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2–6–06 Monday
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FOR: Any person who uses the Federal Register and Code of Federal Regulations.

WHO: Sponsored by the Office of the Federal Register.

WHAT: Free public briefings (approximately 3 hours) to present:

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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.

WHEN: Tuesday, February 7, 2006
9:00 a.m.–Noon

WHERE: Office of the Federal Register
Conference Room, Suite 700
800 North Capitol Street, NW.
Washington, DC 20002

RESERVATIONS: (202) 741–6008

Contents

Federal Register

Vol. 71, No. 24

Monday, February 6, 2006

Reader Aids
Consult the Reader Aids section at the end of this issue for phone numbers, online resources, finding aids, reminders, and notice of recently enacted public laws.

To subscribe to the Federal Register Table of Contents LISTSERV electronic mailing list, go to http://listserv.access.gpo.gov and select Online mailing list archives, FEDREGTOC-L, Join or leave the list (or change settings); then follow the instructions.

CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

3 CFR

Proclamations:

7978.....5967

7 CFR

Proposed Rules:

319.....6011
457.....6016
1250.....6021

10 CFR

Proposed Rules:

430.....6022

14 CFR

39 (3 documents) ...5969, 5971, 5976

Proposed Rules:

39.....6025

21 CFR

17.....5979

40 CFR

9 (2 documents) 6136, 6138
26.....6138
52.....5979
82.....5985
141.....6136
142.....6136

Proposed Rules:

52.....6028
63.....6030

50 CFR

Proposed Rules:

679.....6031

Federal Register
Vol. 71, No. 24
Monday, February 6, 2006

Presidential Documents

Title 3—

The President

Proclamation 7978 of February 1, 2006

American Heart Month, 2006

By the President of the United States of America

A Proclamation

More than 70 million Americans live with some form of heart disease, and this disease remains the leading cause of death in the United States. During American Heart Month, we reinforce our commitment to fighting heart disease by promoting awareness about its risks, its causes, and the ways to reduce the chance of developing this deadly illness.

Many of the factors that lead to heart disease, such as high blood pressure, high blood cholesterol, and obesity, can be controlled with commonsense steps and healthy lifestyles. Through the HealthierUS Initiative, my Administration encourages Americans to work toward four simple goals that can lead to a healthy heart: exercise daily; develop good eating habits; avoid tobacco, drugs, and excessive alcohol; and take advantage of preventive screenings to detect problems early.

First Lady Laura Bush helps lead "The Heart Truth" campaign through her Women's Health and Wellness Initiative. The campaign was launched by business, non-profit, and government organizations, including the National Heart, Lung, and Blood Institute, to educate women about the risks of heart disease and to encourage them to make their cardiovascular health a priority. Along with the American Heart Association's "Go Red for Women" campaign, these initiatives use the red dress as a symbol to remind women to make healthy choices and talk with their doctors about heart disease.

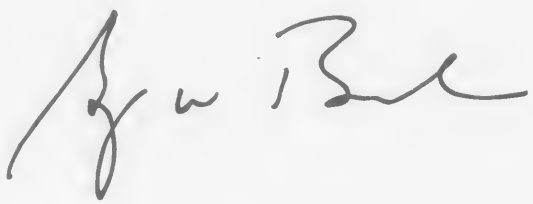
As a result of the Medicare Modernization Act, our seniors have more choices to prevent, diagnose, and treat potential problems before they become worse. Medicare now covers preventive screenings, a "Welcome to Medicare" physical for new beneficiaries, and innovative programs to help seniors fight chronic threats. I urge all Medicare beneficiaries to take advantage of these measures as part of a healthy lifestyle.

All Americans can improve their heart health and live longer, better lives by taking an active role in their health care decisions and consulting their physician for the latest information. As we observe American Heart Month, we recognize those battling heart disease; we express gratitude to the family members and friends who are a source of love and encouragement; and we commend the medical professionals and researchers who provide assistance and work to find cures and improve treatments.

