organism is a "regulated article".

USDA is proposing to regulate only genetically engineered organisms or products which are plant pests or for which there is reason to believe are plant pests, and not to regulate an organism or product merely because of the process by which it was produced. USDA believes that an organism or product is a plant pest if the donor, recipient, vector or vector agent of the genetically engineered organism or product comes from a member of one of the groups listed in § 340.2.

USDA further believes that a genetically engineered organism or product should be designated as a "regulated article" when, based on experience, the Deputy Administrator determines that the organism or product is a plant pest or has reason to believe it is a plant pest.

Basis for Listing Organisms in § 340.2

The list of organisms in § 340.2 was developed based on previous experience with issuing plant pest permits for organisms not altered by genetic engineering. For the past several decades, the Department has been issuing from 1,000 to 3,000 plant pest permits per year for scientific or experimental purposes. This experience, coupled with pest reports from the USA and other countries, and consultation with pathologists, mycologists, nematologists, entomologists, botanists, and other scientists from the Department, has been consolidated into the list in § 340.2 of organisms from a family or genus or organisms known to contain plant pests. The purpose of § 340.2 is to indicate those organisms that are known plant pests or considered potential plant pests.

Section 340.2 does not attempt to list every pest species. That would be impossible. Not only because hundred of thousands of species are involved, but also because within species some subgroups may be pests and other subgroups may not be pests. Also, the pest status of many species is unknown. Section 340.2 lists higher taxa (taxonomic groups) which include known pest species or species for which the Department has reason to believe are pest species.

The taxonomic scheme used in § 340.2 is that of S.P. Parker, *Synopsis and Classification of Living Organisms,* McGraw Hill (1984). This is a five-kingdom system. For most taxa, common names are given merely for convenience of the user. Reliance should be placed upon the Latin scientific names. However, for certain groups, such as viroids, plant viruses, mycoplasma like organisms associated with plants and prions, in which there are no Latin names, the accepted common names are given. Section 340.2 covers all organisms, including donors, vectors, and recipients that may be used in proposed biotechnology projects. Within each taxon, all species are subject to review by the Department, unless there are taxa of lower rank specifically listed, in which instance, only those specifically listed are considered to be plant pests or potential plants pests, and other classified organisms not listed are considered not to be plant pests or potential plant pests.

A number of groups of organisms (particularly microorganisms) were unknown until recent years. Examples are groups such as fungi, bacteria, viruses, viroids, rickettsia, mycoplasma, mycoplasma-like organisms, spirochetes, etc. In every group, a significant number of plant pests are now known. USDA has reason to believe that groups of organisms which are currently unclassified or unknown are likely to contain plant pests, and, therefore, are included in § 340.2.

USDA has also included all viroids and prions on the list of organisms which are or contain plant pests. All viroids and prions known at this time are pathogens. Presently known viroids are pathogenic to plants; the two diseases known to be caused by prions occur in animals. These organisms are difficult to work with and have not been isolated in "pure culture"; they are still under intensive investigation in an effort to learn about the organisms themselves, the diseases they cause, their pathogensis, the genetic mechanisms responsible for their replication, defenses against these organisms, methods for detection, etc. In view of the fact that so little is known about these two groups of infectious "organisms", which are composed, so far as is now known, of naked RNA and protein (viroids) and apparently of protein alone (prions), it is reasonable to include organisms modified through the use of viroids and prions as regulated articles. Thus, prions and viroids are included in § 340.2.

Permits (§ 340.3)

Proposed § 340.3(a) explains that a written application for a permit should be submitted by the responsible person at least 180 days in advance of the proposed introduction by submitting an application form that has been obtained from Plant Protection and Quarantine.

For informational purposes footnote 3 has been added to advise persons that applications for a permit are available from the Biological Assessment Support Staff, Plant Protection and Quarantine, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, or from local offices of the Animal and Plant Health Inspection Service which are listed in telephone directories.

An application for a permit would require the submission of data to USDA needed to assess the risk to argiculture in the United States, when certain

organisms which have been modified or altered through genetic engineering are introduced. The following discussion explains the rationale for requiring that certain data be submitted in an application for a permit.

Proposed § 340.3(a)(2) requires the submission of data concerning the scientific, common, and trade names and all designations necessary to identify the donor organism, recipient organism, vector or vector agent of each regulated article which is a product, and for the regulated article. Such data would be used by USDA in identifying the constituents of the regulated article in order to determine the plant pest status of the regulated article.

Under proposed § 340.3(a)(3) the name and address of the person(s) who developed and/or supplied the regulated article would be used by USDA if additional information was needed concerning the origin and process used to create the regulated article.

Information required under proposed § 340.3(a)(4) concerning the method of movement of the regulated article is needed so that Plant Protection and Quarantine inspectors can anticipate the arrival of the regulated article and ensure that such article is properly inspected.

Data that is required under proposed § 340.3(a) (5) through (8) concerning a detailed description of the anticipated or actual expression of the genetic material in the regulated article and its characteristics; a description of the molecular biology used to produce the regulated article; the country of origin where the donor, recipient, vector or vector agent and regulated article were collected, developed and produced; and a detailed description of the purpose for the introduction, including a detailed description of the proposed experimental and/or production design, would provide Plant Protection and Quarantine with the data necessary to make a determination of the potential plant pest risk and whether a permit could be issued for the regulated article.

Data that is required by proposed § 340.3(a)(9), (11, (12) and (14) concerning the quantity of the regulated article to be introduced and proposed schedule of introductions; a detailed description of the intended destination and distribution of the regulated article; a detailed description of the proposed procedures, processes and safeguards which will be used to prevent escape and dissemination of the regulated article at each intended destination; and a detailed description of the proposed method of final disposition of the regulated article would be used along with the other data that would have to be submitted in a application, to assess the potential environmental impact of issuing a permit.

Data required by proposed § 340.3(a)(10) (a detailed description of the processes, procedures, and safeguards which have or will be used in the United States or in the country of origin to prevent contamination, release, and dissemination and that were used in the production of the donor and recipient organism, vector or vector agent, constituent of each regulated article which is a product, and the regulated article) would be needed to assess the purity of the regulated article. Data required by proposed § 340.3(a)(13) concerning any biological material that may accompany the regulated article during movement is necessary to assess both the purity of the regulated article as well as whether any additional containment safeguards would be necessary, as a condition of introduction.

Proposed § 340.3(b) explains the administrative action that will be taken on an application for a permit submitted pursuant to § 340.3(a).

Under proposed § 340.3(b) upon receipt and review by Plant Protection and Quarantine of an application for a permit, a permit shall be granted or denied. If a permit is denied the responsible person shall be promptly informed of the reasons why the permit was denied. If a permit is granted, the permit will specify the applicable conditions for the introduction of the regulated article.

Proposed § 340.3(c) lists the standard conditions which shall be listed on the permit and which are applicable to the introduction of regulated articles. In addition to the standard conditions, the Deputy Administrator may list supplemental conditions which are applicable to the introduction of a particular regulated article for which a permit has been granted.

The proposed standard conditions to be listed on the permit are:

(1) The regulated article shall be maintained and disposed of (when necessary) in a manner determined necessary by the Deputy Administrator;

(2) All packing material, shipping containers, and any other material accompanying the regulated article shall be treated or disposed of as determined necessary by the Deputy Administrator;

(3) The regulated article shall be kept separate from other organisms, except as specifically allowed in the permit;

(4) The regulated article shall be maintained only in areas and premises specified in the permit;

(5) An inspector shall be allowed access, during regular business hours to the place where the regulated article is maintained;

(6) The regulated article shall, when possible, be kept identified with the label showing the name of the regulated article, and when applicable, the port accession number and date of importation;

(7) The regulated article shall be subject to the application of measures determined by the Deputy Administrator to be necessary to prevent the accidental or unauthorized release of the regulated article;

(8) The regulated article shall be subject to the application of remedical measures (including disposal) determined by the Deputy Administrator to be necessary to prevent the spread of plant pests;

(9) A person who has been issued a permit shall submit to Plant Protection and Quarantine monitoring reports on the performance characteristics of the regulated article, as deemed necessary by the Deputy Administrator;

(10) Plant Protection and Quarantine shall be orally notified immediately, and in writing, within the time periods specified below, in the event of the following ocurrences:

(i) Within 24 hours in the event of any accidental or unauthorized release of the regulated article;

(ii) Within 5 working days if the regulated article is found to have characteristics substantially different from those listed in the application for a permit; and

(iii) Within 5 working days if the regulated article dies.

(11) A permittee or his/her agent who seeks to import a regulated article into the United States shall:

(i) Import or offer the regulated article for entry only at a port of entry which is designated by an asterisk in 7 CFR 319.37-14(b);

(ii) Notify Plant Protection and Quarantine promptly upon arrival of any regulated article at a port of entry, of its arrival by such means as a manifest, customs entry document, commercial invoice, waybill, a broker's document, or a notice form provided for such purpose; and

(iii) Mark and identify the regulated article in accordance with § 340.6 of this part.

The provisions in proposed § 340.3(c) (1) through (4) pertaining to the disposal of regulated articles, treatment and disposal of shipping containers and packing material, segregation and maintenance of regulated articles are necessary to prevent the dissemination and establishment of plant pests.

The proposed provisions in § 340.3(c)(5) and (6) which pertain to allowing an inspector access to the location where the regulated article is maintained as well as keeping the regulated article properly identified is necessary to enable an inspector to make a determination that the conditions of this part are being complied with and to ensure that a regulated article can be properly identified at the site where it is maintained.

The proposed provisions in § 340.3(c)(7) and (8) which provide that a regulated article shall be subject to the application of measures determined by the Deputy Administrator to be necessary to prevent the accidental or unauthorized release of the regulated article, as well as the regulated article being subject to the application of remedial measures necessary to prevent the spread of plant pests, are necessary to prevent the possible dissemination and establishment of plant pests.

Under proposed § 340.3(c)(9) it is necessary to require that a person who has been issued a permit submit monitoring reports on the characteristics of the regulated article, as deemed necessary by the Deputy Administrator in order for Plant Protection and Quarantine, under certain circumstances to make a final determination on the plant pest status of the regulated article.

The reporting requirements in proposed § 340.3(c)(10) are necessary for Plant Protection and Quarantine to take remedial action in the event of an accidental or unauthorized release, or in the event that the regulated article exhibits substantially different characteristics from what was described in an application, or in the event the regulated article dies to determine if the regulated article is a plant pest or was infested or infected by a plant pest.

The provisions in proposed § 340.3(c)(11) pertaining to importation at certain ports of entry designated in 7 CFR 319.37–14(b) are necessary to ensure that regulated articles are imported only at those ports where there are specially trained personnel and treatment facilities in order to prevent the introduction of plant pests that may accompany or be in the regulated article. The arrival notification and marking and identity provisions would assure that Plant Protection and Quarantine is adequately notified in writing of the arrival of such regulated articles and that the articles can be expeditiously processed and identified after such notification at the port of entry.

Proposed § 340.3(d) contains the provisions under which a permit may be withdrawn by the Deputy Administrator or an inspector if a determination is made by him that the holder of the permit has not complied with one or more of the conditions listed on the permit. This subsection provides that the reason for withdrawal of the permit shall be confirmed in writing as promptly as circumstances allow and that the withdrawal may be appealed in writing to the Deputy Administrator within ten (10) days after receiving the written notification of the withdrawal. These provisions set forth due process requirements pertaining to the withdrawal of a permit.

Certificate of exemption (§ 340.4)

Proposed § 340.4 discusses the provisions for the issuance of a certificate of exemption.

Proposed § 340.4(a) provides that the Deputy Administrator may issue a certificate of exemption for the introduction of organisms which have been modified through genetic engineering, but which are not subject to regulation under this part, when the introduction of such organisms might otherwise be impeded because of the similarity of the nonregulated organism to other organisms which are subject to regulation under Part 340.

Thus, a person seeking to introduce a nonregulated organism which has been altered or modified through genetic engineering may wish to apply for a certificate of exemption prior to such introduction in order to facilitate easy introduction of the organism. Such a certificate will establish that the organism is not subject to regulation under Part 340.

Proposed § 340.4(b) explains the procedure for requesting a certificate of exemption. To obtain a certificate of exemption a person should submit an application form which has been obtained from Plant Protection and Quarantine, which contains data required by § 340.3(a) (1), (2), and (5) and should indicate that such data is being submitted as a request for a certificate of exemption. A person should also submit a statement indicating why he or she believes the organism or product is not a plant pest.

Marking and identity (§ 340.5)

Proposed § 340.5 would require certain marking and identification information to be plainly and correctly borne at the time of importation on the outer container of a regulated article. In order to comply with specified requirements of the Plant Quarantine Act, any regulated article for importation, including any article for importation by mail, would be required to bear at the time of importation the general nature and quantity of the contents; the country and locality where collected, developed, manufactured, reared, cultivated, or cultured; the name and address of the shipper, owner, or person shipping or forwarding the article; and the name and address and telephone number of the consignee (in the case of mail the consignee would be Plant Protection and Quarantine).

A regulated article for importation other than by mail would be required to bear an identifying shipper's mark and number. This would enable an inspector to locate the regulated article at the port of entry by comparing the shipper's mark and number on available entry documents (e.g., manifest, waybill) with such information on the container.

Such regulated articles would also be required to bear the number of the written permit authorizing the importation, if one was issued. This would enable the inspector to check whether a valid permit was actually issued for the article in question.

The proposal would also require any regulated article for importation by mail to be mailed to Plant Protection and Quarantine at a port of entry designated by an asterisk in the list of ports of entry in 7 CFR 319.37–14(b). This appears to be necessary in order to prevent direct mailing to the intended recipient, and to ensure the requirements of the proposed part have been met, e.g., that the regulated article is properly marked and shipped in the proper containers. The proposal would further require a package containing a regulated article for importation by mail to contain within each package a sheet of paper bearing the name, address, and telephone number of the intended recipient. This would allow Plant Protection and Quarantine to be able to forward the package to the intended recipient. Also inclusion of the telephone number of the intended recipient for mailed articles would allow Plant Protection and Quarantine to contact the intended recipient for the purpose of obtaining any necessary clarifications for determining eligibility for importation of such articles. With respect to importation of articles other than by mail, this requirement is not necessary because the representative or agent of the intended recipient would be available at the port of entry to provide any necessary clarifications.

It is also proposed that shipments containing regulated articles be required to be accompanied by an invoice or packing list indicating the contents of the shipments. This appears necessary because such information on the outside of a package or on a regulated article

could be rendered illegible, destroyed, or lost because of handling during shipment. This requirement would not be an additional burden on importers since invoices and packing lists are required by the shipping industry and by the U.S. Customs Service.

Container requirements (§ 340.6)

Proposed § 340.6 specifies container requirements for the movement of regulated articles. Such requirements would be imposed to ensure that regulated articles do not inadvertently escape during the movement of the regulated article. The container requirements would be listed on a permit.

Proposed § 340.6(a) is a general provision which requires that a regulated article not be moved unless it complies with the specific container provisions of proposed § 340.6(b).

Proposed § 340.6(b) specifies the container requirements for the following types of regulated articles: plants and plant parts; seeds; live microorganisms and/or etiologic agents, cells, or subcellular elements; insects, mites, and related organisms; and other macroscopic organisms.

Under proposed § 340.6(b)(1) regulated articles which are plants and plant parts (except seeds, cells and subcellular elements) would have to be packed for transport in a sealed plastic bag of at least 5 mil thickness, inside a sturdy, sealed, leak-proof, outer shipping container constructed of corrugated fiberboard, corrugated cardboard, wood, or other material of equivalent strength. It is necessary to place the plastic bags in an outer shipping since plants and plant parts may be of a woody nature and could puncture the plastic packaging material. Such regulated articles need to be properly packaged to minimize the hazard ensuing from puncture and loss of contents during transport. Plastic bags of at least 5 mil thickness would not only contain the plants or plant parts, but should also maintain the plants or plant parts in a relatively healthy environment during the time it would take to ship them to their designation. Placing these bagged plants within a sturdy outer shipping container would further reduce the possibility of possible container puncture and release into the environment.

Under proposed § 340.6(b)(2) seeds would have to be transported in a sealed plastic bag of a least 5 mil thickness, inside a sealed metal container, which would be placed inside a second sealed metal container separated by shock absorbing cushioning material between the two containers. Each metal container would have to be independently capable of protecting the seed and preventing spillage or escape. The metal containers would then have to be enclosed in a sturdy outer shipping container constructed of corrugated fiberboard, corrugated cardboard, wood, or other material of equivalent strength. Certain seeds, especially seeds of parasitic plants, are so small (less than 2 millimeters in diameter) that they are especially susceptible to spillage, loss and dissemination into the environment unless extreme precautions are taken to ensure their enclosure. For this reason the system of sealed containers within an outer container would be required to be used for seeds which are regulated articles.

Proposed § 340.6(b)(3) provides container requirements for live microorganisms and/or etiologic agents, cells, or subcellular elements. The proposed container requirements for such articles are identical to the National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules. The requirements would be similar to the requirements for seeds (above), and would require the organisms to be in a sealed primary container, which would be placed in a secondary container separated by sufficient nonparticulate absorbent packing material to absorb the contents of the primary container. The secondary container would then be placed in a strong outershipping container (wood, corrugated carboard, or equivalent).

The preceding discussion regarding proposed § 340.6(b)(3) applies to volumes not exceeding 50 ml. This subsection also contains provisions for the shipment of volumes greater than 50 ml which are similar to the preceding requirements, and instructions for packing dry ice when it is used as a refrigerant.

Proposed § 340.6(b)(4) provides the container requirements for insects, mites, and related organisms. Such organisms may either be shipped in accordance with the proposed provisions for live microorganisms (referenced immediately above) or they could be transported in chilled escape proof primary containers within insulated secondary shipping containers all contained in an outer shipping container. This type of containerization provides for survival and reduced rate of normal functioning of the insects during transportation.

Proposed § 340.6(b)(5) provides the container requirements for microscopic organisms not covered in § 340.6(b)(1), (2), and (4) above. Microscopic organisms which do not require access to atmospheric oxygen could be contained in accordance with the requirements of §§ 340.6(b)(3) or 340.6(b)(4).

Those microscopic organisms that are not plants and that require continuous access to atmospheric oxygen would have to be placed in primary shipping containers constructed of a sturdy, crush-proof frame of wood, metal, or equivalent strength material surrounded by escape proof mesh or netting. Such primary shipping containers would then have to be placed in a similar secondary container and then within an outer shipping container. Such double enclosures would provide additional protection from escape, and an outer container with air holes would provide extra stability and resistance to puncture of the screening, as well as access to the amounts of air necessary for the survival of these larger organisms.

The container requirements for moving regulated articles appear adequate to prevent the escape and dissemination of regulated articles during movement.

For informational purposes footnote 4 has been added to indicate that the requirements of § 340.6 are in addition to and not in lieu of any other packing requirements such as those for the transportation of etiologic agents prescribed by the Department of Transportation in Title 49 of the Code of Federal Regulations or any other agency of the Federal government.

Costs and charges (§ 340.7)

Proposed § 340.7 relates to costs and charges in connection with the services of an inspector. It is the policy of Plant Protection and Quarantine that the services of an inspector during regularly assigned hours of duty and at the usual places of duty be furnished without cost to persons requiring inspection. Section 340.7 further provides that any costs or charges incidental to inspection, or compliance with the provisions of this part, other than an inspector's services, are not the responsibility of the Department of Agriculture. For informational purposes footnote 5 has been added to explain that the Department's provisions relating to overtime charges for an inspector services are set forth in 7 CFR Part 354.

USDA and EPA jurisdictional agreements pertaining to the review of microorganisms

Certain genetically engineered microorganisms that are intended for nonagricultural purposes, but are also plant pests (because they are pathogenic

to plants) will be regulated jointly by USDA under the FPPA and by the Environmental Protection Agency (EPA) under the Toxic Substances Control Act (TSCA). Such microorganisms may be used to enhance oil recovery, degrade pollutants, degrade paper pulp, or enhance artificial snow formation. Other genetically engineered microorganisms which are plant pests and are used as microbial pesticides would be regulated by USDA under the FPPA and by EPA under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

Pursuant to its statutory mandate under the FPPA, USDA shall review any genetically engineered microorganism that is a plant pest or where there is reason to believe that the microorganism is a plant pest. EPA has stated that certain genetically engineered microorganisms that are deemed "new organisms" shall be subject to review under TSCA. Thus, microorganisms deliberately formed from the genetic material of different genera (intergeneric microorganisms) will be reviewed by EPA under TSCA, and by USDA under the FPPA if it is a plant pest or there is reason to believe it is a plant pest. EPA and USDA will perform independent reviews, focusing on different objectives. In such instances, both agencies shall appoint contact persons who will coordinate the reviews, particularly to ensure data requests are not duplicated.

Genetically engineered microorganisms that are intergeneric in nature and are not or not believed to be or capable of becoming a plant pest shall be reviewed solely by EPA under TSCA unless a genetically engineered organism is intended for use as a pesticide, in which case it shall be reviewed solely by EPA under FIFRA. USDA shall review only if EPA determines in the course of its review that the microorganisms has plant pest qualities.

Genetically engineered microorganisms that are intrageneric in nature (formed from the same genera) that are plant pests or where there is reason to believe are plant pests shall be reviewed by USDA under the FPPA, regardless of whether the microorganism is intended for agricultural use. EPA shall also review the microorganism under TSCA if the microorganism is not intended to be used as a pesticide, if a pesticide it would be reviewed under FIFRA.

Genetically engineered microorganisms that are intrageneric in nature and are not plant pests or which there is no reason to believe are plant pests, and are not intended for use as a pesticide, shall be subject only to section 8(a) reporting requirements under TSCA. Because such microorganisms are not "new" organisms and since they are not believed to have plant pest qualities, such microorganisms are believed to present the least risk. EPA shall be responsible for informing USDA if it believes the microorganisms have plant pest qualities.

The preceding discussion on USDA and EPA reviews of genetically engineered microorganisms may be summarized as follows:

	Intergeneric	Intrageneric
Plant pest	USDA review and EPA review.	USDA review only, if intended for agricultural use; if nonagricultural use EPA reviews as well.
Non-plant pest.	EPA review only unless EPA review indicates presence of plant pests.	Neither agency reviews; EPA collects general information under section 8(a) of TSCA; EPA advises USDA of any potential plant pests.

Confidential Business Information

On September 23, 1985, a document was published in the **Federal Register** (50 FR 38561–38563) establishing the policy of the Animal and Plant Health Inspection Service (APHIS) for protecting certain privileged or confidential business information. The purpose of the policy statement was to establish minimum requirements to control and protect documents received by APHIS that in its judgment contain privileged or confidential business information as defined in IV–E of the policy statement concerning biotechnology and the Veterinary Biologics Program. Although the policy statement indicated that it would be applicable to biotechnology and the Veterinary Biologics Program, the APHIS policy is applicable to confidential business information received under any program within the agency.

The policy statement defined confidential business information (CBI) as information that would be protected from disclosure under section (b)(4) of the Freedom of Information Act (5 U.S.C. 552(b)(4). This includes trade secrets and commercial or financial information found to be confidential. The policy statement indicated that documents containing trade secrets and which the person submitting asserts are trade secrets will be deemed CBI. It was further indicated that documents containing commercial or financial information will be deemed confidential if review establishes that substantial competitive harm would result from disclosure. Persons desiring protection for confidential information must submit a detailed statement containing facts to show that the person faces active competition in the area to which the information relates, and that substantial competitive harm would result from disclosure.

In addition to the procedures described in its policy statement, APHIS shall follow the procedures described in Subpart A "Official Records" of Part 1 of Title 7 of the Code of Federal Regulations which set forth USDA's regulations for the disclosure of records under the Freedom of Information Act. (See 7 CFR 1.1–1.16).

Environmental Impacts

USDA's regulations implementing the National Environmental Policy Act (NEPA) are found in 7 CFR Part 1b and the APHIS Guidelines Concerning Implementation of NEPA Procedures were published in the**Federal Register** on August 28, 1979, and August 31, 1979, (See 44 FR 50381–50384 and 44 FR 51272–51274).

The issuance of all permits for the introduction of a genetically engineered organism would be in accordance with NEPA, the USDA regulations, and APHIS guidelines.

Emergency Authorities

USDA has emergency powers to prevent the introduction and dissemination of a genetically engineered organism which is a plant pest, pursuant to section 105 of the FPPA (7 U.S.C. 150dd), pending the issuance of regulations.

If to prevent an imminent hazard it becomes apparent that it is necessary for the proposed regulations to become effective immediately, USDA will utilize the provisions of 5 U.S.C. 553 which provide for the issuance of an interim rule, which would be effective upon publication, followed by a 60-day comment period.

Executive Order 12291 and Regulatory Flexibility Act

The proposed rule is issued in conformance with Executive Order 12291 and has been determined to be not a "major rule." Based on information compiled by the Department, it has been determined that this proposed rule would not have a significant effect on the economy; would not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and would not have a significant adverse

effect on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

As explained above, the regulations regulate the introduction (importation, interstate movement, and release into the environment) of organisms and products altered or produced through genetic engineering which are plant pests or which there is reason to believe are plant pests. Such organisms and products are deemed regulated articles for which a permit would have to be obtained prior to its introduction.

It is anticipated that the cost of preparing a permit application will cost no more than $5,000 per application. The required information about the organism, and the way it was altered or produced should be available from documents pertaining to the research and development of the regulated article. Thus, a person seeking to obtain a permit should not have to generate any new data, but rather submit to USDA, what should be, existing data. The $5,000 estimated cost is based on the salaries of a Ph.D. researcher and the necessary clerical staff working for approximately 2 weeks in preparing an application for a permit. During the first year, the Department does not expect to receive more than 50 applications. Most other costs associated with complying with the regulations, e.g., container requirements, are merely incidental to a person complying with sound laboratory and research practices. The only other costs associated with complying with the regulations would arise if a supplemental report were required if a regulated article dies, an accidental or unauthorized release of a regulated article, the regulated article is found to have substantially different charcteristics than those listed in the application, or the Deputy Administrator otherwise believes monitoring reports are required. It is anticipated that the cost of such reports in most instances would be minimal.

USDA is requiring that an application for a permit be submitted 180 days prior to the time a person seeks to introduce a regulated article. USDA believes that the 180 day time period required to process a permit application will not be an unreasonable delay in the marketing of organisms or products subject to regulations under Part 340. It is anticipated that if USDA receives only 50 applications, the average time to process any application will be considerably less than 180 days.

Since the timing of when to submit an application to USDA is left to an applicant, USDA believes that both large and small business entities will be able to incorporate the 180 day review period into their corporate planning process so as not to disrupt the marketing of organisms or products that are subject to regulation.

Under the circumstances referred to above, the Administrator of the Animal and Plant Health Inspection Service has determined that this action would not have a significant economic impact on a substantial number of small entities.