In acknowledgement of the importance of the ongoing fight against cardiovascular disease, the Congress, by Joint Resolution approved December 30, 1963, as amended (77 Stat. 843; 36 U.S.C. 101), has requested that the President issue an annual proclamation designating February as "American Heart Month."

NOW, THEREFORE, I, GEORGE W. BUSH, President of the United States of America, do hereby proclaim February 2006 as American Heart Month, and I invite all Americans to participate in National Wear Red Day on February 3, 2006. I also invite the Governors of the States, the Commonwealth of Puerto Rico, officials of other areas subject to the jurisdiction of the United States, and the American people to join me in recognizing and reaffirming our commitment to combating heart disease.

IN WITNESS WHEREOF, I have hereunto set my hand this first day of February, in the year of our Lord two thousand six, and of the Independence of the United States of America the two hundred and thirtieth.



[FR Doc. 06–1098
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Rules and Regulations

Federal Register
Vol. 71, No. 24
Monday, February 6, 2006

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2005–22425; Directorate Identifier 2005–NM–066–AD; Amendment 39–14468; AD 2006–03–04]

RIN 2120–AA64

Airworthiness Directives; McDonnell Douglas Model DC–8–33, DC–8–51, DC–8–53, DC–8–55, DC–8F–54, DC–8F–55, DC–8–63, DC–8–62F, DC–8–63F, DC–8–71, DC–8–73, DC–8–71F, DC–8–72F, and DC–8–73F Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain transport category airplanes, identified above.

This AD requires repetitive inspections for cracks of the doorjamb corners of the main cabin cargo door, and repair if necessary. This AD also provides an optional preventive modification that extends certain repetitive intervals. This AD results from reports of cracks in the fuselage skin at the corners of the doorjamb for the main cabin cargo door. We are issuing this AD to detect and correct fatigue cracks in the fuselage skin, which could result in rapid decompression of the airplane.

DATES: This AD becomes effective March 13, 2006.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in the AD as of March 13, 2006.

ADDRESSES: You may examine the AD docket on the Internet at *http://dms.dot.gov* or in person at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, room PL–401, Washington, DC.

Contact Boeing Commercial Airplanes, Long Beach Division, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Data and Service Management, Dept. C1–L5A (D800–0024), for service information identified in this AD.

FOR FURTHER INFORMATION CONTACT: Jon Mowery, Aerospace Engineer, Airframe Branch, ANM–120L, FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California 90712–4137; telephone (562) 627–5322; fax (562) 627–5210.

SUPPLEMENTARY INFORMATION:

Examining the Docket

You may examine the airworthiness directive (AD) docket on the Internet at *http://dms.dot.gov* or in person at the Docket Management Facility office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Management Facility office (telephone (800) 647–5227) is located on the plaza level of the Nassif Building at the street address stated in the **ADDRESSES** section.

Discussion

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to include an AD that would apply to certain McDonnell Douglas Model DC–8–33, DC–8–51, DC–8–53, DC–8–55, DC–8F–54, DC–8F–55, DC–8–63, DC–8–62F, DC–8–63F, DC–8–71, DC–8–73, DC–8–71F, DC–8–72F, and DC–8–73F airplanes. That NPRM was published in the **Federal Register** on September 16, 2005 (70 FR 54674). That NPRM proposed to require repetitive inspections for cracks of the doorjamb corners of the main cabin cargo door, and repair if necessary. That NPRM also proposed an optional preventive modification that extends certain repetitive intervals.

Comments

We provided the public the opportunity to participate in the development of this AD. We have considered the comment received.