Paperwork Reduction Act

In accordance with section 3507 of the Paperwork Reduction Act of 1980 (44 U.S.C. 3507), the information collection provisions that are included in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB). Written comments concerning any information collection provisions should be submitted to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for APHIS, Washington, DC 20503. A duplicate copy of such documents should be submitted to Dr. James W. Glosser, Associate Administrator, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Room 313-E, Administration Building, 14th and Independence Avenue, SW., Washington, DC 20250.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to the provisions of Executive Order 12372 which requires intergovernmental consultation with State and local officials. (See 7 CFR Part 3015, Subpart V)

List of Subjects in 7 CFR Part 340

Agricultural Commodities, Plant diseases, Plant pests, Plants (agriculture), Quarantine, Transportation, Biotechnology, Genetic engineering.

PART 330—FEDERAL PLANT PEST REGULATIONS; GENERAL; PLANT PESTS; SOIL, STONE AND QUARRY PRODUCTS; GARBAGE

Accordingly, it is proposed to amend Title 7 of the Code of Federal Regulations as follows:

1. The authority citation for 7 CFR Part 330 would be revised to read as follows:

Authority: 7 U.S.C. 147a, 150bb, 150dd–150ff, 161, 162, 450, 2260; 19 U.S.C. 1306; 21 U.S.C. 111, 114a; 31 U.S.C. 9701; 42 U.S.C. 4331, 4332; 44 U.S.C. 3507; 7 CFR 2.17, 2.51, and 371.2(c).

2. The definition of "Plant Pest" in § 330.100(h) would be removed and the following new paragraphs (h)(1) and (h)(2) would be added to read as follows:

§ 330.100 [Amended]

* * * * *

(h)(1) *Plant pest.* Except for §§ 330.200–330.212, "Plant Pest" means any living stage of any insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi, other parasitic plants or reproductive parts thereof, viruses, or any organisms similar to or allied with any of the foregoing, or any infectious substances which can directly or indirectly injure or cause disease or damage in any plants or parts thereof, or any processed, manufactured, or other products of plants.

(2) *Plant pest.* For purposes of §§ 330.200–330.212, "Plant Pest" means any living stage of insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi, other parasitic plants or reproductive parts thereof, viruses, or any organisms similar to or allied with any of the foregoing, or any infectious substances which are not genetically engineered as defined in 7 CFR 340.1 which can directly or indirectly injure or cause disease or damage in any plants or parts thereof, or any processed, manufactured, or other products of plants.

3. Part 340 "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests" would be added to read as follows:

PART 340—INTRODUCTION OF ORGANISMS AND PRODUCTS ALTERED OR PRODUCED THROUGH GENETIC ENGINEERING WHICH ARE PLANT PESTS OR WHICH THERE IS REASON TO BELIEVE ARE PLANT PESTS [1]

Sec.

340.0 Restrictions on the introduction of regulated articles.
340.1 Definitions.
340.2 Groups of organisms which are or contain plant pests.
340.3 Permits.
340.4 Certificate of exemption.
340.5 Marking and identity.
340.6 Container requirements for the movement of regulated articles.
340.7 Cost and charges.

[1] Part 340 regulates the introduction of organisms altered or produced through genetic engineering and their products which are plant pests or which there is reason to believe are plant pests. The introductioninto the United States of such articles may be subject to other regulations promulgated under the Federal Plant Pest Act (7 U.S.C. 150aa *et seq.*), the Plant Quarantine Act (7 U.S.C. 151 *et seq.*), and the Federal Noxious Weed Act (7 U.S.C. 2801 *et seq.*) and found in 7 CFR Parts 319, 321, 330, and 360.

Authority: 7 U.S.C. 150aa–150jj, 151–167, 1622n; 31 U.S.C. 9701; 7 CFR 2.17, 2.51, and 371.2(c).

§ 340.0 Restrictions on the introduction of regulated articles.

(a) No person shall introduce any regulated article unless—

(1) Such introduction is authorized by a permit; and

(2) Such introductionis in conformity with all of the other applicable restrictions in this part.

(b) Any regulated article introduced not in compliance with the requirements of this part shall be subject to the immediate application of such remedial measures or safeguards against escape of plant pests as the inspector determines necessary to prevent the introduction of such plant pests.[2]

§ 340.1 Definitions.

Terms used in the singular form in this part shall be construed as the plural, and vice versa, as the case may demand. The following terms, when used in this part, shall be construed, respectively, to mean:

Certificate of exemption. A written certificate issued by the Deputy Administrator in accordance with § 340.4 of this part.

Classical genetics. Genetic manipulation of organisms by procedures which occur in nature or in conventional breeding, including but not restricted to such methods as natural or hand pollination and natural or artificial insemination and undirected mutagenesis.

Deputy Administrator. The Deputy Administrator for Plant Protection and Quarantine, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, or any other officer or employee of the Department to whom authority to act in his/her stead has been or may hereafter be delegated.

Donor organism. The organism from which genetic material is obtained for transfer to the recipient organism.

Environment. All the land, air, and water; and all living organisms in association with land, air and water.

Genetic engineering. Genetic manipulation of organisms by procedures other than those used in classical genetics, including, but not limited to, protoplast, cell, and embryo fusion; and recombinant DNA engineering; and directed mutagenesis.

Genetic manipulation. The process of causing hereditary variation in an organism through the introduction of change in its DNA or RNA structure or function.

Inspector. Any employee of Plant Protection and Quarantine, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, or other person, authorized by the Deputy Administrator in accordance with law to enforce the provisions of this part.

Interstate. From any State into or through any other State.

Introduce or introduction. To move into or through the United States, to release into the environment, to move interstate, or any attempt thereat.

Move (moving, movement). To ship, offer for shipment, offer for entry, import, receive for transportation, carry, or otherwise transport or move, or allow to be moved into, through, or within the United States.

Mutagen. Agents such as colchicine, radioactive elements, lasers, and ultraviolet light that cause mutations without the exchange of genetic material between organisms.

Organism. Any active, infective, or dormant stage or life form of an entity characterized as living, including vertebrate and invertebrate animals, plants, bacteria, fungi, mycoplasmas, mycoplasma-like organisms, as well as entities such as viroids, viruses, and prions, or any entity related to the foregoing; and any part, copy, or analog thereof, including DNA and RNA, which is infectious.

Pathogen. A virus or microorganism (including its viruses and plasmids, if any) that has the ability to cause disease in other living organisms. Excluded are those microorganisms for which it can be documented that the microorganisms come from nonpathogenic species (e.g., *Bacillus subtilis, Lactobacillus acidophilus,* and *Saccharomyces* species) or come from a nonpathogenic strain of a pathogenic species (e.g., *Escherichia coli,* K–12).

Permit. A written permit issued by the Deputy Administrator for the introduction of a regulated article under conditions determined by the Deputy Administrator not to present a risk of plant pest introduction.

Person. Any individual, partnership, corporation, company, society, association, or other organized group.

Plant. Any living stage or form of any organism of the plant kingdom including, but not limited to, bacteria, prokaryotic algae, eukaryotic algae, fungi, mosses, club mosses, ferns, horsetails, liverworts, angiosperms, gymnosperms, and lichens (which contain algae) including any parts (e.g. pollen, seeds, cells, tubers, stems) thereof, and any cellular components (e.g. plasmids, ribosomes, etc.) thereof.

Plant pest. Any living stage (including active and dormant forms) of insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi, other parasitic plants or reproductive parts thereof; viruses; or any organisms similar to or allied with any of the foregoing; or any infectious agents or substances, which can directly or indirectly injure or cause disease or damage in or to any plants or parts thereof, or any processed, manufactured, or other products or plants.

Plant Protection and Quarantine. The organizational unit within the Animal and Plant Health Inspection Service, U.S. Department of Agriculture, delegated responsibility for enforcing provisions of the Plant Quarantine Act, the Federal Plant Pest Act, and related legislation, and quarantine and regulations promulgated thereunder.

Product. Anything made by or from, or derived from an organism, living or dead.

Recipient organism. The organism which receives genetic material from a donor organism.

Regulated article. Any organism or product which has been altered or produced through genetic engineering, if the donor organism, recipient organism, or vector or vector agent belongs to a group designated in § 340.2 of this part, or any organism or product altered or produced through genetic engineering which the Deputy Administrator determines is a plant pest or has reason to believe is a plant pest. Excluded are microorganisms that are non-pathogenic, non-infectious, and otherwise not plant pests, that have resulted from the addition of genetic material that is well characterized and contains only non-coding regulatory regions (i.e. operators, promoters, origins of replication, terminators, and ribosome binding regions).

Release into environment. The use of a regulated article outside the constraints of physical confinement that are found in a laboratory, contained greenhouse, or a fermenter or other contained structure.

[2] Pursuant to section 105 of the Federal Plant Pest Act (7 U.S.C. 150dd) the Secretary of Agriculture is authorized to order prompt removal from the United States or to seize, quarantine, treat, apply other remedial measures to, destroy, or otherwise dispose of, in such manner as the Secretary deems appropriate, certain regulated articles which are believed to be infested or infected by or contains a plant pest.

Responsible person. The person who has control and will maintain control over the introduction of the regulated article and assure that all conditions contained in the permit and requirements in this part are complied with. A responsible person shall be a resident of the United States or designate an agent who is a resident of the United States.

Secretary. The Secretary of Agriculture, or any other officer or employee of the Department of Agriculture to whom authority to act in his/her stead has been or may hereafter be delegated.

State. Any State, District of Columbia, American Samoa, Guam, Northern Mariana Islands, Puerto Rico, the Virgin Islands of the United States, and any other Territories or Districts of the United States.

United States. All of the States.

Vector or vector agent. Organisms or objects used to transfer genetic material from the donor organism to the recipient organism.

Well-characterized and contains only non-coding regulatory regions (i.e. operators, promoters, origins of replication, terminators, and ribosome binding regions). The genetic material added to a microorganism in which the following can be documented about such genetic material:

(a) The exact nucleotide base sequence of the regulatory region and any inserted flanking nucleotides;

(b) The regulatory region and any inserted flanking nucleotides do not code for protein or peptide; and

(c) The regulatory region solely controls the activity of other sequences that code for protein or peptide molecules or act as recognition sites for the initiation of nucleic acid or protein synthesis.

§ 340.2 Groups of organisms which are or contain plant pests.

The organisms that are or contain plant pests are included in taxa or groups in the classification scheme below. Within each taxon or group all organisms are considered to be plant pests unless there are included taxa or groups of lower rank specifically listed, in which instance only those taxa or groups of lower rank specifically listed are considered to be plant pests or contain plant pests.

Note.—Any genetically engineered organism composed of DNA or RNA sequences, organelles, plasmids, parts, copies, and/or analogs, of or from any of the groups of organisms listed below shall be deemed a regulated article.

Group and Common Name

Viroids
Prions

Superkingdom Prokaryotae

Kingdom Virus

All members of groups containing plant viruses, and all other plant and insect viruses.

Kingdom Monera

Division Bacteria

Bacteria that are pathogenic to insects:
Family Pseudomonadaceae
  Genus Pseudomonas—pseudomonads
  Genus Xanthomonas—xanthomonads
Family Rhizobiaceae
  Genus Rhizobium—rhizobia
  Genus Bradyrhizodium—bradyrhizobia
  Genus Agrobacterium—crown gall
  Genus Phyllobacterium
Family Enterobacteriaceae
  Genus Erwinia—soft rot bacteria
Family Streptomycetaceae
  Genus Streptomyces
Family Actinomycetacease
  Genus Actinomyces
Coryneform group
  Genus Clavibacter
  Genus Arthrobacter
  Genus Curtobacterium
  Genus Corynebacteria—plant pathogenic corynebacteria
Rickettsiaceae
  Rickettsial-like organisms associated with plant diseases
  Rickettsial-like organisms associated with insect diseases
Class Mollicutes
  Order Mycoplasmatales
    Family Spiroplasmataceae
    Genus Spiroplasma
  Mycoplasma-like organisms associated with plant diseases
  Mycoplasma-like organisms associated with insect diseases

Superkingdom Eukaryotae

Kingdom Plantae

Subkingdom Thallobionta

Division Cholorophyta—green algae
    Genus Cephaleuros—parasitic algae
    Genus Rhodochytrium—parasitic algae
    Genus Phyllosiphon—parasitic algae
Division Myxomycota
  Class Plasmodiophoromycetes—plasmodiophorids
Division Eumycota—true fungi
  Fungi associated with diseases of insects
  Class Chytridiomycetes
  Order Chytridiales
  Class Oomycetes
  Order Lagenidiales
    Family Lagenidiaceae
    Family Olpidiopsidaceae
  Order Peronosporales
    Family Albuginaceae
    Family Peronosporaceae
    Family Pythiaceae
  Order Saprolegniales
    Family Saprolegniaceae
    Family Leptolegniellaceae
  Class Zygomycetes
  Order Mucorales
    Family Choanephoraceae
    Family Mucoraceae
    Family Entomophthoraceae
Class Hemiascomycetes
    Family Protomycetaceae
    Family Taphrinaceae
Class Loculoascomycetes
  Order Myriangiales
    Family Elsinoeaceae
    Family Myriangiaceae
  Order Asterinales
  Order Dothideales
  Order Chaetothyriales
  Order Hysteriales
    Family Parmulariaceae
    Family Phillipsiellaceae
    Family Hysteriaceae
  Order Pleosporales
  Order Melanommatales
Class Plectomycetes
  Order Eurotiales
    Family Ophiostomataceae
  Order Ascophaerales
Class Pyrenomycetes
  Order Erysiphales
  Order Meliolales
  Order Xylariales
  Order Diaporthales
  Order Hypocreales
  Order Clavicipitales
Class Discomycetes
  Order Phacidiales
  Order Helotiales
    Family Ascocorticiaceae
    Family Hemiphacidiaceae
    Family Dermataceae
    Family Sclerotiniaceae
  Order Cytarriales
  Order Medeolariales
  Order Pezizales
    Family Sarcosomataceae
    Family Sarcoscyphaceae
Class Teliomycetes
Class Phragmobasidiomycetes
    Family Auriculariaceae
    Family Ceratobasidiaceae
Class Hymenomycetes
  Order Exobasidiales
  Order Agaricales
    Family Corticiaceae
    Family Hymenochaetaceae
    Family Echinodontiaceae
    Family Fistulinaceae
    Family Clavariaceae
    Family Polyporaceae
    Family Tricholomataceae
Class Hyphomycetes
Class Coelomycetes

Subkingdom Embryobionta

Note: *Organisms listed in the Code of Federal Regulations as noxious weeds are regulated under the Federal Noxious Weeds Act.*

Division Magnoliophyta—angiosperms
    Family Balanophoraceae—parasitic species
    Family Cuscutaceae—parasitic species
    Family Hydnoraceae—parasitic species
    Family Krameriaceae—parasitic species
    Family Lauraceae—parasitic species
    Genus Cassytha
    Family Lennoaceae—parasitic species
    Family Loranthaceae—parasitic species
    Family Myzodendraceae—parasitic species
    Family Olacaceae—parasitic species
    Family Orobanchaceae—parasitic species
    Family Rafflesiaceae—parasitic species
    Family Santalaceae—parasitic species
    Family Scrophulariaceae—parasitic species
    Genus Alectra
    Genus Bartsia

Genus Buchnera
Genus Buttonia
Genus Castilleja
Genus Centranthera
Genus Cordylanthus
Genus Dasistoma
Genus Euphrasia
Genus Gerardia
Genus Harveya
Genus Hyobanche
Genus Lathraea
Genus Melampyrum
Genus Melasma
Genus Orthantha
Genus Orthocarpus
Genus Pedicularis
Genus Rhamphicarpa
Genus Rhinanthus
Genus Schwalbea
Genus Seymeria
Genus Siphonostegia
Genus Sopubia
Genus Striga
Genus Tozzia
Family Viscaceae—parasitic species

Kingdom Animalia

Subkingdom Protozoa

Protozoa associated with insect diseases
Genus Phytomonas—protozoa

Subkingdom Eumetazoa

Phylum Nemata
Nematodes that are predaceous on insects or are associated with insect diseases
Class Secernentea
Order Tylenchida
Family Anguinidae
Family Belonolaimidae
Family Caloosiidae
Family Criconematidae
Family Dolichodoridae
Family Fergusobiidae
Family Hemicycliophoridae
Family Heteroderidae
Family Hoplolaimidae
Family Meloidogynidae
Family Nacobbidae
Family Neotylenchidae
Family Nothotylenchidae
Family Paratylenchidae
Family Pratylenchidae
Family Tylenchidae
Family Tylenchulidae
Order Aphelenchida
Family Adhelenchoididae
Class Adenophorea
Order Dorylaimida
Family Longidoridae
Family Trichodoridae
Phylum Mollusca
Class Gastropoda—snails and slugs
Subclass Pulmonata
Order Basommatophora
Superfamily Planorbacea
Order Stylommatophora
Subfamily Strophocheilacea
Family Succineidae
Superfamily Achatinacae
Superfamily Arionacae
Superfamily Limacacea
Superfamily Helicacea
Order Systellommatophora
Superfamily Veronicellacea
Phylum Arthropoda
Class Arachnida
Order Parasitiformes
Suborder Mesostigmata
Superfamily Ascoidea
Superfamily Dermanyssoidea
Order Acariformes
Suborder Prostigmata
Superfamily Eriophyoidea—gall mites
Superfamily Tetranychoidea
Superfamily Eupodoidea
Superfamily Tydeoidea
Superfamily Erythraenoidea
Superfamily Trombidioidea
Superfamily Hydryphantoidea
Superfamily Tarsonemoidea
Superfamily Pyemotoidea
Suborder Astigmata
Superfamily Hemisarcoptoidea
Superfamily Acaroidea
Class Diplopoda
Order Polydesmida—millipedes
Class Insecta
Order Collembola
Family Sminthoridae—springtails
Order Isoptera—termites
Order Thysanoptera—thrips
Order Orthoptera
Family Acrididae—short-horned grasshoppers
Family Gryllidae—crickets
Family Gryllacrididae—leaf-rolling crickets
Family Gryllotalpidae—mole crickets
Family Phasmatidae—walking sticks
Family Ronaleidae
Family Tettigoniidae—longhorned grasshoppers
Family Tetrigidae—tetrigoids
Order Hemiptera
Family Thaumastocoridae
Family Aradidae
Superfamily Piesmatoidea
Superfamily Lygaeoidea
Superfamily Idiostoloidea
Superfamily Coreoidea
Superfamily Pentatomoidea
Superfamily Pyrrhocoroidea
Superfamily Tingoidea
Superfamily Miroidea
Order Homoptera
Order Coleoptera
Family Anobiidae—anoibiids
Family Apionidae—apionids
Family Anthribidae—seed weevils
Family Bostrichidae—twig borers
Family Brentidae—straight-snouted beetles
Family Bruchidae—seed beetles
Family Buprestidae—flatheaded wood borers
Family Byturidae—fruitworm beetles
Family Cantharidae—soldier beetles
Family Carabidae—ground beetles
Family Cerambycidae—long-horned beetles
Family Chrysomelidae—leaf and flea beetles
Family Coccinellidae—ladybird beetles
Subfamily Epilachninae
Family Curculionidae—weevils
Family Dermestidae—skin & carpet beetles
Family Elateridae—click beetles
Family Hydrophilidae
Genus Helophorus
Family Lyctidae—powder-post beetles
Family Meloidae—blister beetles
Family Mordellidae—tumbling flower beetles
Family Platypodidae—pin-hole borers
Family Scarabaeidae
Subfamily Melolonthinae—June beetles
Subfamily Rutelinae—chafers
Subfamily Cetoniinae—flower beetles
Subfamily Dynastinae—rhinoceros beetles
Family Scolytidae—bark beetles
Family Seblytidae—bark beetles
Family Tenebrionidae—darkling beetles
Order Lepidoptera
Order Diptera
Family Agromyzidae—leafminers
Family Anthomyiidae—rootmaggot flies
Family Cecidomyiidae—gall midges, gnats
Family Chloropidae—chloropod flies
Family Ephydridae—shore flies
Family Lonchaeidae—lonchaeid flies
Family Muscidae—muscid flies
Genus Atherigona
Family Otitidae—picture-winged flies
Genus Euxeta
Family Syrphidae—flower flies
Family Tephritidae—fruit flies
Family Tipulidae—crane flies
Order Hymenoptera
Family Apidae—bees
Family Cephidae—stem sawflies
Family Chalcidae—chalcids
Family Cynipidae—gall wasps
Family Eurytomidae—seed chalcids
Family Formicidae—ants
Family Psilidae—rust flies
Family Siricidae—horntails
Family Tenthredinidae—sawflies
Family Torymidae—tormids
Family Xylocopidae—carpenter bees

Unclassified organisms and/or organisms whose classification is unknown.

§ 340.3 Permits.

(a) *Application for permit.* A written application for a permit to introduce a regulated article shall be submitted by

the responsible person on an application form obtained from Plant Protection and Quarantine, to the Biological Assessment Support Staff, Plant Protection and Quarantine, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Federal Building, 6505 Belcrest Road, Hyattsville, Maryland 20782. The application shall be submitted at least 180 days in advance of the proposed introduction and shall include the following information:[3]

(1) Name, title, address, telephone number, signature of the responsible person and type of permit requested (for importation, interstate movement, or release into the environment);

(2) All scientific, common, and trade names, and all designations necessary to identify the: donor organism; recipient organism; vector or vector agent; constituent of each regulated article which is a product; and, regulated article;

(3) Names, addresses, and telephone numbers of the persons who developed and/or supplied the regulated article;

(4) A description of the means of movement, e.g., mail, freight, baggage, or handcarried (and by whom);

(5) A description of the anticipated or actual expression of the altered genetic material in the regulated article and how that expression differs from the expression in the non-modified parental organism (e.g., morphological or structural characteristics, physiological activities and processes, number of copies of inserted genetic material and the physical state of this material inside the recipient organism (integrated or extrachromosomal), products and secretions, growth characteristics);

(6) A detailed description of the molecular biology of the system (e.g., donor-recipient-vector) which is or will be used to produce the regulated article;

(7) Country and locality where the donor organism, recipient organism, vector or vector agent, and regulated article were collected, developed, and produced;

(8) A detailed description of the purpose for the introduction of the regulated article including a detailed description of the proposed experimental and/or production design;

(9) The quantity of the regulated article to be introduced and proposed schedule and number of introductions;

(10) A detailed description of the processes, procedures, and safeguards which have been used or will be used in the country of origin and in the United States to prevent contamination, release, and dissemination in the production of the: donor organism; recipient organism; vector or vector agent; constituent of each regulated article which is a product; and, regulated article;

(11) A detailed description of the intended destination (including final and all intermediate destinations), uses, and/or distribution of the regulated article (e.g., greenhouses, laboratory, or growth chamber location; field trail location; pilot project location; production, propogation, and manufacture location; proposed sale and distribution location);

(12) A detailed description of the proposed procedures, processes, and safeguards which will be used to prevent escape and dissemination of the regulated article at each of the intended destinations;

(13) A detailed description of any biological material (e.g., culture medium, or host material) accompanying the regulated article during movement; and

(14) A detailed description of the proposed method of final disposition of the regulated article.

(b) *Administrative action on applications.* After receipt and review by Plant Protection and Quarantine of the application and the data submitted pursuant to paragraph (a) of this section, including any additional information requested by Plant Protection and Quarantine, a permit shall be granted or denied. If a permit is denied, the applicant shall be promptly informed of the reasons why the permit was denied. If a permit is granted, the permit will specify the applicable conditions for introduction of the regulated article under this part.

(c) *Permit conditions.* A person who is issued a permit and his/her agents shall comply with the following conditions, and any supplemental conditions which shall be listed on the permit, as deemed by the Deputy Administrator to be necessary to prevent the introduction of plant pests:

(1) The regulated article shall be maintained and disposed of (when necessary) in a manner determined necessary by the Deputy Administrator;

(2) All packing material, shipping containers, and any other material accompanying the regulated article shall be treated or disposed of as determined necessary by the Deputy Administrator;

(3) The regulated article shall be kept separate from other organisms, except as specifically allowed in the permit;

(4) The regulated article shall be maintained only in areas and premises specified in the permit;

(5) An inspector shall be allowed access, during regular business hours, to the place where the regulated article is maintained;

(6) The regulated article shall, when possible, be kept identified with a label showing the name of the regulated article, and when applicable, the port accession number and date of importation;

(7) The regulated article shall be subject to the application of measures determined by the Deputy Administrator to be necessary to prevent the accidential or authorized release of the regulated article;

(8) The regulated article shall be subject to the application of remedial measures (including disposal) determined by the Deputy Administrator to be necessary to prevent the spread of plant pests;

(9) A person who has been issued a permit shall submit to Plant Protection and Quarantine monitoring reports on the performance characteristics of the regulated article, as deemed necessary by the Deputy Administrator;

(10) Plant Protection and Quarantine shall be orally notified immediately, and in writing, within the time periods specified below, in the event of the following occurrences:

(i) Within 24 hours in the event of any accidental or unauthorized release of the regulated article;

(ii) Within 5 working days if the regulated article is found to have characteristics substantially different from those listed in the application for a permit; and

(iii) Within 5 working days if the regulated article dies.

(11) A permittee or his/her agent who seeks to import a regulated article into the United States shall:

(i) Import or offer the regulated article for entry only at a port of entry which is designated by an asterisk in 7 CFR 319.37–14(b);

(ii) Notify Plant Protection and Quarantine promptly upon arrival of any regulated article at a port of entry, of its arrival by such means as a manifest, customs entry document, commercial invoice, waybill, a broker's document, or a notice form provided for such purpose; and

(iii) Mark and identify the regulated article in accordance with § 340.5 of this part.

[3] Application forms are available without charge from the Biological Assessment Support Staff, Plant Protection and Quarantine, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Federal Building, 6505 Belcrest Road, Hyattsville, Maryland 20782, or from local offices which are listed in telephone directories. A person should specify in requesting the application that the permit is for the introduction of a regulated article subject to regulation under Part 340.

(d) *Withdrawal of a permit.* Any permit which has been issued may be withdrawn by an inspector or the Deputy Administrator if he/she determines that the holder thereof has not complied with one or more of the conditions listed on the permit. The reasons for the withdrawal shall be confirmed in writing as promptly as circumstances allow. Any person whose permit has been withdrawn may appeal the decision in writing to the Deputy Administrator within ten (10) days after receiving the written notification of the withdrawal. The appeal shall state all of the facts and reasons upon which the person relies to show that the permit was wrongfully withdrawn. The Deputy Administrator shall grant or deny the appeal, in writing, stating the reasons for the decision as promptly as circumstances allow. If there is a conflict as to any material fact, a hearing shall be held to resolve such conflict. Rules of practice concerning such a hearing will be adopted by the Administrator.

§ 340.4 Certificate of exemption.

(a) *Issuance.* The Deputy Administrator may issue a certificate of exemption for the introduction of organisms modified through biotechnology which are not subject to regulation under this part to facilitate movement when the movement might otherwise be impeded because of the similarity of the organism to other organisms regulated under this part.

(b) *Application.* A person seeking a certificate of exemption shall submit on an application form obtained from Plant Protection and Quarantine data required by § 340.3(a) (1), (2), and (5) of this part and shall indicate such data is being submitted as a request for a certificate of exemption. A person should also include a statement explaining why he or she believes the organism or product is not a plant pest.

§ 340.5 Marking and identity.

(a) Any regulated article to be imported other than by mail, shall, at the time of importation into the United States, plainly and correctly bear on the outer container the following information:

(1) General nature and quantity of the contents;

(2) Country and locality where collected, developed, manufactured, reared, cultivated or cultured;

(3) Name and address of shipper, owner, or person shipping or forwarding the organism;

(4) Name, address, and telephone number of consignee;

(5) Identifying shipper's mark and number; and

(6) Number of written permit authorizing the importation.

(b) Any regulated article imported by mail, shall be plainly and correctly addressed and mailed to Plant Protection and Quarantine at a port of entry designated by an asterisk in 7 CFR 319.37–14(b) and shall be accompanied by a separate sheet of paper within the package plainly and correctly bearing the name, address, and telephone number of the intended recipient, and shall plainly and correctly bear on the outer container the following information:

(1) General nature and quantity of the contents;

(2) Country and locality where collected, developed, manufactured, reared, cultivated, or cultured;

(3) Name and address of shipper, owner, or person shipping or forwarding the regulated article; and

(4) Number of permit authorizing the importation.

(c) Any regulated article imported into the United States by mail or otherwise, shall at the time of importation or offer for importation into the United States, be accompanied by an invoice or packing list indicating the contents of the shipment.

§ 340.6 Container requirements for the movement of regulated articles.[4]

(a) *General requirements.* A regulated article shall not be moved unless it complies with the provisions of paragraph (b) of this section.

(b) *Container requirements.*—(1) *Plants and plant parts.* All plants or plant parts, except seeds, cells, and subcellular elements shall be packed in a sealed plastic bag of at least 5 mil thickness, inside a sturdy, sealed, leak-proof, outer shipping container constructed of corrugated fiberboard, corrugated cardboard, wood, or other material of equivalent strength.

(2) *Seeds.* All seeds shall be transported in a sealed plastic bag of at least 5 mil thickness, inside a sealed metal container, which shall be placed inside a second sealed metal container. Shock absorbing cushioning material shall be placed between the inner and outer metal containers. Each metal container shall be independently capable of protecting the seeds and preventing spillage or escape. Each set of metal containers shall then be enclosed in a sturdy outer shipping container constructed of corrugated fiberboard, corrugated cardboard, wood, or other material of equivalent strength.

(3) *Live microorganisms and/or etiologic agents, cells, or subcellular elements.* All regulated articles which are live (non-inactivated) microorganisms, or etiologic agents, cells, or subcellular elements shall be packed as specified below:

(i) *Volume not exceeding 50 ml.* Regulated articles not exceeding 50 ml. shall be placed in a securely closed, watertight container (primary container (test tube, vial, etc.)) which shall be enclosed in a second, durable watertight container (secondary container). Several primary containers may be enclosed in a single secondary container, if the total volume of all the primary containers so enclosed does not exceed 50 ml. The space at the top, bottom, and sides between the primary and secondary containers shall contain sufficient nonparticulate absorbent material (e.g., paper towel) to absorb the entire contents of the primary container(s) in case of breakage of leakage. Each set of primary and secondary containers shall then be enclosed in an outer shipping container constructed of corrugated fiberboard, corrugated cardboard, wood, or other material of equivalent strength.

(ii) *Volume greater than 50 ml.* Regulated articles which exceed a volume of 50 ml. shall comply with requirements specified in paragraph (b)(3)(i) of this section. In addition, a shock absorbing material, in volume at least equal to that of the absorbent material between the primary and secondary containers, shall be placed at the top, bottom, and sides between the secondary container and the outer shipping container. Single primary containers shall not contain more than 1,000 ml. of material. However, two or more primary containers whose combined volumes do not exceed 1,000 ml. may be placed in a single, secondary container. The maximum amount of microorganisms or etiologic agents, cells, or subcellular elements which may be enclosed within a single outer shipping container shall not exceed 4,000 ml.

(iii) *Dry ice.* If dry ice is used as a refrigerant, it shall be placed outside the secondary container(s). If dry ice is used between the secondary container and the outer shipping container, the shock absorbing material shall be placed so that the secondary container does not become loose inside the outer shipping container as the dry ice sublimates.

[4] The requirements of this section are in addition to and not in lieu of any other packing requirements such as those for the transportation of etiologic agents prescribed by the Department of Transportation in Title 49 of the Code of Federal Regulations or any other agency of the Federal government.

(4) *Insects, mites, and related organisms.* Insects, mites, and other small arthropods shall be packed for shipment as specified in this section or in paragraph (b)(3) of this section. Insects (any life stage) shall be placed in an escape-proof primary shipping container (insulated vacuum container, glass, metal, plastic, etc.) and sealed to prevent escape. Such primary container shall be placed securely within a secondary shipping container of crushproof styrofoam or other material of equivalent strength; one or more rigid ice packs may also be placed within the secondary shipping container; and sufficient packing material shall be added around the primary container to prevent movement of the primary shipping container. The secondary (styrofoam or other) container shall be placed securely within an outer shipping container constructed of corrugated fiberboard, corrugated cardboard, wood, or other material of equivalent strength.

(5) *Other macroscopic organisms.* Other macroscopic organisms not covered in paragraphs (b) (1), (2), and (4) of this section which do not require continuous access to atmospheric oxygen shall be packaged as specified in paragraphs (b) (3) or (4) of this section. All macroscopic organisms which are not plants and which require continuous access to atmospheric oxygen shall be placed in primary shipping containers constructed of a sturdy, crush-proof frame of wood, metal, or equivalent strength material, surrounded by escape-proof mesh or netting of a strength and mesh size sufficient to prevent the escape of the smallest organism in the shipment, with edges and seams of the mesh or netting sealed to prevent escape of organisms. Each primary shipping container shall be securely placed within a larger secondary shipping container constructed of wood, metal, or equivalent strength material. The primary and secondary shipping containers shall then be placed securely within an outer shipping container constructed of corrugated fiberboard, corrugated cardboard, wood, or other material of equivalent strength, which outer container may have air holes or spaces in the sides and/or ends of the container, provided that the outer shipping container must retain sufficient strength to prevent crushing of the primary and secondary shipping containers.

§ 340.7 Cost and charges.[5]

The services of the inspector during regularly assigned hours of duty and at the usual places of duty shall be furnished without cost.[5] The U.S. Department of Agriculture will not be responsible for any costs or charges incident to inspections or compliance with the provisions of this part, other than for the services of the inspector.

Done at Washington, DC, this 23rd day of May 1986.

Harvey L. Ford,

Deputy Administrator, Plant Protection and Quarantine, Animal and Plant Health Inspection Service.

[FR Doc. 86-14127 Filed 6-19-86; 4:56 pm]

BILLING CODE 3410-34-M

[5] The Department's provisions relating to overtime charges for an inspector's services are set forth in 7 CFR Part 354.

DEPARTMENT OF AGRICULTURE

Advanced Notice of Proposed USDA Guidelines for Biotechnology Research

AGENCY: Department of Agriculture.

ACTION: Notice for public comment.

SUMMARY: The purpose of this advanced notice is to provide opportunities for input and comments at this stage in the development of the USDA Guidelines for Biotechnology Research to assure as complete a document as possible at the time of publishing the proposed Guidelines. This advanced draft has several key areas that are not yet complete or fully defined, i.e., (1) definitions; (2) special environmental containments; (3) biological containments; (4) classification of organisms; and (5) animal guidelines—essential to restrict to guidelines, not a "field manual." The Guidelines are patterned after the NIH Guidelines for Research Involving Recombinant DNA Molecules and will be issued under the authority of the Food Security Act of 1985 (Pub. L. 99–198). All federally-funded agriculture biotechnology research will be subject to the USDA Guidelines for Biotechnology Research except if the specific research project is supported by and subject to the guidelines or regulations of another Federal agency. They encompass all phases of agricultural biotechnology research, i.e., (1) contained laboratory experiments; (2) specialized isolation research (e.g., greenhouse, biotron); and (3) environmental research release (e.g., controlled and segregated field plots). Voluntary compliance by industry and other nonfederally funded organizations will be encouraged in the manner followed successfully by NIH/RAC for the past decade.

DATE: Written comments concerning these proposed guidelines are invited from interested individuals and organizations. To be considered, all relevant material must be received on or before August 25, 1986.

FOR FURTHER INFORMATION CONTACT: Dr. John Patrick Jordan, Administrator, Cooperative State Research Service (CSRS), USDA, Room 304–A, Administration Building, 14th and Independence Avenue, SW., Washington, DC 20250, telephone (202) 447–4423.

ADDRESS: Written comments must be submitted to the above address. All comments received will be available for public inspection at said office on weekdays between the hours of 8:30 a.m. and 5:00 p.m.

Dated: May 16, 1986.

Approved:

John Patrick Jordan,

Administrator, Cooperative State Research Service.

Comparison of USDA Guidelines to NIH Guidelines

USDA guidelines section	NIH guideline section or provision
___.101 Purpose	I.A. Purpose.
___.102 Applicability	I.C. General Applicability.
___.103 Format	
___.104 Definitions	I.D. General Definitions.
Subpart ___.2 Classification of Research Projects & Organism.	III. Guidelines for Covered Appendices A, B, C.
___.201 General	III. Introduction.
___.202 Category 1—Exempt.	III-D. Exempt Experiments.
___.202-1 Exempt—General.	III-D-1, 2, 3, 4, 5.
___.202-2 Exempt—Exchangers.	III-D-4 and Appendix A.
___.202-3 Exempt—Specific Exemptions.	III-D-5 and Appendix B.
___.203 Category 2—IBC Notification.	III-C IBC Notice.
___.204 Category 3—IBC Approval and (a), (b) USDA Notification.	III-B IBC Approval Introduction.
(c) Modifying Pathogens	III-B-1 Pathogens as H-V Systems.
(1) Class 2, 3, 4 at BL 2, 3, 4, respectively.	(a) Class 2 at BL-2.
(2) Class 5—at BL specified by APHIS.	(b) Class 3 at BL-3.
(3) Plant Pathogens—BL1 unless spec. by APHIS.	(c) Class 4 at BL-4.
	(d) Class 5—case-by-case.
(d) Cloning Genes from Pathogens.	III-B-2 Cloning Pathogen Genes about the same.
(1) Class 2 or 3 at BL 2	
Class 3 or 4 at BL 2, if no pathogenic sequences.	
Can lower to BL 1 if well-characterized	
(e) Viruses in Tissue Culture or Organisms.	III-B-3 and III-B-4 Containment.
Containment—includes more details on plants and animals	
(f) Animal or Plant Transformation Systems.	III-B-4.
___.205 Category 4—IBC & USDA Approval Release of Organisms.	III-A Require NIH & IBC Approval release plus 3 other categories.
—specific for release	III-A-1 Toxins covered at .201(b) and .322. III-A-2 and III-A-4 not covered in agriculture.
(b) NEPA Requirements	
(c) Release of Nonmicroscopic Plants.	Appendix L and "Points to Consider for Plants."
(d) Release of Nonmicroscopic Animals.	
(e) Release of Microorganisms.	"Points to Consider for Release of Microorganisms."
___.206 Classification of Organisms.	Appendix B.
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(d) Classification of Plant Pathogens.	
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Subpart ____.1 General Information

____.101 Purpose.

The Purpose of these Guidelines is to specifiy required laboratory, agricultural and environmental practices for constructing, handling, and experimental testing of plants, animals, and selected microorganisms involved in agricultural biotechnology research.

____.102 Applicability.

(a) Except for the exemptions listed at ____.202, these Guildelines apply to (1) all biotechnolgy research within the United States or its territories which is supported in whole or in part by USDA funds, (2) all agricultural biotechnology research within the United States or its territories which is conducted, or sponsored by, an entity receiving funds or other assistance from USDA for research, and (3) all biotechnology research conducted outside of the United States or its territories if supported by USDA funds.

(b) For purposes of (a)(2), research shall be considered to be sponsored by an entity if the research is conducted on premises which are themselves under the operational control of the entity or if the research is otherwise supported by the entity.

(c) A specific biotechnology research project subject to these guidelines by reason of (a)(1) is exempt from the application of these guidelines if the specific research project is conducted by, supported by, and subject to the guidelines or regulations of another Federal agency.

(d) A specific biotechnology research project subject to these guidelines solely by reason of (a)(2) is exempt from the application of these guidelines if the specific research project is supported by *and* subject to the quidelines or regulations of another Federal agency.

(e) Biotechnology research subject to these guidelines under (a)(3) is exempt from the application of these Guidelines if the host country has established rules for the conduct of agricultural biotechnology projects and a certificate of compliance with the rules of the host country is submitted to USDA. USDA reserves the right to withhold funding if the safety practices to be employed aboard are not reasonably consistent with the USDA guidelines.

(f) Failure to comply with these guidelines may lead to the loss of USDA funds for conducting research.

(g) Any individual or other small entity, which lacks the capability of complying with any procedural requirement contained in these guidelines, should form an association with or be sponsored by an entity which can and does assume the responsibility of complying with that requirement. If such individual or small entity is unable to locate such an entity, they should contact the Office of Agriculture Biotechnology (OAB).

(h) The USDA strongly urges any entity involved in agricultural biotechnology research, which is not subject to these guidelines, to conduct that research in compliance with these guidelines. USDA will provide upon request the same review of research proposals for research projects not otherwise covered by these guidelines as that provided for research projects subject to these guidelines.

____.103 Format The Guidelines are arranged into four major components.

(a) In subpart ____.3 there is a description of the biosafety levels of physical containment applicable to research involving microorganisms (sections ____.302 to ____.306), the host-vector levels of biological containment (sections ____.307 to ____.309), the nonmicroscopic animal biosafety levels applicable to research involving nonmicroscopic animals (sections ____.311 to ____.317), containment practices for research involving nonmicroscopic plants (sections ____.318 to ____.320), containment practices required for large scale uses of organisms containing recombinant DNA molecules (section ____. 321), containment practices required for cloning of genes coding for the biosynthesis of molecules toxic for vertebrates (section ____.322), and containment practices required for shipping (section ____.323). Separate requirements for projects which plan a release into the enviroment are set forth at section ____.205.

(b) In subpart ____.2, there is a classification of microorganisms and a classification of research projects. Microorganisms are classified according to risk in section ____.206. Research projects are classified into four categories:

(1) Sections ____.202–1 to ____.202–3 lists the research projects that are exempt from the containment requirements of these Guidelines.

(2) Section ____.203 lists the laboratory research projects which require Institutional Biosafety Committee (IBC) notification and assigns an appropriate level of containment for each such research project.

(3) Section ____.204 lists the laboratory research projects which require IBC approval and USDA notification and assigns an appropriate level of containment for each such research project.

(4) Section ____.205 sets forth the containment practices required for all research involving planned release of an organism modified by biotechnology.

(c) In subpart ____.4, the Guidelines set forth the respective roles and responsibilities of the various participants in agricultural biotechnology research and procedural requirements for conducting biotechnology research.

(d) In subpart ____.5, the Guidelines urge voluntary compliance on the part of those who are not otherwise required to follow the Guidlines but who are conducting research in agricultural biotechnology. This subpart also addresses procedures adopted to ensure protection of proprietary information.

____.104 Definitions.

(a) Animal: Multicellular organism composed of eukaryotic cells with ingestive nutrition and lacking rigid cell walls and photosynthetic ability; members include coelenterates, flatworms, mollusks, segmented worms, arthropods, echinoderms, and vertebrates.

(b) Assistant Secretary for Science and Education: The Assistant Secretary for Science and Education or his delegatee.

(c) Bacteria: Any of a large group of microscopic or submiscroscopic, prokaryotic organisms having round, rodlike, spiral or filamentous, unicellular or noncellular bodies that are often aggregated into colonies, are enclosed by a cell wall or membrane, and lack fully differentiated nuclei. Bacteria may exist as free living organisms in soil, water, organic matter, or as parasites or pathogens in the live bodies of plants, animals and other microorganisms.

(d) Biotechnology research: The endeavor to discover, develop, or verify knowledge utilizing recombinant DNA (rDNA), recombinant RNA (rRNA), specific molecular gene vectors, cell fusion, or other non-classical genetic manipulation of organisms conducted at the cellular or molecular level. The term does not include classical genetic manipulation which occurs in nature or in conventional breeding such as hand pollination and artificial insemination. For purposes of these guidelines, the term is defined to include only agricultural biotechnology reserach. "Biotechnology research" and

"research," when used in these guidelines, possess the same meaning.

(e) Cell fusion: Formation of a single hybrid cell with nuclei, organelles and cytoplasm from different cells. Certain organisms may be produced as the result of multiplication and development of cells formed by cell fusion.

(f) Entity: Any individual, corporation, partnership, association, public or private institution, Federal agency, or other legally recognizable unit capable of conducting or sponsoring research.

(g) Eukaryote: A cell or organism with a membrane-bound, structurally discrete nucleus and well-developed cell organelles. Eukaryotes include plants, animals, and fungi.

(h) Fungi: Primarily multinucleate organisms with eukaryotic nucleic in walled mycelia, having absorptive nutrition and lacking photosynthetic activity. Certain species are pathogenic to specific plants and animals.

(i) Genetic engineering: The genetic modification of organisms by recombinant DNA, recombinant RNA, or other specific molecular gene transfer or exchange techniques.

(j) Microorganism: A term for organisms having microscopic or submicroscopic forms, and including bacteria, prokaryotes, viruses, and certain fungi.

(k) Recombinant DNA or Recombinant RNA molecules: Hybrid molecules which are (1) constructed outside living cells by covalently joining natural or synthetic DNA (deoxyribonucleic acid) or RNA (ribonucleic acid) segments to DNA or RNA molecules that can replicate in a living cell, or (2) DNA or RNA molecules that result from the replication in living cells of those described in (1) above.

(l) Plant: Multicellular organism characterized by eukaryotic cells surrounded by rigid cell walls, photosynthetic ability, and embryonic development; members include mosses, liverworts, and vascular plants (including most terrestrial crop plants as well as forest and ornamental species).

(m) Prokaryote: A cell or organism lacking membrane-bound, structurally discrete nuclei and organelles. Prokaryotes include bacteria, mycoplasma and blue-green algae.

(n) Transposable element: Segment of DNA which moves from one location to another among and within chromosomes causing genetic change; may be useful as a vector for introducing DNA.

(o) Vector: DNA or RNA molecule used to introduces DNA or RNA into genes in cells. Molecular gene vectors include plasmids, DNA and RNA from viruses, and other forms of DNA such as transposable elements, and are not to be confused with biological vectors of many plant and animal disease agents.

(p) Virus: Any of a large group of noncellular, submicroscopic agents infecting plants, animals or bacteria and unable to reproduce outside of specific host cells. A fully formed virus consists of a genome of nucleic acid (DNA or RNA) surrounded by a protein or lipoprotein coat.

Subpart____2. Classifications or Organisms and Research Projects

____.201 Classifications of Agricultural Research Projects—General.

(a) Agricultural biotechnology research projects are categorized on the basis of assuring safety to the natural and human environment. The category to which a project is assigned provides the basis for determining under what containment measures and procedural requirements the research can proceed. Experiments falling under more than one category must be conducted in accordance with the requirements of that category which requires the highest degree of IBC and USDA involvement or the highest level of containment. All Biosafety Levels of containment are set forth as minimums. Higher levels of containment may be provided. The USDA reserves the right to adjust the containment and practices required for any particular experiment, if scientific evidence demonstrates a change in the safety of conducting the experiment at the required level.

(b) All biotechnology projects which involve the cloning of genes coding for the biosynthesis of molecules toxic for vertebrates shall be conducted under the containment requirements set forth in section ____.322.

(c) Biotechnology research projects which involve release of microorganisms into the environment are assigned to one of two categories, in accordance with the definitions by the Biotechnology Science Coordinating Committee (BSCC) persented in the Preamble to this notice. Release of intrageneric or other organisms specifically excluded from the BSCC definition shall be assigned to category 3 (section ____.204). The BSCC definitions follow:

Intergeneric Organism (New Organism)

Those organisms deliberately formed to contain an intergeneric combination of genetic material; excluded are organisms that have resulted from the addition of intergeneric material that is well-characterized and contains only noncoding regulatory regions such as operators, promoters, origins of replication, terminators and ribosome binding regions. "Well-characterized and contains only noncoding regulatory regions" means that the producer of the microorganism can document the following:

a. The exact nucleotide base sequence of the regulatory region and any inserted flanking nucleotides;

b. The regulatory region and any inserted flanking nucleotides do not code independently for protein, peptide or functional RNA molecules;

c. The regulatory region solely controls the activity of other sequences that code for protein or peptide molecules or act as recognition sites for the initiation of nucleic acid or protein systhesis.

Pathogen

A pathogen is a virus or microorganism (including its viruses and plasmids, if any) that has the ability to cause disease in other living organisms (i.e., humans, animals, plants, microorganisms).

A microorganism will be subject to policies regarding pathogens if:

a. The microorganism belongs to a pathogenic species, according to sources identified by the agency, or from information known to the producer that the organism is a pathogen; excepted are organisms belonging to a strain used for laboratory research or commercial purposes and generally recognized as non-pathogenic according to sources identified by a federal agency, or information known to the producer and the appropriate federal agency; an example of a nonpathogenic strain of a species which contains a pathogenic strain is Escherichia coli K-12; examples of nonpathogenic species are Bacillus subtilis, Lactobacillus acidophilus, and Saccharomyces species; or

b. The microorganism has been derived from a pathogen or has been deliberately engineered such that it contains genetic material from a pathogenic organism as defined in item a. above. Excepted are genetically engineered organisms developed by transferring a well-characterized non-coding regulatory region from a pathogenic donor to a non-pathogenic recipient.

"Well-characterized, non-coding regulatory region" means that the producer of the microorganism can document the following:

a. The exact nucleotide base sequence of the regulatory region and any inserted flanking nucleotides;

b. The regulatory region and any inserted flanking nucleotides do not code independently for protein, peptide, or functional RNA molecules; and,

c. The regulatory region solely controls the activity of other sequences that code for protein or peptide molecules or act as recognition sites for the initiation of nucleic acid or protein synthesis.

This definition excludes organisms such as competitors or colonizers of the same substrates, commensal or mutualistic microorganisms, or opportunistic pathogens.

____.202 Agricultural Research That is Exempt—Category I.

____.202-1 Exempt Research—General.

The following research in the laboratory phase, in which intentional release will not occur, is exempt from the compliance with the procedural or substantive requirements contained in these guidelines, for the reason that USDA does not believe that accidental release of organisms in these experiments will present a significant risk to health and the environment. Research is not exempt if it involves intentional introduction of organisms or pathogens into the environment except as exempted in section ____.201c. Nonexempt experiments require either USDA notification (section ____.204) or USDA approval (section .205), and must be conducted in accordance with procedures described in these sections.

(a) Research using genetic manipulation techniques that do not involve rDNA, rRNA or cell fusion processes.

(b) Research with DNA or rDNA molecules that are not in organisms or viruses.

(c) Research that involves exclusively DNA segments from a single non-chromosomal or viral DNA or RNA source, through one or more of the segments may be a synthetic equivalent.

(d) Research that involves exclusively DNA or RNA from a prokaryotic host, including its indigenous plasmids or viruses, when propagated only in that host (or closely related strain of the same species) or when transferred to another host by classical physiological or genetic means; also, research that involves exclusively DNA from an eukaryotic host, including its chlorophasts, mitochondria, or plasmids (but excluding viruses), when propagated only in that host (or a closely related strain of the same species).

(e) Research that involves recombinant DNA molecules consisting entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent (section ____.202-2).

(f) Exemptions in addition to those listed in this section (____.202) may be obtained for other classes of recombinant DNA molecules if, after appropriate notice, a review by appropriate officials, and an opportunity for public comment, it is found that such molecules will not have a significant adverse effect on human or animal health or on the environment or agriculture.

____.202-2 Exempt Research—DNA or RNA Molecules from Organisms which Exchange DNA by Known Physiological Processes.

(a) Exempt from the coverage of these Guidelines are recombinant DNA molecules consisting entirely of DNA segments from species listed below that exchange DNA by known physiological processes.

(b) To be exempt, the recombinant DNA molecules must be (1) composed entirely of DNA segments from one or more of the organisms within a sublist and (2) propagated in any of the organisms within a sublist.

(c) List of organisms demonstrated to exchange DNA.

Sublist A

1. Genus Escherichia
2. Genus Shigella
3. Genus Salmonella (including Arizona)
4. Genus Enterobacter
5. Genus Citrobacter (including Levinea)
6. Genus Klebsiella
7. Genus Erwinia
8. Pseudomonas aeruginosa, Pseudomonas putida and Pseudomonas fluorescens
9. Serratia marcescens
10. Yersinia enterocolitica

Sublist B

1. Bacillus subtilis
2. Bacillus licheniformis
3. Bacillus pumilus
4. Bacillus globigii
5. Bacillus niger
6. Bacillus nato
7. Bacillus amyloliguefaciens
8. Bacillus aterrimus

Sublist C

1. Streptomyces aureofaciens
2. Streptomyces rimosus
3. Streptomyces coelicolor

Sublist D

1. Streptomyces griseus
2. Streptomyces cyaneus
3. Streptomyces venezuelae

Sublist E

1. One way transfer of Streptococcus mutans or Streptococcus lactis DNA into Streptococcus sanguis.

Sublist F

1. Streptococcus sanguis
2. Streptococcus pneumoniae
3. Streptococcus faecalis
4. Streptococcus pyogenes
5. Streptococcus mutans

____.202-3 Exempt Research—Specific Exemptions.

Research conducted according to one of the following specific exemptions is considered to present no significant risk and is thus exempt as described in ____.202-1.

(a) *Recombinant DNAs in Tissue Culture.* Recombinant DNA molecules derived entirely from nonviral components (that is, no component is derived from a eukaryotic virus) that are propagated and maintained in cells in tissue culture are exempt from these Guidelines with the exceptions listed below.

(1) Experiments described in sections ____.205 which require specific USDA approval before initiation of the experiment.

(2) Experiments involving DNA from Class 3, 4, or 5 organisms or cells known to be infected with these agents (*see* section ____.206).

(3) Experiments involving the deliberate introduction of genes coding for the biosynthesis of molecules toxic for vertebrates (*see* section ____.322).