Request to Refer to Inspections in Service Bulletin

The commenter requests that we change paragraph (f) of the NPRM to refer to the inspections in Paragraph 1.E., Table 1, of Boeing Service Bulletin DC8–53–079, Revision 01, dated June 26, 2002, rather than using the current wording of paragraph (f). As proposed in the NPRM, paragraph (f) states: "Do detailed, high frequency eddy current, and radiographic inspections, as applicable * * *," which the commenter states can be interpreted to require that all inspection types be accomplished for the main cabin cargo door jamb corners. The commenter states that referring to Paragraph 1.E., Table 1, would clarify the intent of the required inspection techniques. The commenter also notes that this change would be consistent with the wording in two other ADs related to door jamb corners: AD 2000–20–08, amendment 39–11919, for passenger and service door jambs; and AD 2005–18–07, amendment 39–14247, for the lower cargo door jamb.

We agree with the commenter. The requested change clarifies the intent of the inspection techniques, and is also consistent with the wording in similar ADs. We have revised paragraph (f) of the final rule to include this change. We have also deleted Note 1, which describes an inspection technique that is no longer mentioned in the AD.

Clarification of Paragraph (g)(2)

We have revised paragraph (g)(2) of this action to clarify that, for any corner where any crack is greater than 2.50 inches in length, the repair should be done using a method approved in accordance with the procedures specified in paragraph (k), rather than just in accordance with paragraph (k).

Clarification of Alternative Method of Compliance (AMOC) Paragraph

We have revised this action to clarify the appropriate procedure for notifying the principal inspector before using any approved AMOC on any airplane to which the AMOC applies.

Conclusion

We have carefully reviewed the available data, including the comment received, and determined that air safety and the public interest require adopting the AD with the changes described previously. We have determined that these changes will neither increase the economic burden on any operator nor increase the scope of the AD.

Costs of Compliance

There are about 225 airplanes of the affected design in the worldwide fleet. The following table provides the estimated costs for U.S. operators to comply with this AD. The average labor rate is $65 per hour.

ESTIMATED COSTS

Action	Work hours	Parts	Cost per airplane	Number of U.S.-registered airplanes	Fleet Cost
Inspection, per inspection cycle.	20	None	$1,300, per inspection cycle.	166	$215,800, per inspection cycle.
Optional preventive modification (per corner).	80	$26,881 to $30,913 (per corner, depending on airplane configuration).	$32,081 to $36,113	Up to 166	Up to between $5,325,446 and $5,994,758 (for one corner).

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in subtitle VII, part A, subpart III, Section 44701, "General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We have determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a "significant regulatory action" under Executive Order 12866;

(2) Is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this AD and placed it in the AD docket. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

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

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The Federal Aviation Administration (FAA) amends § 39.13 by adding the following new airworthiness directive (AD):

2006–03–04 McDonnell Douglas: Amendment 39–14468. Docket No. FAA–2005–22425; Directorate Identifier 2005–NM–066–AD.

Effective Date

(a) This AD becomes effective March 13, 2006.

Affected ADs

(b) None.

Applicability

(c) This AD applies to McDonnell Douglas Model DC–8–33, DC–8–51, DC–8–53, DC–8–55, DC–8F–54, DC–8F–55, DC–8–63, DC–8–62F, DC–8–63F, DC–8–71, DC–8–73, DC–8–71F, DC–8–72F, and DC–8–73F airplanes, certificated in any category; as identified in Boeing Service Bulletin DC8–53–079, Revision 01, dated June 26, 2002.

Unsafe Condition

(d) This AD results from reports of cracks in the fuselage skin at the corners of the doorjamb for the main cabin cargo door. We are issuing this AD to detect and correct fatigue cracks in the fuselage skin, which could result in rapid decompression of the airplane.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Inspections

(f) At the applicable time in paragraph (f)(1) or (f)(2) of this AD: Do the applicable inspections for cracking of the doorjamb corners of the main cabin cargo door in accordance with the Accomplishment Instructions of Boeing Service Bulletin DC8–53–079, Revision 01, dated June 26, 2002; the applicable inspections are specified in Table 1 of Paragraph 1.E. "Compliance" of the service bulletin. Except as provided by paragraphs (g) and (h) of this AD, repeat the inspections thereafter at intervals not to exceed the applicable intervals specified in Table 1 of Paragraph 1.E. "Compliance" of the service bulletin.