(b) *Experiments Involving E. coli K-12 Host-Vector Systems.*

(1) Experiments which use E. coli K-12 host-vector systems, with the exeption of those experiments listed below, are exempt from these Guidelines provided that: (i) the E. coli host shall not contain conjugation proficient plasmids or generalized transducing phages, and (ii) lambda or lambdoid or Ff bacteriophages or nonconjugative plasmids shall be used as vectors. However, experiments involving the insertion into E. coli K-12 of DNA from prokaryotes that exchange genetic information with E. coli may be performed with any E. coli K-12 vector (e.g., conjugative plasmid). When a nonconjugative vector is used, the E. coli K-12 host may contain conjugation-proficient plasmids either autonomous or integrated, or generalized transducing phages.

(2) For these exempt laboratory experiments, BL1 physical containment conditions is recommended.

(3) For large-scale (LS) fermentation to experiments, BL1-LS physical containment conditions is recommended. However, following review by the IBC of appropriate data for a particular low risk host-vector system, some latitude in the application

of BL1–LS requirements as outlined in section ____.321(c) is permitted. Ultimately the containment should at least be equivalent to that required for the non-modified organism, even though that may be less stringent than BL1–LS.

(4) The following experiments are not covered by this exemption:

(i) Experiments described in section ____.205 which require specific USDA approval before initiation of the experiment.

(ii) Experiments involving DNA from Class 3, 4, or 5 organisms (*see* section ____.206) or from cells known to be infected with these agents may be conducted under containment conditions specified in section ____.206(e) with prior IBC review and approval.

(iii) Large-scale experiments (e.g., more than 10 liters of culture) require prior IBC review and approval (*see* section ____.321).

(iv) Experiments involving the deliberate cloning of genes coding for the biosynthesis of molecules toxic for vertebrates (*see* section____.322).

(c) *Experiments Involving Saccharomyces cerevisiae Host-Vector Systems.* (1) Experiments which use Saccharomyces cerevisiae host.vector sytems, with the exception of experiments listed below, are exempt from these Guidelines provided that laboratory strains are used.

(2) For these exempt laboratory experiments, BL1 physical containment conditions are recommended.

(3) For large-scale fermentation experiments BL1–LS physical containment conditions are recommended. However, following review by the IBC or appropriate data for a particular host-vector system some latitude in the application of BL1–LS requirements as outlined in section ____.321(c) is permitted.

(4) The following experiments are not covered by this exemption:

(i) Experiments described in section ____.205 which require specific USDA approval before initiation of the experiment.

(ii) Experiments involving Class 3, 4, or 5 organisms (1) or cells known to be infected with these agents may be conducted under containment conditions specified in section ____.301 with prior IBC review and approval.

(iii) Large-scale experiments (e.g., more then 10 liters of culture) require prior IBC review and approval (*see* section ____.321).

(iv) Experiments involving the deliberate cloning of genes coding for the biosynthesis of molecules toxic for vertebrates (*see* section ____.322).

(d) *Experiments Involving Bacillus subtilis Host-Vector Systems.* Any asporogenic Bacillus subtilis strain which does not revert to a sporeformer with a frequency greater than 10^7 can be used for cloning DNA with the exception of these experiments listed below. Indigenous Bacillus plasmids and phages whose host-range does not include Bacillus cereus or Bacillus anthracis may be used as vectors.

(1) For these exempt laboratory experiments, BL1 physical containment conditions are recommended.

(2) For large-scale fermentation experiments BL1–LS physical containment conditions are recommended. However, following review by the IBC of appropriate data for a particular host-vector system, some latitude in the application of BL1–LS requirements as outlined in section ____.321(c) is permitted. Ultimately, the containment should at least be equivalent to that required for the non-modified organism, even though that may be less stringent than BL1–LS.

(3) The following experiments are not covered by this exemption:

(i) Experiments described in section ____.206 which require specific USDA approval before initiation of the experiment.

(ii) Experiments involving Class 3, 4, or 5 organisms or cells known to be infected with these agents may be conducted under containment conditions specified by section ____.206 with prior IBC review and approval.

(iii) Large-scale experiments (e.g., more than 10 liters of culture) require prior IBC review and approval (*see* section ____.321).

(iv) Experiments involving the deliberate cloning of genes coding for the biosynthesis of molecules toxic for vertebrates (*see* section ____.322).

____.203 Agricultural Research that Requires IBC Notification at Initiation—Category 2.

Agricultural biotechnology research not included in sections ____.202.3 (exempt research), ____.204 (research that requires IBC approval and USDA registration before initiation), and ____.205 (research that requires IBC and USDA approval before initiation), shall be conducted at Biosafety Level 1 of containment. A registration document as described in section ____.204(b) must be completed, dated, and signed by the principal investigator and filed with the IBC prior to or at the time of the initiation of the research project.

____.204 Agricultural Research that Requires IBC Approval and USDA Registration Before Initiation—Category 3.

(a) *General.* Most agricultural research involving the cloning of restricted plant and animal pathogens or recombinant DNA experiments with whole animals and plants as well as certain research work involving pathogens will fall within this category.

(b) *Registration Document Requirements.* Prior to initiating research in this category, principal investigators must submit to their IBC a registration document that contains (1) a description of the source(s) of DNA, (2) a description of the nature of the inserted DNA sequences, (3) a description of the hosts and vectors to be used, (4) a statement as to whether a deliberate attempt will be made to obtain the expression of the inserted gene, and, if so, what protein is intended to be produced, (5) a statement of the Biosafety Level of containment to be applied to the research, (6) a statement as to whether the intent of the research is to develop an organism or a product of a organism for eventual release in an agricultural, environmental, industrial, or pharmaceutical application, and

(7) methodology for monitoring the experiments.

(c) *Agricultural Research To Modify Human, Animal, or Plant Pathogens.* (1) Agricultural research that introduces recombinant DNA or genetic modifications by other biotechnology techniques with Class 2, Class 3, or Class 4 organisms (*see* section ____.206(a) (2), (3), and (4)) shall be conducted at Biosafety Levels of Containment 2, 3, and 4, respectively.

(2) Agricultural research that introduces recombinant DNA or genetic modifications by other biotechnology techniques with Class 5 organisms (*see* section ____.206(c) can be conducted at the biosafety containment level specified in the USDA–APHIS permit for possession and culture of the organism.

(3) Agricultural research that introduces recombinant DNA or genetic modifications by other biotechnology techniques with plant pathogens shall be conducted at Biosafety Level 1, unless the pathogen is of Class A or Class B(a) requiring higher containment (*see* section ____.206(d)—Classification of Plant Pathogens).

(d) *Agricultural Research in which DNA from Human, Animal or Plant Pathogens is Cloned in Nonpathogenic Prokaryotic or Lower Eukaryotic Host-Vector Systems.* (1) Agricultural research involving recombinant DNA and other biotechnology gene insertion techniques in which DNA from Class 2 or Class 3 agents (*see* section ____.206(a) (2) and (3)) is transferred into nonpathogenic prokaryotes of lower

eukaryotes shall be subject to Biosafety Level 2. Experiments in which DNA from Class 4 or Class 5 agents (*see* section ____.206(a)(4) and (c)) is transferred into nonpathogenic prokaryotes or lower eukaryotes shall be subject to Biosafety Level 2 if it has been demonstrated that only a totally and irreversibly defective fraction of the agent's genome is present in a given recombinant. Until such demonstration is made, the research shall be conducted subject to the Biosafety Level required for a culture of the higher-classed agent. Containment for particular experiments in this category may be lowered to Biosafety Level 1 with the approval of the IBC if, prior to instituting such lower level, notification is given to the USDA.

(2) Agricultural research involving recombinant DNA experiments in which DNA from Class A plant pathogens (*see* section ____.206(d)) is transferred into nonpathogenic prokaryotes or lower eukaryotes shall be performed under Biosafety Level 2 containment. Containment for particular experiments in this category may be lowered to Biosafety Level 1 with the approval of the IBC if, prior to instituting such lower level, notification is given to the USDA and demonstration is made that only a totally and irreversibly defective fraction of the agent's genome is present in a given recombinant.

(e) *Agricultural Research Using Animal or Plant Viruses Vectors in Tissue Culture or Whole Plant or Animal Systems.* (1) Agricultural research using vectors derived from DNA or RNA of infectious Class 2, 3, or 4 animal viruses (*see* section ____.206), or defective Class 2, 3, or 4 animal viruses in the presence of a helper virus, can be performed in tissue culture systems at Biosafety Level 2, 3, or 4, respectively.

(2) Agricultural research using vectors derived from DNA or RNA of infectious Class 5 viruses, or defective Class 5 viruses in the presence of a helper virus shall be conducted in tissue culture or whole animal systems at the containment level specified by the USDA–APHIS permit required for possession and culture of the organism.

(3) Agricultural research using vectors derived from DNA or RNA of infectious Class A (*see* section ____.206(d)) plant viruses, or defective Class A plant viruses in the presence of a helper virus, shall be conducted in tissue culture systems or whole plants at Biosafety Level 2.

(4) Agricultural research using vectors derived from DNA or RNA of plant or animal viruses, or defective animal or plant viruses in the presence of a helper virus, that are not included in the above sections may be conducted in tissue culture systems or whole plant systems under Biosafety Level 1, or in whole animals under Biosafety Level 1 or NABS 1 containment.

Caution: Special attention should be used in evaluating the containment levels for experiments which may either enhance the pathogenicity or extend the host range of viruses or viral vectors under conditions which permit a productive infection. In such cases, the investigator and the IBC should seriously consider raising the physical containment by at least one level. Defective viral genomes are usually considered to be a portion of nucleic acid equal to less than two-thirds of the total viral genome.

(f) *Agricultural Research to Transform Whole Animals and Plants by Recombinant DNA Techniques.* (1) DNA from any source except for greater than two-thirds of an eukaryotic viral genome may be transferred to any non-human vertebrate or invertebrate animal and propagated under containment conditions appropriate to the organism under study. All such research must be conducted at a minimum at biosafety level 1. If viral nucleic acid is used as the vector, it should be demonstrated that it does not lead to productive infection.

(2) DNA from any source may be transferred to plants provided the introduced DNA or RNA consists of well-characterized genes containing no sequences harmful to humans, animals, or plants. The vector must consist of DNA or RNA: (i) from exempt host-vector systems listed in section ____.309 (ii) from plants of the same or closely related species; (iii) from nonpathogenic prokaryotes or nonpathogenic lower eukaryotic plants; (iv) from plant pathogens only if sequences resulting in production of disease symptoms have been deleted; or (v) chimeric vectors constructed from sequences defined in (i) to (iv) above. The DNA may be introduced by any suitable method. If sequences of DNA which produce disease symptoms are retained for purposes of introducing the DNA into the plant, greenhouse-grown plants must be shown to be free of such sequence before such plants, plant derivatives, or seed from such plants can be used in field tests (*see* section ____.205(b).

(g) *Agricultural Research that Involves Release of Non-pathogenic, Intrageneric Organisms.* Organisms that fit the category in the BSCC definition are presented in section ____.201(c), involving non-pathogenic organisms of the same genus, may be released into field tests upon IBC approval and USDA registration, as described in ____.204(b).

____.205 Agricultural Research that Requires USDA and IBC Approval Before Initiation: Release of Organisms—Category 4.

(a) *General.* Experiments in this category are those that involve release of an organism modified by genetic engineering, including those developed in exempt categories of laboratory research, into the environment on a small scale for agricultural research purposes. But excepting those in ____.204(g) these experiments may require specific review by the Agriculture Biotechnology Recombinant DNA Advisory Committee (ABRAC) as well as approval by the USDA and IBC before initiation. For these reviews, the IBC shall be expanded (*see* subpart ____.4) to provide expertise for both the organism in question and the geographic area where the research is to be conducted. Requests for approvals shall follow the procedures set forth in these Guidelines. To ensure protection for proprietary data, any public notice regarding a request for an approval which is designated by the entity as proprietary under section ____.502 will be issued only after consultation with the entity as to the content of the notice.

(b) *National Environmental Policy Act Requirements.* All entities submitting for USDA approval a research project under these Guidelines, whether the submission is required or voluntary, which involves the deliberate release of organisms modified by biotechnology, shall include with the submission a draft of a proposal to be used by the Department in preparing an environmental assessment.

(c) *Proposals for the Research Release of Nonmicroscopic Plants.* The following points are to be used by scientists preparing proposals requesting approval for releasing nonmicroscopic plants in small-scale plots for agricultural research purposes. Information on every point will not be necessary in all cases but will depend on the properties of the parental organism and the effect of the modification on these properties.

The proposal shall include a statement of objectives and a description of materials and methods, including methodology for monitoring the experiments, and expected results. A summary of relevant preliminary results shall accompany the proposal. Information to be submitted shall include but not be limited to:

(1) *Description of Plant Materials.* Give common and scientific names of plants. Identify the specific cultivars or genetic lines to be used. Include information on the relative homogeneity

of the plant cultivars or lines and specific genetic markers they are known to possess.

(2) Vectors and Method of Introduction

(i) Describe the cloned DNA segment, if any, and its expression in the new host.

(ii) Give the method(s) by which the proposed DNA vector, if used, was constructed and introduced. Diagrams are very helpful and may be necessary for adequate understanding of the construct. Explain the advantages (and disadvantage(s), if appropriate) of your vectors, if other candidate vectors could be considered.

(iii) If microorganisms are used to introduce vectors or are vectors themselves, indicate how they compare with wild-type strains. If disabled pathogens are used to transmit the vector, indicate factors that will prevent these microorganisms from regaining or acquiring pathogenic potential. If the vector is likely to survive independently of the desired host(s), refer to this possibility, and provide data to assess the potential for such transfer to other organisms.

(iv) If microorganisms are used to introduce vectors, the absence of these microorganisms in the plants to be released in the field should be documented.

(3) Characteristics and Monitoring of Genetically Engineered and Control Plants.

(i) Provide data from greenhouse or growth chamber studies to support the safety of the prospective release. Data should include morphological data for up to two generations of plants as appropriate. Supply any molecular or physiological data, especially as applicable to the trait(s) under consideration, to demonstrate the stability of the incorporated gene. Specify plant monitoring procedures, sensitivity, frequency, and types of data to be obtained.

(ii) Specify design of the field plot. Plants should be grown in controlled access fields under specified conditions appropriate for the plant under study and the geographical location. Such conditions should include provisions for using good cultural and pest control practices, for physical isolation from plants of the same species, or from species which may cross-pollinate with the test species outside of the experimental plot in accordance with pollination characteristics of the species, and for further preventing plants genetically modified by biotechnology from becoming established in an environment by seeds or vegetative propagules.

(iii) Supporting data should include the following: (a) total area and size of plant population; (b) geographical location(s); (c) plot design including replication, row spacing, and nature of border rows; (d) plant monitoring procedures such as sensitivity and frequency of monitoring, types of data to be obtained including leaf, seed, fruit, or root characteristics, and disease, insect and other animal population monitoring as appropriate; (e) techniques for monitoring the vector or altered DNA; and (f) access and security measures.

(d) *Proposals for the Release of Nonmicroscopic Animals.* The following points shall be used by scientists preparing proposals requesting approval for releasing nonmicroscopic animals for agricultural research purposes. Information on every point will not be necessary in all cases but will depend on the properties of the parental animal and the effect of the modification on these properties.

The proposal shall include a statement of objectives and a description of materials and methods, including methodology for monitoring the experiments, and expected results. A summary of relevant preliminary results must accompany the proposal. Information to be submitted shall include but not be limited to:

(1) *Description of Animals.* Give common and scientific names of the animals. Identify the specific breeds or genetic lines to be used. Include information on the relative homogeneity of the breed or line and specific genetic markers they are known to possess.

(2) Vectors and Method of Introduction.

(i) Describe the cloned DNA segment, if any, and its expression in cells and in the transgenic animal.

(ii) Give the method(s) by which the proposed DNA vector, if used, was constructed. Diagrams are very helpful and may be necessary for adequate understanding of the construct. Explain the advantages (and disadvantage(s), if appropriate) of your vectors, if other candidate vectors could be considered.

(iii) Give the method of introducing the genetic modification. If microorganisms are used to introduce vectors or are vectors themselves, or if disabled pathogens are used to transmit the vector, indicate factors that will most likely prevent these microogranisms from regaining or acquiring pathogenic potential. If the vector or the inserted sequence is likely to survive independently of the desired host(s) or to combine with DNA of the host or indigenous viruses to survive independently, refer to this possibility and provide any available data to assess the probability of such transfer to other organisms.

(3) Characteristics and Monitoring of Genetically Engineered and Control Animals.

(i) Provide data to support the safety of prospective release. Data shall include morphological data for up to two generations of animals as appropriate. Molecular or physiological data, demonstrating the stability of the incoprorated gene, especially as applicable to the trait(s) under consideration, should be supplied together with monitoring procedures, sensitivity, frequency, and types of data to be obtained.

(ii) Specify design of the field location. Animals shall be housed under specified conditions appropriate for the animal under study and the nature of the modification. Such conditions shall include provisions for using good animal husbandry and pest control practices, for physical isolation from animals of the same species, or of species which may cross-breed with the test species outside of the experimental area in accordance with reproductive characteristics of the species. Procedures for assessing alterations in the the spread of modified organisms containing recombinant DNA shall be developed.

(iii) Supporting data should include the following: (A) total area and size of the trial—number of animals and dimensions of the enclosure; (B) geographical location; (C) animal monitoring procedures, frequency, types of data to be obtained including disease, insect, and other animal population monitoring as appropriate; (d) techniques for monitoring the vector and/or altered DNA; and (e) access and security measures.

(e) *Proposals for the Release of Microorganisms.* The following points are to be used by scientists preparing proposals requesting approval for releasing microorganisms, including viruses, for research in agricultural systems. Information on every point will not be necessary in all cases, but will depend on the properties of the parental organism and the effect of the modification on these properties.

Approval of small-scale field tests will depend upon the demonstration of safety using results of laboratory and greenhouse testing of the modified organism. Data from small-scale field tests will provide information on enviornmental effects of the modified organism and may be necessary in

consideration for approval of large-scale tests and commercial applications.

(1) *Summary.* Present a summary of the proposed trial including objectives, significance, and justification of the request.

(2) Genetic Considerations of Modified Organism to be Tested.

(i) Characteristics of the Non-modified Parental Organism.

(a) Information on identification, taxonomy, source, and strain.

(B) Information on organism's reproductive cycle and capacity for genetic transfer.

(ii) Molecular Biology of the Modified Organism.

(A) Introduced Genes. Give source and function of the DNA sequence used to modify the organism to be tested in the environment. Identify and give the taxonomy, source and strain of organisms donating the DNA.

(B) Construction of the Modified Organism: (*1*) describe the method(s) by which the vector with insert(s) has been constructed (include diagrams as appropriate), (*2*) describe the method of introduction of the vector carrying the insert into the organism to be modified and the procedure for selection of the modified organism, (*3*) specify the amount and nature of any vector and/or donor DNA remaining in the modified organism, (*4*) give the laboratory containment conditions specified in these Guidelines for the modified organisms.

(C) Genetic Stability and Expression: Present results and interpretation of preliminary tests designed to measure genetic stability and expression of the introduced DNA in the modified organism.

(3) Proposed Field Trials.

(i) Pre-Field Trial Considerations. Provide data related to any anticipated effects of the modified microorganism on target and nontarget organisms from microcosm, greenhouse, or growth chamber experiments that stimulate trial conditions. The methods of detection and sensitivity of sampling techniques and periodicity of sampling should be indicated. These studies should include, where relevant, assessment of the following items:

(A) Survival of the modified organism.

(B) Replication of the modified organism.

(C) Dissemination of the modified organism by wind, water, soil, mobile organisms, and other means.

(ii) Conditions of the trial. Describe the trial involving release of the modified organisms into the environment.

(A) Numbers of organisms and methods of application.

(B) Provide information including diagrams of the experimental location and the immediate surroundings. Describe characteristics of the site that would influence containment or dispersal.

(C) If the modified organism has a target organism, provide its identification and taxonomy and the anticipated mechanism and result of the interaction between the released microorganism and the target organism.

(iii) Containment. Indicate containment procedures in the event of accidental release as well as international release and procedures for emergency termination of the experiment. Specify access and security measures for the area(s) in which the tests will be performed.

(iv) Monitoring. Describe monitoring procedures and their limits of detection for survival, dissemination, and nontarget interactions of the modified microorganism. Include periodicity of sampling and rationale for monitoring procedures. Collect data to compare the modified organisms with the non-modified microorganism most similar to the modified organism at the time of the trial. Results of monitoring should be submitted to the OAB according to a schedule specified at the time of approval.

____.206 Classifications of Organisms on the Basis of Hazard.

(a) Classification of Human and Animal Etiologic Agents.

(1) *Class 1 Agents.* All bacterial, parasitic, fungal, viral, rickettsial, and chlamydial agents not included in higher classes.

(2) *Class 2 Agents.*

(i) *Bacterial Agents.*

Acinetobacter calcoaceticus
Actinobacillus—all species
Aeromonas hydrophiia
Arizona hinshawii-all serotypes
Bacillus anthracis
Bordetella—all species
Borrelia recurrentis, B. vincenti
Campylobacter fetus
Campylobacter jejuni
Chlamydia psittaci
Chlamydia trachomatis
Clostridium botulism, Cl. chauvoei, Cl. haemolyticum, Cl. histolyticum, Cl. novyi, Cl. septicum, Cl. tatani
Corynebacterium diphtheriae, C. equi, C. haemalyticum, C. pseudotuberculosis, C. pyogenes, C. renale
Edwardsiella tarda
Erysipelothrix insidiosa
Escherichia coli—all enteropathogenic enterotoxigenic, enteroinvasive and strains bearing Kl antigen
Haemophilus ducreyi, H. Influenzae
Klebsiella—all species and all serotypes
Legionello pneumphila
Leptospira interrogans—all serotypes
Listeric—all species
Moraxelia—all species
Mycobacteria—all species except those listed in Class 3
Mycoplasma—all species except Mycoplasma mycoides and Mycoplasma agaiactiae, which are in Class 5
Neisseric gonorrhoeae, N. Meningitis
Pasteurella—all species except those listed in Class 3
Salmonella—all species and all serotypes
Shigella—all species and all serotypes
Sphaerophorus necrophorus
Staphlococcus aureus
Streptobacillus monififormis
Streptococcus pneumoniae
Streptococcus pyogenes
Treponemo carateum, T. pallidum, and T. pertenue
Vibrio cholerae
Vibrio parahemolyticus
Yersinia enterocolitica

(ii) *Fungal Agents.*

Actinomycetes (including Nocardia species, Actinomyces species, and Arachnia propionica) (2)
Blastomyces dermatitis
Cryptococcus neoformans
Paracoccidioides braziliensis

(iii) *Parasitic Agents.*

Endamoeba histolytica
Leishmania sp.
Naegleria gruberi
Schistosoma mansoni
Toxoplasma gondii
Toxocara canis
Trichinella spiralis
Trypanosoma cruzi

(iv) *Viral, Rickettsial, and Chlamydial Agents.*

Adenoviruses—human—all types
Cache Valley virus
Coxackie A and B viruses
Cytomegaloviruses
Echoviruses—all types
Encepnalomyocarditis virus (EMC)
Flanders virus
Hart Park virus
Hepatitis-associated antigen material
Herpes viruses—except Herpesvirus simiae (Monkey B virus) which is in Class 4
Corona viruses
Influenza viruses—all types except A/PR8/34, which is in Class 1
Langat virus
Lymphogranuloma venereum agent
Measles virus

Mumps virus
Parainfluenza virus—all types except Parainfluenza virus 3, SF4 strain, which is in Class 1
Polioviruses—all types, wild and attenuated
Poxviruses—all types except Alastrim, Smallpox, and Whitepox which are Class 5 and Monkey pox which, depending on experiments, is in Class 3 or Class 4
Rabies virus—all strains except Rabies street virus which should be classified in Class 3
Reoviruses—all types
Respiratory Syncytial virus
Rhinoviruses—all types
Simian viruses—all types except Herpesvirus simiae (Monkey B virus) and Marburg virus which are in Class 4
Sindbis virus
Tensaw virus
Turlock virus
Vaccinia virus
Varicella virus
Vesicular stomatitis virus(3)
Vole rickettsia
Yellow fever virus, 17D vaccine strain

(3) Class 3 Agents.

(i) *Bacterial agents.*
Bartonella—all species
Brucella—all species
Francisella tularensis
Mycobacterium avium, M. bovis, M. tuberculosis
Pasteurella multocide type B ("buffalo" and other foreign virulent strains) (3)
Pseudomonas mallei(3)
Pseudomonas pseudmallei(3)
Yersinia pestis

(ii) *Fungal Agents.*
Coccidioides immitis
Histoplasma capsulatum
Histoplasma capsulatum var. duboisii.

(iii) *Parasitic Agents.*
None.

(iv) *Viral, Rickettsial, and Chlamydia Agents.*
Monkey pox, when used in vitro (4)
Arboviruses—all strains except those in Class 2 and 4 (Arboviruses indigenous to the United States are in Class 3 except those listed in Class 2. West Nile and Semliki Forest viruses may be classed up or down depending on the conditions of use and geographical location of the laboratory)
Dengue virus, when used for transmission or animal inoculation experiments
Lymphocytic choriomeningitis virus (LCM)
Rabies street virus
Rickettsia—all species except Vole rickettsia when used for transmission or animal inoculation experiments
Yellow fever virus—wild, when used in vitro

(4) Class 4 Agents.

(i) *Bacterial Agents.*
None.

(ii) *Fungal Agents.*
None.

(iii) *Parasitic Agents.*
None.

(iv) *Viral, Rickettsial, and Chlamydia Agents.*
Ebola fever virus
Monkey pox, when used for transmission or animal inoculation experiments (4)
Hemorrhagic fever agents, including Crimean hemorrhagic fever (Congo), Junin, and Machupo viruses, and others as yet undefined
Herpesvirus simiae (Monkey B virus)
Lassa virus
Markburg virus
Tick-borne encephalitis virus comples, including Russian spring-summer encephalitis, Kyasanur forest disease, Omsk hemorrhagic fever, and Central European encephalitis viruses
Venezuelan equine encephalitis virus, epidemic strains, when used for transmission or animal inoculation experiments
Yellow fever virus—wild, when used for transmission or animal inoculation experiments
Yellow fever virus—wild, when used for transmission or animal inoculation experiments

(b) *Classification of Oncogenic Viruses on the Basis of Potential Hazard.*

(1) *Low-Risk Oncogenic Viruses.*
Rous sarcoma
SV-40
CELO
AD7-SV40
Polyoma
Bovine papilloma
Rat mammary tumor
Avian leukosis
Murine sarcoma
Mouse mammary tumor
Rat leukemia
Hamster leukemia
Bovine leukemia
Dog sarcoma
Mason-Pfizer monkey virus
Marek's
Guinea pig herpes
Lucke (Frog)
Adenovirus
Shope fibroma
Shope papilloma

(2) *Moderate-Risk Oncogenic Viruses.*
Ad2-SV40
FeLV
HV Saimiri
EBV
SSV-1
GalV
HV ateles
Yaba
FeSV

(c) *Class 5 Agents.*

(1) *Animal Disease Organisms Which are Forbidden Entry into the United States by Law.*
Foot and mouth disease virus.

(2) *Animal Disease Organisms and Vectors Which are Forbidden Entry into the United States by USDA Policy.*
African horse sickness virus
African swine fever virus
Besnoitia besnoiti
Borna disease virus
Bovine infectious petechial fever
Camel pox virus
Ephemeral fever virus
Fowl plague virus
Goat pox virus
Hog cholera virus
Louping ill virus
Lumpy skin disease virus
Narobi sheep disease virus
Newcastle disease virus (Asiatic strains)
Mycoplasma agalactiae (contagious agalactia of sheep)
Rickettsia ruminatium (heart water)
Rift Valley fever virus
Rhinderpest virus
Sheep pox virus
Swine vesicular disease virus
Teschen disease virus
Trypanosoma vivax (Nagana)
Trypanosoma evanisi
Theileria parva (East Coast fever)
Theileria annulata
Theileria lawrencei
Theileria bovis
Theileria hirci
Vesicular exanthema virus
Wesselsbron disease virus
Zyonema

(3) *Organisms which may not be Studied in the United States Except at Specified Facilities.*
Small pox
Alastrim
White pox

(d) *Classification of Plant Pathogens.*

(1) Plant and Insect pathogens are classified into two subgroups:

(i) Class 1A—all organisms subject to quarantine restrictions by State and Federal programs for any of the following reasons:

(A) Not known to occur in the United States;

(B) Not widely distributed throughout the ecological range of their hosts:

(C) Subject to Federal or State eradication or suppression programs.

(ii) Class 1B—All those not in Class 1A

(2) More specifically, USDA/APHIS/Plant Protection and Quarantine Programs have placed plant pathogenic organisms into three categories according to risk:

(i) Class A: Pathogens presenting risks of spreading into noninfested areas: (A) foreign pathogens new to or not widely distributed in the United States: (B) domestic pathogens of limited United States distribution, including problem pathogens: (C) State regulated pathogens, and (D) exotic strains of domestic pathogens.

(ii) Class B: Biocontrol Agents and Pollinators.

(A) High risk—weed antagonist; shipments accompanied by prohibited plant material or accompanied by organisms falling under paragraph (c)(1) of this section.

(B) Low risk—pure cultures of known beneficial organisms.

(iii) Class C: Domestic pathogens that have attained their ecological range.

Subpart ____.3 Containment

____.301 General Information.

(a) The object of containment is to confine hazardous organisms and thus to reduce the potential for exposure of the laboratory worker, persons outside of the laboratory, and the environment.

(b) The first principle of containment is a strict adherence to good microbiological practices. Consequently, all personnel directly or indirectly involved in experiments must receive adequate instruction. *See* section ____.402(e). This shall, at a minimum, include instructions in aseptic techniques and inthe biology of the organisms used in the experiments so that the potential biohazards can be understood and appreciated.

(c) Any entity working with agents with a known or potential biohazard shall have an emergency plan which describes the procedures to be followed if an accident contaminates personnel or the environment. The Principal Investigator (PI) must ensure that everyone in the laboratory is familiar with both the potential hazards of the work and the emergency plan. If an entity is working with a known pathogen for which there is an effective vaccine, the vaccine shall be made available to all workers. Where serological monitoring is clearly appropriate, it shall be provided.

(d) Physical containment is achieved through the use of laboratory practices, containment equipiment, and special laboratory design. Four levels of increasing physical confinement applicable to microorganisms and small laboratroy animals are described below (section ____.302 through ____.305). The containment practices described in these levels shall be applied to agricultural biotechnology research activities governed by these Guidelines. The enumeration of these minimum practices is not intended to foreclose the adoption of more strigent practices in any particular agricultural biotechnology research project.

(e) In addition, four levels of increasing physical confinement applicable to all nonmicroscopic animals utilized in agricultural biotechnology research are described in sections ____.312 through ____.317, *infra.*

(f) Sections ____.318 through ____.320 sets forth the conditions applicable to agricultural research involving nonmicroscopic plants.

(g) Moreover, biological organisms by their very nature lend themselves to biological containment, that is, the application of highly specific biological barriers. Biological specificity exists which limits either (1) the infectivity of a *vector,* or *vehicle,* (plasmid or virus) for specific hosts or (2) its dissemination and survival in the environment. For example, the vectors that provide the means for replication of the recombinant DNAs or host cells in which they replicate can be genetically designed to decrease by many orders or magnitude the probability of dissemination of the modified organisms. Further details on biological containment may be found in sections ____.307 and ____.309.

(h) Possible alternate combinations of physical and biological containment safeguards are set forth in section ____.310. The USDA will consider further relaxing the physical containment levels required for research if proven biological containment practices so warrant.

____.302 Laboratory Research Involving Microorganisms—Biosafety Level 1.

Biosafety Level 1 is suitable for work involving agents of no known or minimal potential hazard to laboratory personnel and the environment. The laboratory is not separated from the general traffic patterns in the bulding. Work is generally conducted on open bench tops. Special containment equipment is not required or generally used. Laboratory personnel have specific training in the procedures conducted in the laboratory and are supervised by a scientist with general training in microbiology or a related science.

(a) *Physical Containment—Standard Practices.*

(1) Access to the laboratory shall be limited or restricted at the discretion of the laboratory director when experiments are in progress.

(2) Work surfaces shall be decontaminated once a day and after any spill of viable material.

(3) All contaminated liquid or solid wastes shall be decontaminated before disposal.

(4) Mechanical-pipetting devices shall be used; mouth pipetting is prohibited.

(5) Eating, drinking, smoking, and applying cosmetics are not permitted in the work area. Food may be stored in cabinets or refrigerators designated and used for this purpose only.

(6) Persons shall wash their hands after they handle materials involving organisms containing recombinant DNA molecules, and animals, and before leaving the laboratory.

(7) All procedures shall be performed carefully to minimize the creation of aerosols.

(8) It is recommended that laboratory coats, gowns, or uniforms shall be worn to prevent contamination or soiling of street clothes.

(b) *Physical Containment—Special Practices.*

(1) Contaminated materials that are to be decontaminated at a site away from the laboratory shall be placed in a durable, leakproof container which is closed before being removed from the laboratory.

(2) An insect and rodent control program shall be in effect.

(c) *Physical Containment—Equipment.* Special containment equipment generally shall not be required for manipulations of agents assigned to Biosafety Level 1.

(d) *Physical Containment—Laboratory Facilities.*

(1) The laboratory shall be designed so that it can be easily cleaned.

(2) Bench tops shall be impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat.

(3) Laboratory furniture shall be sturdy. Spaces between benches, cabinets, and equipment shall be accessible for cleaning.

(4) Each laboratory shall contain a sink for handwashing.

(5) If the laboratory has windows that open, they shall be fitted with fly screens.

____.303 Laboratory Research Involving Microorganisms—Biosafety Level 2.

Biosafety Level 2 is similar to Level 1 and is suitable for work involving agents of moderate potential hazard to personnel and the environment. It differs in that the laboratory personnel have specific training in handling pathogenic agents and are directed by competent scientists, access to the laboratory is

limited when work is being conducted, and certain procedures in which infectious aerosols are created are conducted in biological safety cabinets or other physical containment equipment.

(a) *Physical Containment—Standard Practices.*

(1) Access to the laboratory shall be limited or restricted by the laboratory director when work with organisms containing recombinant DNA molecules is in progress.

(2) Work surfaces shall be decontaminated at least once a day and after any spill of viable material.

(3) All contaminated liquid or solid wastes shall be decontaminated before disposal.

(4) Mechanical pipetting devices shall be used; mouth pipetting is prohibited.

(5) Eating, drinking, smoking, and applying cosmetics are not permitted in the work area. Food may be stored in cabinets or refrigerators designated and used for this purpose only.

(6) Persons shall wash their hands after handling materials involving organisms containing recombinant DNA molecules and animals, and when they leave the laboratory.

(7) All procedures shall be performed carefully to minimize the creation of aerosols.

(8) Experiments of lesser biohazard potential can be carried out concurrently in carefully demarcated areas of the same laboratory.

(b) *Physical Containment—Special Practices.*

(1) Contaminated materials that are to be decontaminated at a site away from the laboratory shall be placed in a durable leakproof container which shall be closed before being removed from the laboratory.

(2) The laboratory director shall limit access to the laboratory. The director has the final resonsibility for assessing each circumstance and determining who may enter or work in the laboratory.

(3) The laboratory director shall establish policies and procedures whereby only persons who have been advised of the potential hazard and who meet any specific entry requirements (*e.g.*, immunization) may enter the laboratory or animal rooms.

(4) When the organisms containing recombinant DNA molecules in use in the laboratory require special provisions for entry (*e.g.*, vaccination, a hazard warning sign incorporating the universal biohazard symbol shall be posted on all access doors to the laboratory work area. The hazard warning sign shall identify the agent, list the name and telephone number of the laboratory director or other responsible person(s), and indicate the special requirement(s) for entering the laboratory.

(5) An insect and rodent control program shall be in effect.

(6) [Reserved].

(7) [Reserved].

(8) Laboratory coats, gowns, smocks, or uniforms shall be worn while in the laboratory. Before leaving the laboratory for nonlaboratory areas (*e.g.*, cafeteria, library, administrative offices), this protective clothing shall be removed and left in the laboratory or covered with a clean coat not used in the laboratory.

(9) Animals not involved in the work being performed shall not be permitted in the laboratory.

(10) Special care shall be taken to avoid skin contamination with organisms containing recombinant DNA molecules; gloves shall be worn when handling experimental animals and when skin contact with the agent is unavoidable.

(11) All wastes from laboratories and animal rooms shall be appropriately decontaminated before disposal.

(12) Hypodermic needles and syringes shall be used only for parenteral injection and aspiration of fluids from laboratory animals and diaphragm bottles. Only needle-locking syringes or disposable syringe-needle units (*i.e.*, needle is integral to the syringe) shall be used for the injection or aspiration of fluids containing organisms that contain recombinant DNA molecules. Extreme caution shall be used when handling needles and syringes to avoid autoinoculation and the generation of aerosols during use and disposal. Needles shall not be bent, sheared, replaced in the needle sheath or guard or removed from the syringe following use. The needle and syringe shall be promptly placed in a puncture-resistant container and decontaminated, preferably by autoclaving, before discard or reuse.

(13) Spills and accidents which result in overt exposures to organisms containing recombinant DNA molecules shall be immediately reported to the laboratory director. Medical evaluation, surveillance, and treatment shall be provided as appropriate and written records shall be maintained.

(14) When appropriate, considering the agent(s) handled, baseline serum samples for laboratory and other at-risk personnel shall be collected and stored. Additional serum specimens may be collected periodically depending on the agents handled or the function of the facility.

(15) A biosafety manual shall be prepared or adopted. Personnel shall be advised of special hazards and shall be required to read instructions on practices and procedures and to follow them.

(c) *Physical Containment—Equipment.* Biological safety cabinets (Class I or II) (*see* section ____.306) or other appropriate personal protective devices shall be used whenever—

(1) Procedures with a high potential for creating aerosols are conducted (These may include centrifuging, grinding, blending, vigorous shaking or mixing, sonic disruption, opening containers of materials whose internal pressures may be different from ambient pressures, inoculating animals intranasally, and harvesting infected tissues from animals or eggs), or

(2) High concentrations or large volumes of organisms containing recombinant DNA molecules are used. (Such materials may be centrifuged in the open laboratory if sealed heads or centrifuge safety cups are used and if they are opened only in a biological safety cabinet.)

(d) *Physical Containment—Laboratory Facilities.*

(1) The laboratory shall be designed so that it can be easily cleaned.

(2) Bench tops shall be impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat.

(3) Laboratory furniture shall be sturdy and spaces between benches, cabinets, and equipment shall be accessible for cleaning.

(4) Each laboratory shall contain a sink for handwashing.

(5) If the laboratory has windows that open, they shall be fitted with fly screens.

(6) An autoclave for decontaminating laboratory wastes shall be available.

____.304. Laboratory Research Involving Microorganisms—Biosafety Level 3.

Biosafety Level 3 is applicable to clinical, diagnostic, teaching, research, or production facilities in which work is done with indigenous or exotic agents which may cause serious or potentially lethal disease as a result of exposure by the inhalation route. Laboratory personnel have specific training in handling pathogenic and potentially lethal agents and are supervised by competent scientists who are experienced in working with these agents. All procedures involving the manipulation of infectious material are conducted within biological safety cabinets or other physical containment devices or by personnel wearing appropriate personal protective clothing and devices. The laboratory has special engineering and design features. It is recognized, however, that many existing

facilities may not have all the facility safeguards recommended for Biosafety Level 3 (e.g., access zone, sealed penetrations, and directional airflow, etc.) In these circumstances, acceptable safety may be achieved for routine or repetitive operations (e.g., diagnostic procedures involving the propagation of an agent for identification, typing, and susceptibility testing) in laboratories where facility features satisfy Biosafety Level 2 recommendations provided the recommended "Standard Microbiological Practices," "Special Practices," and "Containment Equipment" for Biosafety Level 3 are rigorously followed. The decision to implement this modification of Biosafety Level 3 recommendations should be made only by the laboratory director.

(a) *Physical Containment—Standard Practices.*

(1) Work surfaces shall be decontaminated at least once a day and after any spill of viable material.

(2) All contaminated liquid or solid wastes shall be decontaminated before disposal.

(3) Mechanical pipetting devices shall be used; mouth pipetting is prohibited.

(4) Eating, drinking, smoking, storing food, and applying cosmetics are prohibited in the work area.

(5) Persons shall wash their hands after handling materials involving organisms containing recombinant DNA molecules and animals, and when they leave the laboratory.

(6) All procedures shall be performed carefully so as to minimize the creation of aerosols.

(7) Persons under 16 years of age shall not be permitted to enter the laboratory.

(8) If experiments involving other organisms which require lower levels of containment are to be conducted in the same laboratory concurrently with experiments requiring biosafety level 3 containment, they shall be conducted in accordance with all biosafety level 3 laboratory practices.

(b) *Physical Containment—Special Practices.*

(1) Laboratory doors shall be kept closed when experiments are in progress.

(2) Contaminated materials that are to be decontaminated at a site away from the laboratory shall be placed in a durable leakproof container which shall be closed before being removed from the laboratory.

(3) The laboratory director shall control access to the laboratory and shall restrict access to persons whose presence is required for program or support purposes. The director has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory.

(4) The laboratory director shall establish policies and procedures whereby only persons who have been advised of the potential biohazard, who meet any specific entry requirement (*e.g.*, immunization), and who comply with all entry and exit procedures may enter the laboratory or animal rooms.

(5) When organisms containing recombinant DNA molecules or experimental animals are present in the laboratory or containment module, a hazard warning sign incorporating the universal biohazard symbol shall be posted on all laboratory and animal room access doors. The hazard warning sign shall identify the agent, list the name and telephone number of the laboratory director or other responsible person(s), and indicate any special requirement for entering the laboratory, such as the need for immunizations, respirators, or other personal protective measures.

(6) All activities involving organisms containing recombinant DNA molecules shall be conducted in biological safety cabinets or other physical containment devices within the containment module. No work in open vessels shall be conducted on the open bench.

(7) The work surfaces of biological safety cabinets and other containment equipment shall be decontaminated when work with organisms containing recombinant DNA molecules is finished. Plastic-backed paper toweling shall be used on nonperforated work surfaces within biological safety cabinets to facilitate clean-up.

(8) An insect and rodent control program shall be in effect.

(9) Laboratory clothing that protects street clothing (*e.g.*, solid front and wrap-around gowns, scrub suits, coveralls) shall be worn in the laboratory. Laboratory clothing shall not be worn outside the laboratory, and it shall be decontaminated before being laundered.

(10) Special care shall be taken to avoid skin contamination with contaminated materials; gloves shall be worn when handling infected animals and when skin contact with infectious materials is unavoidable.

(11) Molded surgical masks or respirators shall be worn in rooms containing experimental animals.

(12) Animals and plants not related to the work being conducted are not permitted in the laboratory.

(13) Laboratory animals held in a biosafety level 3 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 placed on holding racks equipped with ultraviolet radiation lamps and reflectors.

Note.—Conventional caging systems may be used provided that all personnel wear appropriate personal protective devices. These shall include at a minimum wrap-around gowns, head covers, gloves, shoe covers, and respirators. All personnel shall shower on exit from areas where these devices are required.

(14) All wastes from laboratories and animal rooms shall be appropriately decontaminated before disposal.

(15) Vacuum lines shall be protected with high efficiency particulate air (HEPA) filters and liquid disinfectant traps.

(16) Hypodermic needles and syringes shall be used only for parenteral injection and aspiration of fluids from laboratory animals and diaphragm bottles. Only needle-locking syringes and disposable syringe-needle units (*i.e.*, needle is integral to the syringe) shall be used for the injection or aspiration of fluids containing organisms that contain recombinant DNA molecules. Extreme caution shall be used when handling needles and syringes to avoid autoinoculation and the generation of aerosols during use and disposal. Needles should not be bent, sheared, replaced in the needle sheath or guard or removed from the syringe following use. The needle and syringe shall be promptly placed in a puncture-resistant container and decontaminated, preferably by autoclaving, before discard or reuse.

(17) Spills and accidents which result in overt or potential exposures to organisms containing recombinant DNA molecules shall be immediately reported to the laboratory director. Appropriate medical evaluation, surveillance, and treatment shall be provided and written records shall be maintained.

(18) Baseline serum samples for all laboratory and other at-risk personnel shall be collected and stored. Additional serum specimens may be collected periodically depending on the agents handled or the function of the laboratory.

(19) A biosafety manual shall be prepared or adopted. Personnel shall be advised of special hazards and shall be required to read instructions on practices and procedures and to follow them.

(20) *Alternative Selection of Containment Equipment.* Experimental procedures involving a host-vector system that provides a one-step higher level of biological containment than that

specified can be conducted in the BL3 laboratory using containment equipment specified for the BL2 level of physical containment. Experimental procedures involving a host-vector system that provides a one-step lower level of biological containment than that specified can be conducted in the BL3 laboratory using containment equipment specified for the BL4 level of physical containment. Alternative combination of containment safeguards are shown in section ____.310.

(c) *Physical Containment—Equipment.* Biological safety cabinets (Class I, II, or III) (*see* section ____.306) or other appropriate combinations of personal protective or physical containment devices (*e.g.*, special protective clothing masks, gloves, respirators, centrifuge safety cups, sealed centrifuge rotors, and containment caging for animals) shall be used for all activities with organisms containing recombinant DNA molecules which pose a threat of aerosol exposure. These include: Manipulation of cultures and of those clinical or environmental materials which may be a source of aerosols; the aerosol challenge of experimental animals; and harvesting infected tissues or fluids from experimental animals and embryonate eggs, and necropsy of experimental animals.

(d) *Physical Containment—Laboratory Facilities.*

(1) The laboratory shall be separated from areas which are open to unrestricted traffic flow within the building. Passage through two sets of doors is the basic requirement for entry into the laboratory from access corridors or other contiguous areas. Physical separation of the high containment laboratory from access corridors or other laboratories or activities may also be provided by a double-doored clothes change room (showers may be included), airlock, or other access facility which requires passage through two sets of doors before entering the laboratory.

(2) The interior surfaces of walls, floors, and ceilings shall be water resistant so that they can be easily cleaned. Penetrations in these surfaces shall be sealed or capable of being sealed to facilitate decontaminating the area.

(3) Bench tops shall be impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat.

(4) Laboratory furniture shall be sturdy and spaces between benches, cabinets, and equipment shall be accessible for cleaning.

(5) Each laboratory shall contain a sink for handwashing. The sink shall be foot, elbow, or automatically operated and shall be located near the laboratory exit door.

(6) Windows in the laboratory shall be closed and sealed.

(7) Access doors to the laboratory or containment module shall be self-closing.

(8) An autoclave for decontaminating laboratory wastes shall be available preferably within the laboratory.

(9) A ducted exhaust air ventilation system shall be provided. This system shall create directional airflow that draws air into the laboratory through the entry area. The exhaust air shall not be recirculated to any other area of the building, shall be discharged to the outside, and shall be dispersed away from the occupied areas and air intakes. Personnel must verify that the direction of the airflow (into the laboratory) is proper. The exhaust air from the laboratory room can be discharged to the outside without being filtered or otherwise treated.

(10) The HEPA filtered exhaust air from Class I or Class II biological safety cabinets shall be discharged directly to the outside or through the building exhaust system. Exhaust air from Class I or II biological safety cabinets may be circulated within the laboratory if the cabinet is tested and certified at least every twelve months. If the HEPA-filtered exhaust air from Class I or II biological safety cabinets is to be discharged to the outside through the building exhaust air system, it must be connected to this system in a manner (*e.g.*, thimble unit connection) that avoids any interference with the air balance of the cabinets or building exhaust system.

____.305 Laboratory Research Involving Microorganisms—Biosafety Level 4.

(a) *Physical Containment—Standard Practices.*

(1) Work surfaces shall be decontaminated at least once a day and immediately after any spill of viable material.

(2) Only mechanical pipetting devices shall be used.

(3) Eating, drinking, smoking, storing food, and applying cosmetics are not permitted in the laboratory.

(4) All procedures shall be performed carefully in order to minimize the creation of aerosols.

(b) *Physical Containment—Special Practices.*

(1) Biological materials to be removed from the Class II cabinets or from the maximum containment laboratory in a viable or intact state shall be transferred to a nonbreakable, sealed primary container and then enclosed in a nonbreakable, sealed secondary container which shall be removed from the facility through a disinfectant dunk tank, fumigation chamber, or an airlock designed for this purpose.

(2) No materials, except for biological materials that are to remain in a viable or intact state, shall be removed from the maximum containment laboratory unless they have been autoclaved or decontaminated before they leave the facility. Equipment or material which might be damaged by high temperatures or steam shall be decontaminated by gaseous or vapor methods in a airlock or chamber designed for this purpose.

(3) Only persons whose presence in the facility or individual laboratory rooms is required for program or support purposes shall be authorized to enter. The supervisor shall have the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory. Access to the facility shall be limited by means of secure, locked doors; accessibility shall be managed by the laboratory director, biohazards control officer, or other person responsible for the physical security of the facility. Before entering, persons shall be advised of the potential biohazards and instructed as to appropriate safeguards for ensuring their safety. Authorized persons shall comply with the instructions and all other applicable entry and exit procedures. A logbook signed by all personnel shall indicate the date and time of each entry and exit. Practical and effective protocols for emergency situations shall be established.

(4) Personnel shall enter and leave the facility only through the clothing change and shower rooms. Personnel shall shower each time they leave the facility. Personnel shall use the airlocks to enter or leave the laboratory only in an emergency.

(5) Street clothing shall be removed in the outer clothing change room and kept there. Complete laboratory clothing, including undergarments, pants, and shirts or jumpsuits, shoes, and gloves, shall be provided and used by all personnel entering the facility. Head covers shall be provided for personnel who do not wash their hair during the exit shower. When leaving the laboratory and before proceeding into the shower area, personnel shall remove their laboratory clothing and store it in a locker or hamper in the inner change room.

(6) When materials that contain organisms containing recombinant DNA molecules or experimental animals are

present in the laboratory or animal rooms, a hazard warning sign incorporating the universal biohazard symbol shall be posted on all access doors. The sign shall identify the agent, list the name of the laboratory director or other responsible person(s), and indicate any special requirements for entering the area (e.g., the need for immunizations or respirators).

(7) Supplies and materials needed in the facility shall be brought in by way of the double-doored autoclave, fumigation chamber, or airlock which is appropriately decontaminated between each use. After securing the outer doors, personnel within the facility shall retrieve the materials by opening the interior doors or the autoclave, fumigation chamber, or airlock. These doors shall be secured after materials are brought into the facility.

(8) An insect and rodent control program shall be in effect.

(9) Materials (e.g., plants, animals, and clothing) not related to the experiment being conducted shall not be permitted in the facility.

(10) Hypodermic needles and syringes shall be used for parenteral injection and aspiration of fluids from laboratory animals and diaphragm bottles. Only needle-locking syringes or disposable syringe-needle units (i.e., needle is integral part of unit) shall be used for the injection or aspiration of fluids containing organisms that contain recombinant DNA molecules. Needles shall not be bent, sheared, replaced in the needle sheath or guard or removed from the syringe following use. The needle and syringe shall be placed in a puncture-resistant container and decontaminated, preferably by autoclaving before discard or reuse. Whenever possible, cannulas shall be used instead of sharp needles (e.g., gavage).

(11) A system shall be set up for reporting laboratory accidents and exposures and employee absenteeism and for the medical surveillance of potential laboratory-associated illnesses. Written records are prepared and maintained. An essential adjunct to such a reporting-surveillance system is the availability of a facility for quarantine, isolation, and medical care of personnel with potential or known laboratory associated illnesses.

(12) Laboratory animals involved in experiments requiring BL4 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 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.

(13) Alternative Selection of Containment Equipment. Experimental procedures involving a host-vector system that provides a one-step higher level of biological containment than that specified can be conducted in the BL4 facility using containment equipment requirements specified for the BL3 level of physical containment. Alternative combinations of containment safeguards are shown in section ____.310.

(c) *Physical Containment—Equipment.* All procedures within the facility with agents assigned to Biosafety Level 4 shall be conducted in the Class III biological safety cabinet (*see* section ____.306) or in Class I or II biological safety cabinets used in conjunction with one-piece positive pressure personnel suits ventilated by a life-support system.

(d) *Physical Containment—Laboratory Facilities.*

(1) The maximum containment facility shall consist of either a separate building or a clearly demarcated and isolated zone within a building. Outer and inner change rooms separated by a shower shall be provided for personnel entering and leaving the facility. A double-doored autoclave, fumigation chamber, or ventilated airlock shall be provided for passage of those materials, supplies, or equipment which are not brought into the facility through the change room.

(2) Walls, floors, and ceilings of the facility shall be constructed to form a sealed internal shell which facilitates fumigation and is animal and insect proof. The internal surfaces of this shell shall be resistant to liquids and chemicals, thus facilitating cleaning and decontamination of the area. All penetrations in these structures and surfaces shall be sealed. Any drains in the floors contain traps shall be filled with a chemical disinfectant of demonstrated efficacy against the target agent, and they shall be connected directly to the liquid waste decontamination system. Sewer and other ventilation lines shall contain HEPA filters.

(3) Internal facility appurtenances, such as light fixtures, air ducts, and utility pipes, shall be arranged to minimize the horizontal surface area on which dust can settle.

(4) Bench tops shall have seamless surfaces which are impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat.

(5) Laboratory furniture shall be of simple and sturdy construction, and spaces between benches, cabinets, and equipment shall be accessible for cleaning.

(6) A foot, elbow, or automatically operated hand-washing sink shall be provided near the door of each laboratory room in the facility.

(7) If there is a central vacuum system, it shall not serve areas outside the facility. In-line HEPA filters shall be placed as near as practicable to each use point or service cock. Filters shall be installed to permit in-place decontamination and replacement. Other liquid and gas services to the facility shall be protected by devices that prevent backflow.

(8) If water fountains are provided, they shall be foot operated and located in the facility corridors outside the laboratory. The water service to the fountain shall not be connected to the backflow-protected distribution system supplying water to the laboratory areas.

(9) Access doors to the laboratory shall be self-closing and lockable.

(10) All windows shall be breakage resistant.

(11) A double-doored autoclave shall be provide for decontaminating materials passing out of the facility. The autoclave door which opens to the area external to the facility shall be sealed to the outer wall and automatically controlled so that the outside door can only be opened after the autoclave "sterilization" cycle has been completed.

(12) A pass-through dunk tank, fumigation chamber, or an equivalent decontamination method shall be provided so that materials and equipment that cannot be decontaminated in the autoclave can be safely removed from the facility.

(13) Liquid effluents from laboratory sinks, biological safety cabinets, floors, and autoclave chambers shall be decontaminated by heat treatment before being released from the maximum containment facility. Liquid wastes from shower rooms and toilets shall be decontaminated with chemical disinfectants or by heat in the liquid waste decontamination system. The procedure used for heat decontamination of liquid wastes shall be evaluated mechanically and biologically by using a recording thermometer and an indicator microorganism with a defined heat susceptibility pattern. If liquid wastes from the shower room are decontaminated with chemical disinfectants, the chemical used shall be of demonstrated efficacy against the target or indicator microorganisms.

(14) An individual supply and exhaust air ventilation system shall be provided. The system shall maintain pressure differentials and directional airflow as required to assure flows inward from areas outside of the facility toward areas of highest potential risk within the facility. Manometers shall be used to sense pressure differentials between adjacent areas maintained at different pressure levels. If a system malfunctions, the manometers shall sound an alarm. The supply and exhaust airflow shallbe interlocked to assure inward (or zero) airflow at all times.

(15) The exhaust air from the facility shall be filtered through HEPA filters and discharged to the outside so that it is dispersed away from occupied buildings and air intakes. Within the facility, the filters shall be located as near the laboratories as practicable in order to reduce the length of potentially contaminated air ducts. The filter chambers shall be designed to allow in situ decontamination before filters are removed and to facilitate certification testing after they are replaced. Coarse filters and HEPA filters shall be provided to treat air supplied to the facility in order to increase the lifetime of the exhaust HEPA filters and to protect the supply air system should air pressures become unbalanced in the laboratory.

(16) The treated exhaust air from Class I and II biological safety cabinets can be discharged into the laboratory room environment or the outside through the facility air exhaust system. If exhaust air from Class I or II biological safety cabinets is discharged into the laboratory, the cabinets shall be tested and certified at 6-month intervals. The treated exhaust air from Class III biological safety cabinets shall be discharged, without recirculation through two sets of HEPA filters in series, via the facility exhaust air system. If the treated exhaust air from any of these cabinets is discharged to the outside through the facility exhaust air system, it shall be connected to this system in a manner (e.g., thimble unit connection) that avoids and interference with the air balance of the cabinets or the facility exhaust air system.

(17) A specically designed suit area shall be provided in the facility. Personnel who enter this area shall wear a one-piece positive pressure suit that is ventilated by a life-support system. The life-support system includes alarms and emergency backup breathing air tanks. Entry to this area shall be through an airlock fitted with airtight doors. A chemical shower shall be provided to decontaminate the surface of the suit before the worker leaves the area. The exhaust air from the suit area shall be filtered by two sets of HEPA filter installed in series. A duplicate filtration unit, exhaust fan, and an automatically starting emergency power source shall be provided. The air pressure with the suit area shall be lower than than that of any adjacent area. Emergency lighting and commumications systems are provided. All penetrations into the internal shell of the suit area shall be sealed. A double-doored autoclave shall be provided for decontaminating waste materials to be removed from the suit area.

____.306 Supplementary Information Relating to Biosafety Levels.

Biological safety cabinets referred to in this section are classified as Class I, Class II, or Class III cabinets.

(a) A Class I is a ventilated cabinet for personnel protection having an inward flow of air away from the operator. The exhaust air from this cabinet is filtered through a high-efficiency particulate air (HEPA) filter. This cabinet is used in three operational modes: (1) With a full-width open front, (2) with an installed front closure panel (having four 8-inch diameter openings) without gloves, and (3) with an installed front closure panel equipped with arm-length rubber gloves. The face velocity of the inward flow of air through the full-width open front is 75 feet per minute or greater.

(b) A Class II cabinet is a ventilated cabinet for personnel and product protection having an open front with inward air flow for personnel protection, and HPEA filtered mass recirculated air flow for product protection. The cabinet exhaust air is filtered through a HEPA filter. The face velocity of the inward flow of air through the full-width open front is 75 feet per minute or greater. Design and performance specifications for Class II cabinets have been adopted by the National Sanitation Foundation, Ann Arbor, Michigan.

(c) A Class III cabinet is a closed front ventilated cabinet of gas-tight construction which provides the highest level of personnel protection of all biohazard safety cabinets. The interior of the cabinet is protected from contaminants exterior to the cabinet. The cabinet is fitted with arm-length rubber gloves and is operated under a negative pressure of at least 0.5 inches water guage. All supply air is filtered through HEPA Filters. Exhaust air is filtered through two HEPA filters or one HEPA filter and incinerator before being discharged to the outside environment. National Sanitation Foundation Standard 49, 1986. Class II (Laminar Flow) Biohazard Cabinetry, Ann Arbor, Michigan

____.307 Biological Containment-Levels.

(a) *General Considerations.* In consideration of biological containment for organisms modified by rDNA or rRNA, 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 is to provide biological containment must be chosen or constructed so that the following types of "escape" are minimized: (1) survival of the vector in its host outside the laboratory, and (2) transmission of the vector from the propagation host to other nonlaboratory hosts.

(b) *Levels Established.* 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.

(1) *HV1.* A host-vector system which provides a moderate level of containment. Specific systems are:

(i) EK1. The host is always E. coli K-12 or a derivative thereof, and the vectors include nonconjugative plasmids (e.g., pSC101, ColE1, or derivatives thereof (1-7) and variants of bacteriophage, such as lambda (8-15). The E. coli K-12 hosts shall not contain conjugation-proficient plasmids, whether autonomous or integrated, or generalized transducing phages.

(ii) Other HV1. Hosts and vectors shall be, at a minimum, comparable in containment to E. coli K-12 with a non-conjugative plasmid or bacteriophage vector. The data to be considered and a mechanism for approval of such HV1 systems are described below (Appendix I-II).

(2) *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 INA to other organisms should be less than 1/10 G58 under specified conditions. Specific systems are:

(i) 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 survial of the original host or

as a consequence of transmission of the cloned DNA fragment.

(ii) 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: (A) as a prophage (in the inserted or plasmid form) in the laboratory host used for phage propagation or (B) by suriving in natural environments and transferring a cloned DNA fragment to other hosts (or their resident prophages).

____.308 Biological Containment—Certification of Host-Vector Systems.

(a) *Responsibility.*

(1) HV1 systems other than E. coli K-12 and HV2 host-vector systems may not be designated as such until they have been certified by the USDA. Application for certification of a host-vector system shall be made by written application to OAB.

(2) Host-vector systems that are proposed for certification will be reviewed by the ABRAC. The Assistant Secretary for Science and Education is responsible for certification.

(3) When new host-vector systems are certified, notice of the certification will be sent ABRAC, 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 OAB at any time.

(4) The Assistant Secretary for Science and Education may at any time rescind the certification of any host-vector system. If certification of a host-vector system is rescinded, USDA will instruct investigators to transfer cloned DNA into a different system or use the clones at a higher physical containment level unless USDA determines that the already constructed clones incorporate adequate biological containment.

(5) 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 the Assistant Secretary for Science and Education. 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. Substantial modifications of a certified system require the submission of complete testing data.

(b) *Data to be Submitted for Certification.*

(1) *HV1 Systems Other than E. coli K-12.* The following types of data shall be submitted, modified as appropriate for the particular system under consideration: (i) a description of the organism and vector including the strain's natural habitat and growth requirements, its physiological properties (particularly those related to its reproduction and survival), and the mechanisms by which it exchanges genetic information, the range of organisms with which this organism normally exchanges genetic information and what sort of information is exchanged, and 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; and (iii) a general description of the range of experiments contemplated with emphasis on the need for developing such an HV1 system.

(2) *HV2 Systems.* Investigators planning to request HV2 certification for host-vector systems can obtain instuctions from OAB concerning data to be submitted (14–15). 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) quantitative 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 nonpermissive laboratory conditions designed to represent the relevant natural environment; (iv) data or transmissibility of the vector and/or a cloned DNA fragment under both permissive and nonpermissive conditions; (v) data on all other properties of the system which affect containment and utility, including information on yields of phage or plasmid molecules, ease of DNA isolation, and ease of transfection or transformation; and (vi) in some cases, the investigator may be asked to submit data on survival and vector transmissibility from experiments in which the host-vector is fed to laboratory animals and human subject., Such in vivo data may be required to confirm the validity of predicting in vivo survival on the basis of in vitro experiments.

(3) *Submission to be in Writing.* Data must be submitted in writing to USDA. Investigators are encouraged to publish their data on the construction, properties, and testing of proposed HV2 systems prior to consideration of the system by the ABRAC and its subcommittee. More specific instructions concerning the type of data to be submitted to USDA for proposed EK2 systems involving either plasmids or bacteriophage in E. coli K-12 are available from OAB.

____. 309 Certified Host-Vector Systems.

While many experiments using *E. coli* K-12, Saccharomyces cerevisiae and Bacillus subtilis are currently exempt from the Guidelines under section ____. 202-3, some derivatives of these host-vector systems were previously classified as HV1 or HV2. A listing of those systems follows:

(a) *Bacillus subtilis.*

(1) HV1. The following plasmids are accepted as the vector components of certified *B. subtilis* HV1 systems: pUB110, pC194, pS194, pSA2100, pE194, pT127, pC221, pC223, and pAB124. *B. subtilis* strains RUB 331 and BGSC 1S53 have been certified as the host component of HV1 systems based on these plasmids.

(2) HV2d. The asporogenic mutant derivative of Bacillus subtillis, ASB 298, with the following plasmids as the vector component: pUB110, pC194, pS194, pSA2100, pE194, pT127, pUB112, pC221, pC223, and pAB124.

(b) *Saccharomyces cerevisiae.* HV2. The following sterile strians of *Saccharomyces cerevisiae,* all of which have the ste-VC9 mutation, SHY1, SYY2, SHY3, and SHY4. The following plasmids are certified for use: Y1p1, YEp2, YEp4, YEp6, YRp7, Yep20, YEp21, YEp24, YIp25, YIp26, YIp27, YIp28, YIp29, YIp30, YIp31, YIp32, and YIp33.

(c) *Escherichia coli.*

(1) EK2 Plasmid Systems. The E. coli K-12 strain chi-1776. The following plasmids are certified for use: pSC101, pMB9, pBR313, pBR322, pDH24, pBR325, pBR327, pGL101, pHB1. The following E. coli/S. cerevisiae hybrid plasmids are certified as EK2 vectors when used in E. coli chi-1776 or in the sterile yeast strains, SHY1, SHY2, SHY3, and SHY4; yIp1, YEp2, YEp4, YIp5, YEp6, YRp7, YEp20, YEp21, YEp24, YIp25, YIp26, YIp27, YIp28, YIp29, YIp30, YIp31, YIp32, YIp33.

(2) EK2 Bacteriophage Systems. The following are certified EK2 systems based on bacteriophage lambda:

Vector	Host
gtWES B	DP50supF.
gt WES B	DP50supF.
gtZJvir. B	E. coli K-12
gt ALO B	DP50supF.
Charon 3A	DP50 or DP50supF.
Charon 4A	DP50 or DP50supF.
Charon 16A	DP50 or DP50supF.

Vector	Host
Charon 21A	DP50supF.
Charon 23A	DP50 or DP50supF.
Charon 24A	DP50 or DP50supF.

(3) E. coli K-12 strains chi-2447 and chi-2281 are certified for use with lambda vectors that are certified for use with strain DP50 or DP50supF provided that the su strain not be used as a propagation host.

(d) *Neurospora crassa.* HV1. The following specified strains of Neurospora crassa which have been modified to prevent aerial dispersion:

(1) Inl (inositolless) strains 37102, 37401, 46316, 64001, and 89601.

(2) Csp-1 strain UCLA37 and csp-2 strains FS 590, UCLA101 (these are conidial separation mutants).

(3) Eas strain UCLA191 (an "easily wettable" mutant).

(e) *Streptomyces.* HV1. The following Streptomyces species: Streptomyces coelicolor, S. lividans, S. parvulus, and S. griseus. The following are accepted as vector components of certified Streptomyces HV1 systems; Streptomyces plasmids SCP2, SLP1.2, pIJ101, actinophage phi C31, and their derivatives.

(f) *Pseudomonas putida.* HV1. Pseudomonas putida strain KT2440 with plasmid vectors pKT262, pKT263, and pKT264.

____.310 Alternate Combinations of Physical and Biological Containment. The following table sets forth alternate combinations of physical and biological containment:

TABLE 1.—POSSIBLE ALTERNATE COMBINATIONS OF PHYSICAL AND BIOLOGICAL CONTAINMENT SAFEGUARDS

Classification of physical and biological containment	Alternate physical containment			Alternate biological containment
	Laboratory facilities	Laboratory practices	Containment equipment	
BL3/HV2	BL3	BL3	BL3	HV2
	BL3	BL3	BL4	HV1
BL3/HV1	BL3	BL3	BL3	HV1
	BL3	BL3	BL2	HV2
BL4/HV1	BL4	BL4	BL4	HV1
	BL4	BL4	BL3	HV2

____.311 Research Involving Nonmicroscopic Animals—General.

(a) *Introduction.* Research covered under this section includes all agricultural biotechnology research involving nonmicroscopic animals. The principal purpose of animal containment is to prevent unintentional transmission of the recombinant DNA. Two categories of research are covered. First, research intending to modify the germ line is covered in sections ____.312 to ____.316, Second, research not intending to modify the germ line is covered in section ____.317.

(b) *Transport of Nonmicroscopic Animals.* Any genetically engineered animal can be used for experimentation at the entity of origin or at other entities. If animals are to be transported from one institution to another, the IBC at the entity of origin must approve the transport of animals, and the receiving investigator at another entity must obtain IBC approval from his or her entity to receive the animals. Method of transport will conform to appropriate State and Federal regulations.

(c) *Disposal of Nonmicroscopic Animals.* When a genetically engineered animal is sacrificed or dies, the carcass must be incinerated or otherwise destroyed to prevent its use as food for human beings or for domestic animals. A permanent record must be maintained of the experimental use and disposal of each genetically engineered animal.

____.312 Nonmicroscopic Animals in which the Germ Line is Modified—NABS 1.

(a) This level applies to work with rDNA which is only transmissible by sexual reproduction.

(b) Containment of genetically engineered nonmicroscopic animals at NABS level 1 is designed to prevent sexual transmission of the modified genome.

(c) Normal females into which genetically engineered embryos have been transplanted must be contained to minimize the possibility of theft or unintentional release of the pregnant animal.

(d) All genetically engineered neonates will be permanently marked within 72 hours after birth.

(2) Genetically engineered animals will be held under conditions designed to minimize the possibility of theft or unintentional release. The containment areas will be key locked and patrolled or monitored at frequent intervals. Access to animals will be limited to authorized personnel.

(f) Sexually mature nonmicroscopic animals will be held in facilities designed to prevent unintentional transmission of the recombinant DNA by sexual reproduction. These facilities will include double barriers as appropriate between males and females. Reproductive incapacitation can be utilized if needed.

____.313 Nonmicroscopic Animals in which the Germ Line is Modified—NABS 2.

(a) This level applies to work with rDNA which is transmissible by sexual reproduction and possibly by arthropod transmission.

(b) Containment of genetically engineered nonmicroscopic animals at NABS level 2 is designed to prevent sexual transmission as described in NABS 1 and also to prevent arthropod-borne vectors from transmitting self-replicating recombinant DNA material.

(c) The agent used shall not require higher than BL2 (*see* section ____.303) for its cultivation.

(d) Containment is the same as for NABS 1 plus isolation of the nonmicroscopic animal(s) from arthropods. This may be achieved by appropriate screening and other insect control programs.

(e) Other precautions described by BL2 (*see* section ____.303) are applicable to NABS 2.

____.314 Nonmicroscopic Animals in Which the Germ Line is Modified—NABS 3 and 4: General Requirements.

(a) These levels cover the use of agents for which these Guidelines require BL3 or BL4, respectively, for research in conjunction with nonmicroscopic animals.

(b) The IBC (*see* sections ____.403 and ____.404) after considering both transmissibility and infectious risk of the agents, will assign the appropriate NABS level.

(c) Work with Class 5 organisms requires containment specified by the USDA-APHIS permit for the organism.

____.315 Nonmicroscopic Animals in Which the Germ Line is Modified—NABS 3.

(a) Containment of genetically engineered nonmicroscopic animals at NABS 3 is designed to prevent transmission of rDNA by sexual reproduction, by arthropod vectors, or other infectious releases.

(b) The principle determining the NABS 3 level is infectious transmission of genetic material through animal waste or an aerosol.

(c) NABS 3 containment will prevent escape of genetically engineered material from exhaust air or waste materials from the containment zone. At this containment level, the animal room becomes the primary barrier. Conditions described for BL3 should be followed.

(d) Exhaust air from NABS level 3 containment zone must be double High Efficiency Particulate Air Filter (HEPA) filtered or incinerated before release to atmosphere. A HEPA filter must be installed in the inlet air ventilation system. The Heating Ventilation Air Conditioning (HVAC) supply and exhaust ducts and filter housing must

have no air loss in one-half hour at 3" of water gauge pressure, or pass a halogen test with a leak rate of less than .0001 cc/sec at 3" water gauge pressure.

(e) A double-doored interlocked steam and/or ethylene oxide sterilizer is required and positioned to allow removal of sterilized material from the facility.

(f) Liquid effluent from laboratory sinks, biological safety cabinets, floor drains, and sterilizers is decontaminated by heat treatment before being released from the containment facility. Liquid wastes from shower rooms and toilets may be decontaminated with chemical disinfectants or by heat in the liquid waste decontamination system. The procedure used for heat decontaminations of liquid wastes is to be monitored with a recording thermometer and the waste is to be monitored for biological activity by introducing an appropriate indicator microorganism with a defined heat susceptibility pattern and culturing samples of treated waste for presence of the organism. If liquid wastes from the shower room are decontaminated with chemical disinfectants, the chemical used is of demonstrated efficiency against the target or indicator microorganisms.

(g) The animal room must have an air leak rate (decay rate) not to exceed 7% per minute (logorithm of pressure against time) over a 20-minute period at 2" of water gauge pressure. Nominally, 0.05" of water gauge pressure loss in 1 minute at 2" of water gauge pressure.

(h) All animals must be sacrificed at the end of their experimental usefulness and the carcasses shall be incinerated or sterilized. Documents regarding animal experimental use and disposal shall be maintained in a permanent log book.

(i) Personnel shall enter and leave the facility only through the clothing change and shower rooms. Street clothing shall be removed in the outer clothing change room and kept there. Complete laboratory clothing, including undergarments, pants, and shirts or jumpsuits, shoes, and gloves, shall be provided and used by all personnel entering the facility. When leaving the NABS level 3 zone and before proceeding into the shower area, personnel shall remove their laboratory clothing in the inner change room and with appropriate discard for sterilization. Personnel shall shower each time they leave the facility. Personnel shall use the airlocks to enter or leave the laboratory only in an emergency.

(j) Personnel entering the animal containment zone must use the appropriate respiratory protective device(s).

(k) A hazard warning sign incorporating the universal biohazard symbol shall be posted on all access doors. The sign shall identify the agent, lists the name of the laboratory director or other responsible person(s), and indicates any special requirements for entering the area (e.g., the need for immunizations, respirators, or other special protective clothing).

(l) Restraining devices for animals are required to prevent damage to the integrity of the containment facility.

____.316 Nonmicroscopic Animals in Which the Germ Line is Modified—NABS 4.

(a) Containment of genetically engineered nonmicroscopic animals at NABS 4 is designed to prevent transmission through the vectors stated for NABS 3 when the source of rDNA comes from a Class 4 infectious agent or from certain restricted Class 5 animal pathogens.

(b) Facility features described for BL4 are applicable for NABS 4 animal containment.

(c) Based on pathogenicity of the agent, the IBC may stipulate use of a one-piece, positive pressure suit that is ventilated by a life-support system for all personnel entering the containment area.

(d) NABS 4 requires more restrictive sealing of the penetrations of the containment zone from the outside that does NABS 3.

____.317 Nonmicroscopic Animals used for Biotechnology Research in Which the Germline has not Been Modified.

Nonmicroscopic animals in which rDNA was inserted into a cell genome, but where the genetic material is excluded from the germ line, should be housed and managed at least at NABS 1.

____.318 Research Involving Nonmicroscopic Plants.

(a) Conditions are described for growing nonmicroscopic plants which have been genetically modified by recombinant DNA.

(b) Such plants should be destroyed at the termination of the experiment and should not be used as food or feed for animals or humans.

____.319 Research With Nonmicroscopic Plants in Laboratory-Contained Facilities and Greenhouses.

(a) Where the Guidelines specify growth of plants under BL1 or BL2 conditions, containment practices described in sections ____.302 through ____.306 of these Guidelines shall be followed.

(b) Questions on interpretation of the procedures shall be addressed to USDA.

____.320 Research With Crop Plants in Field Tests.

This section describes principals of containment to prevent dispersal and escape of the introduced gene via pollen, seeds, and vegetative propagules. Gene escape via a sexual transfer is not expected to occur and will not be considered. Provisions are addressed in section ____.205(c) for requesting approval of field tests with certain genetically engineered plants.

(a) *Containment for Gene Escape via Pollen.*

(1) Gene escape by pollen dispersal can be eliminated by growing the genetically engineered crop in geographical isolation from any plants with which it is biologically compatible and will cross-pollinate.

(2) Physical isolation can be achieved by removing all cross-compatible plants within the known effective pollinating distance of the particular species.

(3) Production of viable pollen can be prevented biologically by using genetic male sterility in some crops, chemically by application of a gametocide, or physically by removing all reproductive structures.

(4) Pollen escape can be prevented by blocking pollen dispersal by covering the flowers or by screening out known pollinating insects.

The mechanism of containment chosen shall depend on the particular crop.

(b) *Prevention of Seed Development or Release.*

(1) Seed set can be prevented biologically by utilizing self-incompatible plants or by eliminating pollen from biologically-compatible plants within the pollinating distance.

(2) Seed release during intentional seed development can be physically contained by encasing the developing seed structures soon after pollination. This provides additional protection from seed dispersal by animals or birds.

(c) *Prevention of Vegetative Propagule Escape.* Stolons, tubers, rhizomes, or storage roots can be recovered from the soil mechanically, followed by chemical soil sterilization and herbicidal treatment of volunteer plants the following season.

____.321 Physical Containment for Large-Scale Uses of Organisms Containing Recombinant DNA Molecules.

This part of the Guidelines specifies physical containment guidelines for large-scale (greater than 10 liters of

culture) research or production involving viable organisms containing recombinant DNA molecules.

(a) *General Applicability of the Guidelines.* All provisions of the Guidelines shall apply to large-scale agricultural research or production activities with the following modifications:

(1) Section ____.321 shall replace sections ____.302 through ____.306 when quantities in excess of 10 liters of culture are involved in research or production.

(2) The entity shall appoint a Biological Safety Officer (BSO) if it engages in large-scale agricultural research or production activities involving viable organisms containing recombinant DNA molecules. The duties of the BSO shall include those specified in section ____.405 of the Guidelines.

(3) The entity shall establish and maintain a health surveillance program for personnel engaged in large-scale agricultural research or production activities involving viable organisms containing recombinant DNA molecules which require BL3 containment at the laboratory scale. The program shall include: preassignment and periodic physical and medical examinations; collection, maintenance and analysis of serum specimens for monitoring serologic changes that may result from the employee's work experience; and provisions for the investigation of any serious, unusual or extended illnesses of employees to determine possible occupational origin.

(b) *Selection of Physical Containment Levels.* (1) The selection of the physical containment level required for recombinant DNA research or production involving more than 10 liters of culture is based on the containment guidelines established in subpart ____.3 of the Guidelines.

(2) For purposes of large-scale research or production, three physical containment levels are established. These are referred to as BL1-LS, BL2-LS, and BL3-LS. The BL-LS level of physical containment is required for large-scale research or production of viable organisms containing recombinant DNA molecules which require BL1 containment at the laboratory scale.

(3) The BL1-LS level of physical containment is recommended for large-scale research or production of viable organisms for which BL1 is recommended at the laboratory scale such as those described in section ____.202-3.

(4) The BL2-LS level of physical containment is required for large-scale research or production of viable organisms containing recombinant DNA molecules which require BL2 containment at the laboratory scale.

(5) The BL3-LS level of physical containment is required for large-scale research or production of viable organisms containing recombinant DNA molecules which require BL3 containment at the laboratory scale.

(6) No provisions are made for large-scale research or production of viable organisms containing recombinant DNA molecules which require BL4 containment at the laboratory scale. If necessary, these requirements will be established by USDA on an individual basis.

(c) *BL1-LS Level.*

(1) Cultures of viable organisms containing recombinant DNA molecules shall be handled in a closed system (e.g., closed vessel used for the propagation and growth of cultures) or other primary containment equipment (e.g., biological safety cabinet containing a centrifuge used to process culture fluids) which is designed to reduce the potential for escape of viable organisms. Volumes less than 10 liters may be handled outside of a closed system or other primary containment equipment provided all physical containment requirements specified in section ____.302 of the Guidelines are met.

(2) Culture fluids (except as allowed in paragraph (3)) shall not be removed from a closed system or other primary containment equipment unless the viable organisms containing recombinant DNA molecules have been inactivated by a validated inactivation procedure. A validated inactivation procedure is one which has been demonstrated to be effective using the organism that will serve as the host for propagating the recombinant DNA molecules.

(3) Sample collection from a closed system, the addition of materials to a closed system, and the transfer of culture fluids from one closed system to another shall be done in a manner which minimizes the release of aerosols or contamination of exposed surfaces.

(4) Exhaust gases removed from a closed system or other primary containment equipment shall be treated by filters which have efficiencies equivalent to HEPA filters or by other equivalent procedures (e.g., incineration) to minimize the release of viable organisms containing recombinant DNA molecules to the environment.

(5) A closed system or other primary containment equipment that has contained viable organisms containing recombinant DNA molecules shall not be opened for maintenance or other purposes unless it has been sterilized by a validated sterilization procedure. A validated sterilization procedure is one which has been demonstrated to be effective using the organism that will serve as the host for propagating the recombinant DNA molecules.

(6) Emergency plan required by section ____.404(c)(4) shall include methods and procedures for handling large losses of culture on an emergency basis.

(d) *BL2-LS Level.*

(1) Cultures of viable organisms containing recombinant DNA molecules shall be handled in a closed system (e.g., closed vessel used for the propagation and growth of cultures) or other primary containment equipment (e.g., Class III biological safety cabinet containing a centrifuge used to process culture fluids) which is designed to prevent the escape of viable organisms. Volumes less than 10 liters may be handled outside of a closed system or other primary containment equipment provided all physical containment requirements specified in section ____.303 of the Guidelines are met.

(2) Culture fluids (except as allowed in paragraph (3)) shall not be removed from a closed system or other primary containment equipment unless the viable organisms containing recombinant DNA molecules have been inactivated by a validated inactivation procedure. A validated inactivation procedure is one which has been demonstrated to be effective using the organism that will serve as the host for propagating the recombinant DNA molecules.

(3) Sample collection from a closed system, the addition of materials to a closed system, and the transfer of culture fluids from one closed system to another shall be done in a manner which prevents the release of aerosols or contamination of exposed surfaces.

(4) Exhaust gases removed from a closed system or other primary containment equipment shall be treated by filters which have efficiencies equivalent to HEPA filters or by other equivalent procedures (e.g., incineration) to prevent the release of viable organisms containing recombinant DNA molecules to the environment.

(5) A closed system or other primary containment equipment that has contained viable organisms containing recombinant DNA molecules shall not be opened for maintenance or other purposes unless it has been sterilized by a validated sterilization procedure. A validated sterilization procedure is one which has been demonstrated to be effective using the organism that will

serve as the host for propagating the recombinant DNA molecules.

(6) Rotating seals and other mechanical devices directly associated with a closed system used for the propagation and growth of viable organisms containing recombinant DNA molecules shall be designed to prevent leakage or shall be fully enclosed in ventilated housings that are exhausted through filters which have efficiencies equivalent to HEPA filters or through other equivalent treatment devices.

(7) A closed system used for the propagation and growth of viable organisms containing recombinant DNA molecules and other primary containment equipment used to contain operations involving viable organisms containing recombinant DNA molecules shall include monitoring or sensing devices that monitor the integrity of containment during operations.

(8) A closed system used for the propagation and growth of viable organisms containing recombinant DNA molecules shall be tested for integrity of the containment features using the organism that will serve as the host for propagating recombinant DNA molecules. Testing shall be accomplished prior to the introduction of viable organisms containing recombinant DNA molecules and following modification or replacement of essential containment features. Procedures and methods used in the testing shall be appropriate for the equipment design and for recovery and demonstration of the test organism. Records of tests and results shall be maintained on file.

(9) A closed system used for the propagation and growth of viable organisms containing recombinant DNA molecules shall be permanently identified. This identification shall be used in all records reflecting testing, operation, and maintenance and in all documentation relating to use of this equipment for research or production activities involving viable organisms containing recombinant DNA molecules.

(10) The universal biohazard sign shall be posted on each closed system and primary containment equipment when used to contain viable organisms containing recombinant DNA molecules.

(11) Emergency plans required by section ____.404(c)(4) shall include methods and procedures for handling large losses of culture on an emergency basis.

(e) *BL3-LS Level.*

(1) Cultures of viable organisms containing recombinant DNA molecules shall be handled in a closed system (e.g., closed vessels used for the propagation and growth of cultures) or other primary containment equipment (e.g., Class III biological safety cabinet containing a centrifuge used to process culture fluids) which is designed to prevent the escape of viable organisms. Volumes less than 10 liters may be handled outside of a closed system provided all physical containment requirements specified in section ____.304 of the Guidelines are met.

(2) Culture fluids (except as allowed in paragraph (3)) shall not be removed from a closed system or other primary containment equipment unless the viable organisms containing recombinant DNA molecules have been inactivated by a validated inactivation procedure. A validated inactivation procedure is one which has been demonstrated to be effective using the organisms that will serve as the host for propagating the recombinant DNA molecules.

(3) Sample collection from a closed system, the addition of materials to a closed system, and the transfer of culture fluids from one closed system to another shall be done in a manner which prevents the release of aerosols or contamination of exposed surfaces.

(4) Exhaust gases removed from a closed system or other primary containment equipment shall be treated by filters which have efficiencies equivalent to HEPA filters or by other equivalent procedures (e.g., incineration to prevent the release of viable organisms containing recombinant DNA molecules to the environment.)

(5) A closed system or other primary containment equipment that has contained viable organisms containing recombinant DNA molecules shall not be opened for maintenance or other purposes unless it has been sterilized by a validated sterilization procedure. A validated sterilization procedure is one which has been demonstrated to be effective using the organisms that will serve as the host for propagating the recombinant DNA molecules.

(6) A closed system used for the propagation and growth of viable organisms containing recombinant DNA molecules shall be operated so that the space above the culture level will be maintained at a pressure as low as possible, consistent with equipment design, in order to maintain the integrity of containment features.

(7) Rotating seals and other mechanical devices directly associated with a closed system used to contain viable organisms containing recombinant DNA molecules shall be designed to prevent leakage or shall be fully enclosed in ventilated housings that are exhausted through filters which have efficiencies equivalent to HEPA filters or through other equivalent treatment devices.

(8) A closed system used for the propagation and growth of viable organisms containing recombinant DNA molecules and other primary containment equipment used to contain operations involving viable organisms containing recombinant DNA molecules shall include monitoring or sensing devices that monitor the integrity of containment during operations.

(9) A closed system used for the propagation and growth of viable organisms containing recombinant DNA molecules shall be tested for integrity of the containment features using the organisms that will serve as the host for propagating the recombinant DNA molecules. Testing shall be accomplished prior to the introduction of viable organisms containing recombinant DNA molecules and following modification or replacement of essential containment features. Procedures and methods used in the tests shall be appropriate for the equipment design and for recovery and demonstration of the test organism. Records of tests and results shall be maintained on file.

(10) A closed system used for the propagation and growth of viable organisms containing recombinant DNA molecules shall be permanently identified. This identification shall be used in all records reflecting testing, operation, and maintenance and in all documentation relating to the use of this equipment for research production activities involving viable organisms containing recombinant DNA molecules.

(11) The universal biohazard sign shall be posted on each closed system and primary containment equipment when used to contain viable organisms containing recombinant DNA molecules.

(12) Emergency plans required by section ____.404(c)(4) shall include methods and procedures for handling large losses of culture on an emergency basis.

(13) Closed systems and other primary containment equipment used in handling cultures of viable organisms containing recombinant DNA molecules shall be located within a controlled area which meets the following requirements:

(i) The controlled area shall have a separate entry area. The entry area shall be a double-doored space such as an air lock, anteroom, or change room that separates the controlled area from the balance of the facility.

(ii) The surfaces of walls, ceilings, and floors in the controlled area shall be such as to permit ready cleaning and decontamination.

(iii) Penetrations into controlled area shall be sealed to permit liquid or vapor phase space decontamination.

(iv) All utilities and service or process piping and wiring entering the controlled area shall be protected against contaminations.

(v) Hand-washing facilities equipped with foot, elbow, or automatically operated valves shall be located at each major work area and near each primary exit.

(vi) A shower facility shall be provided. This facility shall be located in close proximity to the controlled area.

(vii) The controlled area shall be designed to preclude release of culture fluids outside the controlled area in the event of an accidental spill or release from the closed systems or other primary containment equipment.

(viii) The controlled area shall have a ventilation system that is capable of controlling air movement. The movement of air shall be from areas of lower contamination potential to areas of higher contamination potential. If the ventilation system provides positive pressure supply air, the system shall operate in a manner that prevents the reversal of the direction of air movement or shall be equipped with an alarm that would be actuated in the event that reversal in the direction of air movement were to occur. The exhaust air from the controlled area shall not be recirculated to other areas of the facility. The exhaust air from the controlled area may be discharged to the outdoors without filtration or other means for effectively reducing an accidental aerosol burden provided that it can be dispersed clear of occupied buildings and air intakes.

(14) The following personnel and operational practices shall be required:

(i) Personnel entry into the controlled area shall be through the entry area specified in section ____.321(e)(13)(i).

(ii) Persons entering the controlled area shall exchange or cover their personal clothing with work garments such as jumpsuits, laboratory coats, pants and shirts, hair cover, and shoes or shoe covers. On exit from the controlled area the work clothing may be stored in a locker separate from that used for personal clothing or discarded for laundering. Clothing shall be decontaminated before laundering.

(iii) Entry into the controlled area during periods when work is in progress shall be restricted to those persons required to meet program or support needs. Prior to entry all persons shall be informed of the operating practices, emergency procedures, and the nature of the work conducted.

(iv) Persons under 18 years shall not be permitted to enter the controlled area.

(v) The universal biohazard sign shall be posted on entry doors to the controlled area and all internal doors when any work involving the organism is in progress. This includes periods when decontamination procedures are in progress. The sign posted on the entry doors to the controlled area shall include a statement of agents in use and personnel authorized to enter the controlled area.

(vi) The controlled area shall be kept neat and clean.

(vii) Eating, drinking, smoking, and storage of food are prohibited in the controlled area.

(viii) Animals and plants shall be excluded from the controlled area.

(ix) An effective insect and rodent control program shall be maintained.

(x) Access doors to the controlled area shall be kept closed, except as necessary for access, while work is in progress. Serve doors leading directly outdoors shall be sealed and locked while work is in progress.

(xi) Persons shall wash their hands when leaving the controlled area.

(xii) Persons working in the controlled area shall be trained in emergency procedures.

(xiii) Equipment and materials required for the management of accidents involving viable organisms containing recombinant DNA molecules shall be available in the controlled area.

(xiv) The controlled area shall be decontaminated in accordance with established procedures following spills or other accidental release of viable organisms containing recombinant DNA molecules.

____.322 *Containment Conditions for Cloning of Genes Coding for the Biosynthesis of Molecules Toxic for Vertebrates.*

(a) *General Information.* This section specifies the containment to be used for the deliberate cloning of genes coding for the biosynthesis of molecules toxic for vertebrates. The cloning of genes coding for molecules toxic for vertebrates that have an LD_{50} of less than 100 nanograms per kilogram body weight (e.g., microbial toxins such as the botulinum toxins, tetanus toxin, diphtheria toxin, Shigella dysenteriae neurotoxin) requires USDA approval before initiation. No specific restrictions shall apply to the cloning of genes if the protein specified by the gene has an LD_{50} of 100 micrograms or more per kilogram of body weight. Experiments involving genes coding for toxic molecules with an LD_{50} of 100 micrograms or less per kilogram body weight shall be registered with USDA prior to initiating the experiments. A list of toxic molecules classified as to LD_{50} is available from USDA. Testing procedures for determining toxicity of toxic molecules not on the list are available from USDA. The results of such tests shall be forwarded to USDA.

(b) *Containment Conditions for Cloning of Toxic Molecule Genes in E. coli K-12.*

(1) Cloning of genes coding for molecules toxic for vertebrates that have an LD_{50} in the range of 100 nanograms to 1000 nanograms per kilogram body weight (e.g., aprin, Clostridium perfringens epsilon toxin) may proceed under BL2+EK2 or BL3+EK1 containment conditions.

(2) Cloning of genes for the biosynthesis of molecules toxic for vertebrates that have an LD_{50} in the range of 100 micrograms per kilogram body weight may proceed under BL1+EK1 containment conditions (e.g., Staphylococcus aureus alpha toxin, Staphylococcus aureus beta toxin, ricin, Pseudomonas aeruginosa exotoxin A, Bordatella pertussis toxin, the lethal factor of Bacillus anthracis, the Pasteurella pestis murine toxins, the oxygen-labile hemolysins such as streptolysin O, and certain neurotoxins present in snake venoms and other venoms).

(3) Some enterotoxins are substantially more toxic when administered enternally than parenterally. The following enterotoxins shall be subject to BL1 + EK1 containment conditions: cholera toxin, the heat labile toxins of E. coli, Klebsiella, and other related proteins that may be identified by neutralization with an antiserum monospecific for cholera toxin, and the heat stable toxins of E. coli and of Yersinia enterocolitica.

(c) *Containment Conditions for Cloning of Toxic Molecule Genes in Organisms Other than E. coli K-12.* Requests involving the cloning of genes coding for molecules toxic for vertebrates in host-vector systems other than E. coli K-12 will be evaluated by USDA.

____.323 *Shipment.*

Recombinant DNA molecules contained in an organism or virus shall be shipped only as an etiologic agent under requirements of the U.S. Public Health Service, and the U.S. Department of Transportation (section 72.3, Part 72, Title 42, and sections 173.386-.388, Part 173, Title 49, U.S. Code of Federal Regulations (CFR)) as specified below:

(a) Recombinant DNA molecules contained in an organism or virus

requiring BL1, BL2, or BL3 physical containment, when offered for transportation or transported, are subject to all requirements of section 72.3(a)–(e), Part 72, Title 42 CFR, and sections 173.386–.388, Part 173, Title 49 CFR.

(b) Recombinant DNA molecules contained in an organism or virus requiring BL4 physical containment, when offered for transportation or transported, are subject to the requirements listed above under paragraph (a) above and are also subject to section 72.3(f), part 72, Title 42 CFR.

(c) Information on packaging and labeling of etiologic agents is available from OAB.

(d) A USDA permit, required for import and interstate transport or pathogens, may be obtained from the Animal and Plant Health Inspection Service, USDA, Federal Building, Hyattsville, MD 20782.

Subpart ____.4 Roles and Responsibilities

____.401 Policy.

(a) Responsiblity for safety in agricultural biotechnology research resides to a large degree on the individuals who conduct the research. Every possible situation cannot be anticipated in the Guidelines. Motivation, integrity and good judgment are keys to safe conduct and application of agricultural biotechnology.

(b) The Guidelines are intended to help the entity, institutional biosafety committee (IBC), biological safety officer (BSO), and principal investigator (PI) determine practices that are to be followed. Guideline development is a continuing process over time since all conceivable experiments involving agricultural biotechnology cannot be foreseen. Therefore, it is the responsibility of entities and those conducting research to adhere to the intent as well as to the specifics of the Guidelines.

(c) The entities, the IBCs, and the PIs are responsible for ensuring that agricultural biotechnology activities comply with these Guidelines. The following roles and responsibilities constitute an administrative framework in which safety is an essential and integral part of biotechnology research.

____.402 Responsibilities of the Entity—General Information.

Each entity conducting or sponsoring agricultural biotechnology research covered by these Guidelines shall ensure that research is carried out in conformity with the provisions of the Guidelines. In order to fulfill this responsibility, the entity shall:

(a) Establish and implement policies that provide for the safe conduct of agricultural biotechnology research in compliance with these Guidelines. Entities may establish additional procedures to discharge responsibilities of entities and IBCs under the Guidelines. These may include: (1) statements formulated by the entity for general implementation of the Guidelines and (2) additional precautionary steps the entity may deem appropriate.

(b) Establish or associate with an IBC that meets the requirements set forth in section ____.403 and carries out the functions detailed in section ____.404. If an individual or other small entity lacks the capability of establishing an IBC and is unable to locate an IBC with which to form an association, the individual or other small entity shall contact OAB.

(c) If necessary, appoint a BSO if the entity is engaged in agricultural biotechnology research at the BL3 or BL4 containment level. The BSO shall be a member of the IBC and shall carry out the duties specified in section ____.405.

(d) Require that investigators responsible for research covered by these Guidelines comply with the provisions of section ____.406 and assist investigators to do so.

(e) Ensure appropriate training for the chairperson and members of the IBC, the BSO, PIs, and laboratory staff regarding the Guidelines, their implementation, and laboratory and release safety. Responsibility for training IBC members may be carried out through the IBC chairperson. Responsibility for training laboratory staff may be carried out through the PI. The entity is responsible for insuring that the PI has sufficient training but may delegate this responsibility to the IBC.

(f) Determine the necessity for health or environment surveillance of research personnel and facilities, and conduct surveillance programs if appropriate.

(g) Report within 30 days to the Assistant Secretary for Science and Education any significant problems with or violations of the Guidelines and significant research-related accidents and illnesses or diseases of workers, animals or plants, unless the PI or IBC has done so.

____.403 Membership and Procdures of IBCs.

The IBC shall be maintained by the entity with whom it is primarily associated. The Committee shall meet the following requirements which include or supplement those encompassed in the NIH Guidelines.

(a) The IBC shall include at least eight members.

(b) As a group, IBCs shall include experience and expertise in r-DNA and related technologies and capability to assess safety of research and experimentation with reference to health, environment, and agroecosystems.

(c) IBCs shall include persons with expertise in recombinant DNA technology, biological safety, physical containment, field testing, ecology, and agricultural sciences.

(d) Two or more members of IBCs shall be unaffiliated with the entity, representing the interest of the community, such as—(1) members of state and local public health agencies, (2) members of state and local environmental or agricultural agencies, (3) persons active in human or animal medical and health concerns, and (4) persons active in agricultural environmental concerns. (Employment solely as a member of the IBC does not itself make the member an affiliated members.)

(e) IBCs shall include at least one member of a technical laboratory staff.

(f) IBCs shall include the entity's biological safety officer.

(g) IBCs are encouraged to utilize consultants in institutional policy issues, applicable laws and regulations, standards of professional conduct and practice, community attitudes and the enviornment, and private sector-industry issues.

(h) Meetings of IBCs shall be open to the public, consistent with protection of privacy and proprietary interests. (i) Upon request, entities shall make available to the public all minutes of IBC meetings and any documents submitted to or received from funding agencies which those agencies are authorized to make available to the public. If comments are made by members of the public on IBC actions, entities shall forward to USDA both the comments and IBC responses.

(j) IBC membership shall be reviewed and approved by ABRAC. Entities shall identify committee members by name in a report to ABRAC and shall include relevant information on each member in such form and at such times as may be required.

(k) A member of an IBC may not be involved in the review or approval of a project in which he or she has been or expects to be engaged or has a direct financial interest, except to provide information requested by the IBC.

(l) Except for unaffiliated members, member of an IBC for an entity not otherwise covered by the Guidelines

may participate in the review and approval of a project in which the member has a direct financial interests so long as the member has not been and does not expect to be engaged in the project, notwithstanding paragraph (k) above.

(m) Entities ultimately responsible for the effectiveness of IBCs may establish procedures that IBCs will follow in initial and continuing review of applications, proposals, and activities.

____.404 Functions of Institutional Biosafety Committees.

(a) IBCs are responsible for review of biotechnology research projects for compliance with the USDA Guidelines for Biotechnology Research. IBCs shall approve and register research projects in accordance with the Guidelines and assure the correct classification of research.

(b) IBC review shall include: (1) Assessment of containment levels required by these Guidelines for proposed agricultural research and (2) assessment of facilities, procedures, practices, training, and expertise of research personnel.

(c) IBCs shall: (1) notify PIs of results of their reviews, (2) set containment levels as specified in subpart ____.3, (3) Review periodically agricultural biotechnology research to insure that the requirements of the Guidelines are being fulfilled, and (4) adopt emergency plans covering accidental releases.

(d) IBCs shall report within 30 days to the appropriate institutional official and to OAB any significant problems with or violations of the Guidelines and any significant research-related accidental releases or illnesses and diseases of workers, animals or plants unless the PI has done so.

(e) IBCs may not authorize initiation of experiments not explicitly covered by the Guidelines until USDA establishes the containment requirement.

(f) IBCs may perform other functions as delegated by the entities.

____.405 Biological Safety Officer (BSO).

The entity shall appoint a BSO if it deems one is necessary. The officer shall be a member of the IBC, and his or her duties shall include (but need not be limited to):

(a) Ensuring through periodic inspections that safety standards are rigorously followed;

(b) Reporting to the IBC and the entity all significant problems with and violations of these Guidelines and all significant research-related accidents and illnesses of which the BSO becomes aware unless the BSO determines that the PI has already done so;

(c) Developing emergency plans for dealing with accidents;

(d) Providing advice on security of facilities where agricultural biotechnology research is conducted; and

(e) Providing technical advice to the PI and the IBC on research safety procedures.

____.406 Principal Investigator (PI).

On behalf of the entity, the PI is responsible for complying fully with these Guidelines in conducting any/agricultural biotechnology research.

(a) *PI—General:* As part of his or her responsibilities, the PI shall:

(1) Obtain appropriate approvals and give appropriate notifications prior to initiating, or modifying ongoing research activities;

(2) Determine initially whether experiments are covered by these Guidelines and follow the appropriate procedures;

(3) Report within 30 days to the IBC and OAB all significant problems with and violations of the Guidelines and all significant research-related accidental releases and illnesses or diseases of workers, animals or plants;

(4) Report to the IBC and to OAB new information bearing on the Guidelines;

(5) Be adequately trained in good microbiological and agricultural science techniques;

(6) Adhere to IBC-approved emergency plans for dealing with accidents; and

(7) Comply with applicable shipping requirements of USDA–APHIS regarding plant and animal health protection policies, and the need for permits and containment conditions for possession of certain organisms.

(b) *Submissions by the PI to USDA (Assistant Secretary for Science and Education).* The PI shall:

(1) Submit information to USDA in order to have new host-vector systems certified;

(2) Petition USDA with notice to the IBC for exemptions to these Guidelines;

(3) Petition USDA with concurrence of the IBC for approval to conduct research specified in section ____.205 of the Guidelines; and

(4) Petition USDA for determination of containment for agricultural research experiments which require review on an individual basis for experiments not covered by the Guidelines.

(c) *Submissions by the PI to the IBC.* The PI shall:

(1) Make the initial determination of the required containment and procedures in accordance with the Guidelines;

(2) Select appropriate practices to be used in the research;

(3) Submit the initial research protocol if covered under Guidelines sections ____.206(d), through ____.322 if required by the entity (and also subsequent changes—e.g., changes in the source of DNA or host-vector system) to the IBC for review and approval or registration; and

(4) Remain in communication with the IBC throughout the conduct of the project.

(d) *PI Responsibilities Prior to Initiating Agricultural Research.* The PI is responsible for:

(1) Making available to the project staff copies of the protocols that describe practices to be taken to diminish the potential biohazards;

(2) Instructing and training project staff in practices and techniques required to ensure safety and in procedures for dealing with accidents; and

(3) Informing the project staff of reasons and provisions for precautionary medical practices advised or requested, such as vaccinations or serum collection.

(e) *PI Responsibilities During the Conduct of the Research.* The PI is responsible for:

(1) Supervising safety performance of the staff to ensure that required safety practices and techniques are employed;

(2) Investigating and reporting in writing to OAB, the BSO (where applicable), and the IBC any significant problems pertaining to the operation and implementation of containment practices and procedures;

(3) Correcting work errors and conditions that may result in unsafe situations.

(4) Ensuring the integrity of biological containment (e.g., purity, and genotypic and phenotypic characteristics of organisms) and physical containment (e.g., containment parameters of laboratories, growth chambers, greenhouses).

____.407 Responsibilities of the Assistant Secretary for Science and Education.

The Secretary has established an *Office of Agriculture Biotechnology* (OAB), as an administrative office reporting to the Assistant Secretary for Science and Education. OAB will assist the Assistant Secretary in implementing and coordinating the Department's policies and procedures pertaining to all facets of biotechnology. This includes the conduct of laboratory and field research, experimentation on biotechnological products prior to their

commercialization, and all matters of oversight of biotechnology in agriculture. In addition the specific responsibilities of the Assistant Secretary in relation to agricultural research shall include the following:

(a) *Agriculture Biotechnology Recombinant DNA Advisory Committee.* Establishing and maintaining;

(b) *Biotechnology Guidelines.* Promulgating requirements as necessary to implement the Guidelines;

(c) *National Biological Impact Assessment Program.* Establishing and maintaining the NBIAP;

(d) *Committee on Biotechnology in Agriculture.* Providing, with the Assistant Secretary for Marketing and Inspection Services, administrative support for the Committee on Biotechnology in Agriculture and acting as cochairman of the CBA;

(e) *Review of Proposals.* In carrying out the responsibilities set forth in this section, the Assistant Secretary will weigh each proposed action through appropriate analysis and consultation to determine that it complies with the Guidelines and adequately reflects safeguards to health and the environment.

(1) *Major Actions:* To execute major actions the Assistant Secretary, at his discretion, may publish a proposed decision in the **Federal Register** for 30 days of comment before final action is taken. The Assistant Secretary's final decision, along wtih the response to the comments, will be published in the **Federal Register.** The BSCC, CBA, ABRAC, NMBAP and IBC's will be notified of the following decision:

(i) Changing containment levels for types of research specified in the Guidelines when a major action is involved;

(ii) Assigning containment levels for types of research not explicitly considered in the Guidelines when a major action is involved;

(iii) Promulgating and amending a list of classes of recombinant molecules and biotechnology-modified organisms to be exempt from these Guidelines because they do not present a significant risk to health or the environment;

(iv) Permitting research specified by section ____.205 of the Guidelines;

(v) Certifying new host-vector systems with the exception of minor modifications of already certified systems with the exception of minor modifications of already certified systems; and

(vi) Adopting other changes in the Guidelines.

(2) *Lesser Actions.* When executing lesser actions, the Assistant Secretary will notify the CBA, ABRAC, NBIAP and IBC's of decisions in the following areas:

(i) Interpreting and determining safety levels;

(ii) Changing containment levels for research in subpart ____.3; and

(iii) Assigning levels for research not explicitly considered in the Guidelines.

(3) *Other Actions.* The Assistant Secretary will:

(i) Transmit decisions to the ABRAC, CBA, NBIAP and IBC's;

(ii) Interpret the Guidelines for research to which the Guidelines specifically assign safety levels;

(iii) Determine appropriate safety conditions for research according to case precedents developed; and

(iv) Conduct, support, and assist in training programs in laboratory safety for IBC members, BSOs, PIs, and laboratory staff as appropriate.

(v) Publish in the **Federal Register:**

(A) Announcements of ABRAC meetings and agendas at least 30 days in advance;

(B) Proposed major actions of the type falling under section ____.409(b)(1) at least 30 days prior to the ABRAC meeting at which they will be considered;

(C) The final decision of the Assistant Secretary for Science and Education on recommendations made by the ABRAC; and

(D) Such notices are as needed.

(vi) Provide certifications for maximum containment (BL4) facilities, inspecting them periodically, and inspecting other recombinant DNA facilities as deemed necessary.

____.408 The Office of Agriculture Biotechnology

(a) The Secretary of Agriculture has established the Office of Agricultural Biotechnology (OAB) under the auspices of the Assistant Secretary of Science and Education. This office has the responsibility to provide administrative support for developing and coordinating Departmental policies and activities pertaining to biotechnology research and performing related interagency and public liaison functions. The Office will:

(1) Assist in developing and implementing policies and procedures pertaining to the conduct of laboratory and field research and experimentation on biotechnological products prior to their commercialization.

(2) Perform a staff role for the intraagency Committee on Biotechnology in Agriculture, established by **Federal Register** Notice of November 14, 1985 (50 FR 47174–47195) and for the Agriculture Biotechnology Research Advisory Committee (ABRAC).

(3) Serve as the focal point for coordinating the National Biological Impact Assessment Program.

(4) Maintain records of research and regulatory activities carried out under the biotechnology authorities of the Secretary of Agriculture.

(5) Provide ABRAC Executive Secretary.

____.409 Agriculture Biotechnology Recombinant DNA Advisory Committee

(a) The Agriculture Biotechnology Recombinant DNA Advisory Committee (ABRAC) is responsible for carrying out specified functions cited below as well as others assigned under its charter or by the Secretary.

(1) Overseeing the review of research projects on genetically engineered organisms.

(2) Evaluating the adequacy of draft proposals to be used by the Department in preparing environmental assessments of the above research projects.

(3) Recommending additions and alterations to research guidelines and protocols as necessary.

(4) Providing advice to other Federal and State agencies on agriculture-related research projects.

(5) Providing information to and maintaining cognizance of the IBCs to assure their capability to carry out their agriculture related functions.

(b) The ABRAC membership shall be conjoined with the governing body of the National Biological Impact Assessment Program (NBIAP) and shall be organized as follows:

(1) Members and chair shall be appointed by the Secretary

(2) The Committee shall consist of twelve members with expertise represented in R–DNA research in plants, animals and microbes; ecology/epidemiology/environmental science; agricultural production practices; biological containment; biological field release; applicable laws and regulations standards of professional conduct and practice; public attitudes; public health; occupational health and ethics.

(3) Representatives from the relevant Federal and State agencies and organizations shall be nonvoting members and may be utilized to provide advice and expertise.

(4) Expert consultants may be called upon for advice on an ad hoc basis.

(5) The Office of Agricultural Biotechnology (OAB) shall coordinate and provide support for ABRAC and NBIAP.

____.410 The National Biological Impact Assessment Program

(a) The Secretary of Agriculture will establish the National Biological Impact Assessment Program (NBIAP) under the auspices of the Assistant Secretary for Science and Education to provide advice on laboratory and field biotechnology research. The Program has two objectives;

(1) Provide the Department with scientific evaluations of proposed research projects to ensure public and environmental safety.

(2) Draw upon existing agricultural science network (public and private) for research monitoring of genetically engineered organisms to assess their onsite performance in controlled release experiments and to assess the impact of their presence in the ecosystem over time.

(b) NBIAP can draw upon long established procedures for evaluating the safety and efficacy of field testing of new strains of crops, livestock, and microbes developed through conventional breeding techniques.

(c) NBIAP will be called upon by the Assistant Secretary and/or ABRAC to provide assessments and evaluations of projects in diverse agriculture-related areas. The Office of Agricultural Biotechnology will coordinate and provide administrative support for these activities.

(d) The responsibilities of NBIAP will be:

(1) Establish and implement procedures for the review of research proposals on genetically engineered organisms.

(2) Establish a roster of experts representing a broad range of agriculture-related disciplines.

(i) Solicit from the agricultural reseach community nominees and assemble lists of potential panel participants in all appropriate disciplines.

(ii) Create a computerized roster of individuals and establish a corresponding data base.

(3) Develop procedures for selecting experts with specific competence to evaluate individual project proposals.

(4) Evaluate and review the scientific adequacy of environmental assessments which accompany individual project proposals.

(5) Identify and recommend research sites for potential use in safe, controlled field testing of genetically engineered organisms.

(6) Make periodic expert reviews of research guidelines and protocols and, as necessary, make recommendations for addition and alterations to improve their effectiveness.

(7) Establish and carry out procedures for providing advice requested by other Federal and State agencies or agriculture-related research projects.

(e) In addition to the above activities NBIAP will also:

(1) Develop and operate a system for gathering, registering and assessing information on the status of the agroecosystem on a continuing basis.

(i) Prepare an inventory of existing research sites suitable for establishment of long term monitoring programs.

(ii) Create a network for accessing above databases on ecosystem components.

(iii) Utilize and improve conceptual modeling techniques to predict the consequences of the release and dissemination of genetically engineered organisms into the environment.

(iv) Identify research needs to improve the monitoring of genetically engineered organisms released into the ecosystem, and develop guidelines to meet these needs.

____.411 Compliance.

As a condition for USDA funding of agricultural recombinant DNA research, entities must ensure that such research conducted at or sponsored by the entity, irrespective of the source of funding, shall comply with these Guidelines. The policies on noncompliance are as follows:

(a) All USDA funded projects involving biotechnology research must comply with these Guidelines. Noncompliance may result in: (1) suspension, limitation, or termination of financial assistance for such projects and of USDA funds for other recombinant DNA research at the entity, or (2) a requirement for prior USDA approval of any or all recombinant DNA projects at the entity.

(b) All non-USDA funded projects involving agricultural biotechnology research conducted at or sponsored by an entity that receives USDA funds for projects involving such techniques must comply with the USDA Guidelines. Noncompliance may result in: (1) suspension, limitation, or termination of USDA funds for recombinant DNA research at the entity, or (2) a requirement for prior USDA approval of any or all recombinant DNA projects at the entity.

(c) Information concerning noncompliance with the Guidelines may be brought forward by any person. It should be delivered to both USDA and the relevant entity. The entity, generally through the IBC, shall take appropriate action. The entity shall forward a complete report of the incident to USDA recommending any further action.

(d) In cases where USDA proposes to suspend, limit, or terminate financial assistance because of noncompliance with the Guidelines, applicable USDA procedures shall govern.

Subpart ____.5 Voluntary Compliance and Proprietary Information

____.501 Basic Policy.

(a) Entities conducting research in agricultural biotechnology but not funded by USDA are encouraged to follow the standards and procedures set forth in subparts ____.1 to ____.4 of these Guidelines.

(b) For purposes of complying with the Guidelines, an individual intending to carry out research involving agricultural biotechnology is encouraged to affiliate with an entity that has an IBC approved under the Guidelines.

(c) Since commercial organizations have special concerns, such as protection of proprietary data, some modifications and explanations of the procedures in subparts ____.1 to ____.4 are provided below to address these concerns.

____.502 Protection of Proprietary Data.

(a) Members of the NBIAP are "special Government employees."

(b) In submitting information to USDA for purposes of complying voluntarily with the Guidelines, an entity may designate those items of information which the entity believes constitute trade secrets, privileged, confidential commercial or financial information.

(c) If USDA receives a request under the Freedom of Information Act for information so designated, USDA will:

(1) Provide the business information submitter with prompt notification of a request for that information (unless it is readily determined by USDA that the information requested should not be disclosed, or on the other hand, that the information is not exempt by law from disclosure).

(2) Notify the requester of the need to inform the submitter of a request for submitted business information.

(3) Afford business information submitters time in which to object to the disclosure of any specified portion of the information. The submitter must explain fully all grounds upon which disclosure is opposed. For example, if the submitter maintains that disclosure is likely to cause substantial harm to its competitive position, the submitter must explain item-by-item why disclosure would cause such harm. Information provided by a business submitter pursuant to this paragraph may itself be subject to disclosure under FOIA.

(4) Provide business information submitters with notice of any

determination to disclose such records prior to the disclosure date, in order that the matter may be considered for possible judicial intervention.

(5) Notify business information submitters promptly of all instances in which FOIA requesters bring suit seeking to compel disclosure of submitter information.

(d) *Presubmission review.*

(1) Any entity not otherwise covered by the Guidelines, which is considering submission of data or information voluntarily to USDA, may request presubmission review of the records involved to determine whether, if the records are submitted, USDA will or will not make part or all of the records available upon request under the Freedom of Information Act.

(2) A request for presubmission review should be submitted to the USDA (Assistant Secretary for Science and Education) along with the records involved. These records must be clearly marked as being the property of the entity on loan to USDA solely for the purpose of making a determination under the Freedom of Information Act. The Assistant Secretary will then seek a determination from the Science and Education Freedom of Information Officer, the responsible official under USDA regulations as to whether the records involved (or some portion) are or are not available to members of the public under the Freedom of Information Act. Pending such a determination the records will be kept separate from any other files, will be considered records of the entity, any will not be received as part of any other files. No copies will be made of the records.

(3) The Assistant Secretary will inform the entity of the Science and Education Freedom of Information Officer's determination and follow the entity's instructions as to whether some or all of the records involved are to be returned to the entity or to become a part of USDA files. If the entity instructs USDA to return the records, no copies or summaries of the records will be made or retained by USDA.

(4) The Science and Education Freedom of Information Officer's determination will represent that official's judgment at the time of the determination as to whether the records involved (or some portion) would be exempt from disclosure under the Freedom of Information Act if at the time of the determination the records were in USDA files and a request were received for them under the Act.

——503 National Agricultural Biotechnology Research Registry.

[Reserved]

(The Department of Agriculture will maintain a registry of all approvals for agricultural research on biotechnology releases and participate as appropriate in the review process and post-release monitoring.)

[FR Doc. 86–14128 Filed 6–19–86; 4:56 pm]

BILLING CODE 3410-22-M

federal register

Thursday
June 26, 1986

Part IV

Department of Defense

General Services Administration

National Aeronautics and Space Administration

48 CFR Parts 15 and 53

Federal Acquisition Regulation (FAR); Submission of Contract Price Proposal; Proposed Rule

48 CFR Part 13 et al.

Federal Acquisition Regulation (FAR); Set-asides Under "Applicable" Small Purchase Limitation; Proposed Rule

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 15 and 53

Federal Acquisition Regulation (FAR); Submission of Price Proposal

AGENCIES: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Proposed rule.

SUMMARY: The Civilian Agency Acquisition Council and the Defense Acquisition Regulatory Council are considering changes to Federal Acquisition Regulation (FAR) 15.804–6 concerning submission of price proposals and 53.301–1411, Contract Pricing Proposal Cover Sheet, Standard Form (SF) 1411.

DATE: Comments should be submitted to the FAR Secretariat at the address shown below on or before August 25, 1986 to be considered in the formulation of a final rule.

ADDRESS: Interested parties should submit written comments to: General Services Administration, FAR Secretariat (VRS), 18th & F Streets NW., Room 4041, Washington, DC 20405.

Please cite FAR Case 86–32 in all correspondence related to this issue.

FOR FURTHER INFORMATION CONTACT: Ms. Margaret A. Willis, FAR Secretariat, Telephone (202) 523–4755.

SUPPLEMENTARY INFORMATION:

A. Background

This rule change is necessary to ensure that the contracting officer and the authorized representative have access to all the data which impacts contract price.

B. Regulatory Flexibility Act

The proposed revisions to FAR 15.804–6 and SF 1411 will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601, et seq.) because they only clarify existing policy and do not constitute significant revisions.

C. Paperwork Reduction Act

The Paperwork Reduction Act (Pub. L. 96–511) does not apply because the proposed revisions to FAR 15.804–6 and SF 1411 do not impose any additional reporting or recordkeeping requirements or collection of information from offerors, contractors, or members of the public which require the approval of OMB under 44 U.S.C. 3501, et seq.

List of Subjects in 48 CFR Parts 15 and 53

Government procurement.

Dated: June 17, 1986.

Lawrence J. Rizzi,

Director, Office of Federal Acquisition and Regulatory Policy.

Therefore, it is proposed that 48 CFR Parts 15 and 53 amended as set forth below:

1. The authority citation for Parts 15 and 53 continues to read as follows:

Authority: 40 U.S.C. 486(c); 10 U.S.C. Chapter 137; and 42 U.S.C. 2453(c).

PART 15—CONTRACTING BY NEGOTIATION

2. Section 15.804–6 is amended by revising in paragraph (b)(2), paragraph 5 in Table 15–2 to read as follows: 15.804–6 Procedural requirements.

* * * * *

5. By submitting offeror's proposal, the offeror, if selected for negotiation, grants the contracting officer or an authorized representative the right to examine, at any time before award, those books, records, documents, and other types of factual material, regardless of form or whether such supporting data is specifically referenced or included in the proposal as the basis for pricing, that will permit an adequate evaluation of the proposed price.

* * * * *

PART 53—FORMS

2. Section 53.301–1411, Standard Form 1411, Contract Pricing Proposal Cover Sheet, is amended by revising the text preceding Block 15 reading "This proposal is submitted in response to the RFP, contract, modification, etc. in item 1 and reflects our best estimates and/or actual costs as of this date" to read:

53.301–1411 Contract pricing proposal cover sheet.

* * * * *

This proposal, submitted in response to the RFP, contract, modification, etc. in item 1, reflects our best estimates and/or actual costs as of this date and conforms with the instructions in FAR 15.804–6(b)(2), Table 15–2. By submitting this proposal, the offeror, if selected for negotiation, grants the contracting officer or an authorized representative the right to examine, at any time before award, those books. records, documents, and other types of factual material, regardless of form or whether such supporting material is specifically referenced or included in the proposal as the basis for pricing, that will permit an adequate evaluation of the proposed price.

* * * * *

[FR Doc. 86–14409 Filed 6–21–86; 8:45 am]

BILLING CODE 6820-61-M

48 CFR Parts 13, 19, 20, and 52

Federal Acquisition Regulation (FAR); Set-Asides Under "Applicable" Small Purchase Limitation

AGENCIES: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Proposed rule.

SUMMARY: The Defense Acquisition Regulatory Council and the Civilian Agency Acquisition Council are considering changes to FAR Parts 13, 19, 20, and 52 to provide for the use of small purchase procedures in awarding set-aside contracts between $10,000 and $25,000.

DATE: Comments should be submitted to the FAR Secretariat at the address shown below on or before July 28, 1986 to be considered in the formulation of a final rule.

ADDRESS: Interested parties should submit written comments to: General Services Administration, FAR Secretariat (VRS), 18th & F Streets NW., Room 4041, Washington, DC 20405.

Please cite FAR Case 86–23 in all correspondence related to this issue.

FOR FURTHER INFORMATION CONTACT: Ms. Margaret A. Willis, FAR Secretariat, Telephone (202) 523–4755.

SUPPLEMENTARY INFORMATION:

A. Background

Pub. L. 95–507 required that all purchases under $10,000 be set-aside for small business. At the time, $10,000 was the small purchase limitation. Since the small purchase limitation was raised to $25,000 there has been some confusion regarding the proper procedure to use in awarding set-asides between $10,000 and $25,000. This revision provides for the use of small purchase procedures in awarding such contracts.

B. Regulatory Flexibility Act.

The Regulatory Flexibility Act (Pub. L. 96–354) does not apply because the proposed revisions are not "significant revisions" as defined in FAR 1.501–1; i.e., they do not alter the substantive meaning of any coverage in the FAR having a significant cost or administrative impact on contractors or offerors, or a significant effect beyond

the internal operating procedures of the issuing agencies. Accordingly, and consistent with section 1212 of Pub. L. 98–525 and section 302 of Pub. L. 98–577 pertaining to publication of proposed regulations (as implemented in FAR Subpart 1.5, Agency and Public Participation), solicitation of agency and public views on the proposed revisions is not required. Since such solicitation is not required, the Regulatory Flexibility Act does not apply. Although such solicitation is not required, comments are invited.

C. Paperwork Reduction Act

The Paperwork Reduction Act (Pub. L. 96–511) does not apply because the proposed changes do not impose any additional reporting or recordkeeping requirements or collection of information from offerors, contractors, or members of the public which require the approval of OMB under 44 U.S.C. 3501, et seq.

List of Subjects in 48 CFR Parts 13, 19, 20, and 52

Government procurement.

Dated: June 17, 1986.

Lawrence J. Rizzi,

Director, Office of Federal Acquisition and Regulataory Policy.

Therefore, it is proposed that 48 CFR Parts 13, 19, 20, and 52 be amended as follows:

1. The authority citation for Parts 13, 19, 20, and 52 continues to read as follows:

Authority: 40 U.S.C. 486(c); 10 U.S.C. Chapter 137; and 42 U.S.C. 2453(c).

PART 13—SMALL PURCHASE AND OTHER SIMPLIFIED PURCHASE PROCEDURES

2. Section 13.101 is amended by revising paragraph (c) of the definition "Small purchase procedures" to read as follows:

13.101 Definitions

* * * * *

(c) Contracts awarded through (1) sealed bidding (see Part 14) or (2) the negotiation procedures in Part 15.

PART 19—SMALL BUSINESS AND SMALL DISADVANTAGED BUSINESS CONCERNS

3. Section 19.303 is amended by revising paragraph (a) to read as follows:

19.303 Determining product or service classifications.

(a) The contracting officer shall determine the appropriate product or service classification and related small business size standard and include them in solicitations.

* * * * *

4. Section 19.501 is amended by revising in paragraph (g) the first sentence to read as follows:

19.501 General.

* * * * *

(g) Once a product or service has been acquired successfully by a contracting officer on the basis of a small business set-aside, all future requirements of that office for that particular product or service shall, if required by agency regulations, be acquired on the basis of a repetitive set-aside. * * *

* * * * *

5. Section 19.502–4 is amended by revising paragraph (a) to read as follows:

19.502–4 Methods of conducting set-asides.

(a) Total and partial small business set-asides may be conducted by using sealed bids (see Part 14) or competitive proposals (see Part 15). Total small business set-asides may be conducted using small purchase procedures (see Part 13). See Part 6 for competition requirements.

* * * * *

19.503 [Amended]

6. Section 19.503 is amended by removing paragraph (c)(2) and redesignating the existing paragraphs (c)(3) and (c)(4) as (c)(2) and (c)(3).

PART 20—LABOR SURPLUS AREA CONCERNS

7. Section 20.202 is revised to read as follows:

20.202 Contract clause.

The contracting officer shall insert the clause at 52.220–2, Notice of Total Labor Surplus Area Set-Aside, in solicitations and contracts that are totally set-aside for LSA concerns.

8. Section 20.204 is amended by revising the first sentence in paragraph (a) to read as follows:

20.204 Award procedures.

(a) The contracting officer shall award contracts involving total LSA set-asides by using sealed bids (see Part 14), competitive proposals (see Part 15), of small purchases procedures (see Part 13). * * *

* * * * *

PART 52—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

9. Section 52.219–6 is amended by inserting a colon in the introductory text following the word "clause" and removing the remainder of the sentence; by removing in the title of the clause the date "(APR 1984)" and inserting in its place the date "(JUN 1986)"; by adding a third sentence to paragraph (c) of the clause; and by removing the derivation lines following "(End of clause)" to read as follows:

52.219–6 Notice of Total Small Business Set-Aside.

* * * * *

(c) * * * In connection with purchases processed under small procedures, a nonmanufacturer may furnish any domestically produced or manufactured end item.

* * * * *

52.220–2 [Amended]

10. Section 52.220–2 is amended by inserting a colon in the introductory text following the word "clause" and removing the remainder of the sentence.

[FR Doc. 86–14408 Filed 6–25–86; 8:45 am]

BILLING CODE 6820–61–M

federal register

Thursday
June 26, 1986

Part V

Department of Agriculture

Use of Penalty Mail in the Location and Recovery of Missing Children; Notice

DEPARTMENT OF AGRICULTURE

Use of Penalty Mail in the Location and Recovery of Missing Children

AGENCY: Department of Agriculture.

ACTION: Final directive.

SUMMARY: This Department of Agriculture directive authorizes USDA, through its component agencies, to use penalty mail to aid in the location and recovery of missing children. The directive further provides procedures under which penalty mail may be used to assist in the location and recovery of missing children in accordance with 39 U.S.C. 3220(a)(2), (Pub. L. 99–87, August 9, 1985), in conformance with the Department of Justice, Office of Juvenile Justice and Delinquency Prevention (OJJDP) preliminary guidelines which were published in the **Federal Register** on November 8, 1985, (50 FR 46622) pursuant to 39 U.S.C. 3220(a)(1).

EFFECTIVE DATE: This directive is effective July 28, 1986.

FOR FURTHER INFORMATION CONTACT: Bill Montgomery, Mail and Reproduction Management Division, Office of Operations, U.S. Department of Agriculture, Room 1540–South Building, 14th and Independence Avenue S.W., Washington, D.C. 20250, telephone number (202) 382–1666.

SUPPLEMENTARY INFORMATION: The enactment of 39 U.S.C. 3220(a)(2) (Pub. L. 99–87, August 9, 1985), is indicative of the increasing public concern with the problem of missing and exploited children. The Missing Children's Assistance Act of 1984, added as Title IV of the Juvenile Justice and Delinquency Prevention Act of 1974, as amended by the Comprehensive Crime Control Act of 1984 (Pub. L. 98–473, October 12, 1984), recognized the problem and provided a Federal coordination and assistance role in addressing this interstate problem. This directive is intended to comply with 39 U.S.C. 3220(a)(2), and the OJJDP guidelines, in order to assist in the location and recovery of missing children through the use of penalty mail.

I. Contact Person for Matters Related to Program and Directive Implementation.

Bill Montgomery, Departmental Mail Manager, USDA Office of Operations, Room 1540 South Building, 14th and Independence Avenue S.W., Washington, D.C. 20250, Telephone (202) 382–1666.

II. Plan

The Department of Agriculture will assist in the national effort to locate and recover missing children by using penalty mail. Priority will be given to: (1) Penalty mail that is addressed to members of the public for receipt in the United States, its territories and possessions; (2) inter- and intra-agency magazines, newsletters, etc., that will be widely disseminated to and viewed by Federal employees; and, (3) the use of flyer inserts in high volume letter mail when appropriate and cost-effective.

The Department is unique with its high-volume, time-sensitive, nation-wide mailings of newsletters, magazines, and bulletins which are distributed to states down to the county level. Maximum attention will be directed to utilizing these mailings to disseminate missing children information.

The National Center for Missing and Exploited Children (National Center) will be the sole source from which the Department of Agriculture will acquire the camera-ready and other photographic and biographical materials. Photographs which were reasonably current at the time of the child's disappearance shall be the only acceptable form of visual media or pictorial likeness used on or in penalty mail.

The Department of Agriculture will discontinue the use of any missing children material, within a 90-day period, when notified by the National Center that the material has been withdrawn. No material which has a shelf-life of more than 90-days will be appropriate for this program. The National Center is responsible for informing the Departmental Mail Manager of the need to withdraw material.

Plans include a continuing evaluation of the methods of dissemination covered in the guidelines, plus other ways to present missing children information. Suggestions and/or recommendations for innovative, cost-effective techniques should be forwarded to the Departmental Mail Manager. The Departmental Mail Manager will conduct periodic meetings of Departmental representatives to review and discuss the current plan and evaluate suggestions and needs for future plans.

This directive applies to the use of penalty mail in support of the Missing Children Program. Agencies may also use missing children information in any appropriate portion of their mail that is processed as commercial mail.

This will be the sole Missing Children Program directive for the Department of Agriculture.

III. Cost and Percentage Estimates

It is estimated that this program will cost the Department of Agriculture $6500 in the first year.

It is the Department of Agriculture's objective that 20 percent of its penalty mail will contain missing children photographs and information when the program is fully implemented.

IV. Report of the Office of Juvenile Justice and Delinquency Prevention (OJJDP)

The Department of Agriculture will compile and submit to OJJDP, by June 30, 1987, a consolidated report on its experience in implementation of 32 U.S.C. 3220(a)(2), the OJJDP guidelines, and the Department of Agriculture's directive. This report will contain information gathered from individual agencies. It will provide details on:

(A) The Department of Agriculture's experience in implementation including problems encountered, successful and/or innovative methods adopted to use missing children photographs and information on or in penalty mail, the estimated number of pieces of penalty mail containing such information, and the percentage of total penalty mail directed to members of the public which included missing children information,

(B) The estimated total cost to implement the program, with supporting detail, and

(C) Recommendations for changes in the program to make it more effective.

V. Notice to Department of Agriculture Agencies of Implementation and Procedures

Following are roles and responsibilities for the program within the Department of Agriculture.

(A) The Departmental Mail Manager will:

(1) Serve as the Department of Agriculture's sole representative for ordering materials, including camera-ready negatives, from the National Center,

(2) Serve as the Department of Agriculture's sole supplier of materials to authorized agency personnel,

(3) Maintain current records of personnel within each agency who are authorized to order materials,

(4) Notify agencies whenever permission to use information on a missing child has been withdrawn,

(5) Ensure that only current missing children materials are distributed to agencies and that only those requests from authorized Departmental representatives are filled,

(6) Prepare all required Departmental reports concerning the program,

(7) Promulgate any Department-wide operating instructions deemed appropriate for the program,

(8) Chair periodic meetings of agency Mail Managers and other representatives to discuss the program and identify additional opportunities to use the missing children data with penalty mail, and

(9) Ensure that Departmental policies and procedures are cost-effective and in keeping with the purpose of the Missing Children Program.

(B) All Departmental agencies will:

(1) Designate a person to act as the agency's sole representative to the Department for requesting missing children materials and receiving notification to withdraw materials from use,

(2) Provide the Department Mail Manager with the name, title, telephone number, and room number of the agency's sole representative for the program, and notify the Department of changes,

(3) Ensure that missing children information is not used if permission to use the information on the particular child has been withdrawn,

(4) Order missing children information, as appropriate, from the Departmental Mail Manager,

(5) Comply with policies, procedures, and operating instructions issued by the Department,

(6) Maintain necessary information to prepare required reports and submit them in accordance with requirements,

(7) Control the use of missing children materials and information,

(8) Use the missing children information in agency magazines, newsletters, etc. when appropriate.

(9) Use flyer inserts in volume letter mail when appropriate and cost-effective, and

(10) Ensure that missing children information is not used on material with a shelf-life or storage-life of over 90-days.

Frank Gearde, Jr.,

Director, Office of Operations.

[FR Doc. 86-14487 Filed 6-25-86; 8:45 am]

BILLING CODE 3410-98-M

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LIST OF PUBLIC LAWS

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This is a continuing list of public bills from the current session of Congress which have become Federal laws. The text of laws is not published in the **Federal Register** but may be ordered in individual pamphlet form (referred to as "slip laws") from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 (phone 202-275-3030).

H.J. Res. 479/Pub. L. 99-343

To designate October 8, 1986, as "National Fire Fighters Day." (June 23, 1986; 100 Stat. 671; 1 page) Price: $1.00

S.J. Res. 321/Pub. L. 99-344

To designate October 1986, as "National Down Syndrome Month." (June 23, 1986; 100 Stat. 672; 1 page) Price: $1.00