(1) For airplanes that have been converted from passenger to cargo under Amended Type Certificate Data Sheet 4A25, Notes 25 and 26, and McDonnell Douglas Supplemental Type Certificates SA3749WE and SA3403WE: Within 15,000 flight cycles after the conversion; or within 12 months after the effective date of this AD; whichever occurs later.

(2) For airplanes that have not been converted from passenger to cargo: Before the accumulation of 15,000 total flight cycles, or within 3,000 flight cycles after the effective date of this AD, whichever occurs later.

Corrective Actions and New Repetitive Intervals

(g) If any crack is found during any inspection required by this AD, before further flight: Do the applicable action in paragraph (g)(1) or (g)(2) of this AD in accordance with the Accomplishment Instructions of Boeing Service Bulletin DC8–53–079, Revision 01, dated June 26, 2002.

(1) For any corner where all cracks are 2.50 inches or less in length, install an external doubler in accordance with the service bulletin: Before the accumulation of 17,000 flight cycles after the installation, do the next inspection of that corner as specified in paragraph (f) of this AD. Repeat the inspections in paragraph (f) of this AD for that corner thereafter at intervals not to exceed 4,400 flight cycles.

(2) For any corner where any crack is greater than 2.50 inches in length, repair the

crack using a method approved in accordance with the procedures specified in paragraph (k) of this AD.

Optional Preventive Modification

(h) Installing an external doubler on a corner in accordance with the Accomplishment Instructions of Boeing Service Bulletin DC8–53–079, Revision 01, dated June 26, 2002, terminates the repetitive inspection intervals of paragraph (f) of this AD for that corner. Before the accumulation of 17,000 flight cycles after the installation: Do the next inspection of that corner, as specified in paragraph (f) of this AD. Repeat the inspections in paragraph (f) of this AD for that corner thereafter at intervals not to exceed 4,400 flight cycles.

No Reporting Required

(i) Although the service bulletin referenced in this AD specifies to submit certain information to the manufacturer, this AD does not include that requirement.

Actions Accomplished In Accordance With Previous Issue of Service Bulletin

(j) Actions accomplished before the effective date of this AD in accordance with McDonnell Douglas Service Bulletin C8–53–079, dated January 31, 2001, are acceptable for compliance with the corresponding action in this AD.

Alternative Methods of Compliance (AMOCs)

(k)(1) The Manager, Los Angeles Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

(2) Before using any AMOC approved in accordance with § 39.19 on any airplane to which the AMOC applies, notify the appropriate principal inspector in the FAA Flight Standards Certificate Holding District Office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD, if it is approved by an Authorized Representative for the Boeing Commercial Airplanes Delegation Option Authorization Organization who has been authorized by the Manager, Los Angeles ACO, to make those findings. For a repair method to be approved, the repair must meet the certification basis of the airplane and 14 CFR 25.571, Amendment 45, and the approval must specifically refer to this AD.

(4) Inspections required by this AD of specified areas of Principal Structural Element (PSE) 53.08.044 are acceptable for compliance with the applicable requirements of paragraphs (a) and (b) of AD 93–01–15, amendment 39–8469 (58 FR 5576, January 22, 1993). The remaining areas of the affected PSEs must be inspected and repaired as applicable, in accordance with AD 93–01–15.

Material Incorporated by Reference

(l) You must use Boeing Service Bulletin DC8–53–079, Revision 01, dated June 26, 2002, to perform the actions that are required by this AD, unless the AD specifies otherwise. The Director of the Federal Register approved the incorporation by reference of this document in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Contact Boeing Commercial Airplanes, Long Beach Division, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Data and Service Management, Dept. C1–L5A (D800–0024), for a copy of this service information. You may review copies at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street, SW., room PL–401, Nassif Building, Washington, DC; on the Internet at *http://dms.dot.gov;* or at the National Archives and Records Administration (NARA). For information on the availability of this material at the NARA, call (202) 741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Issued in Renton, Washington, on January 24, 2006.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 06–987 Filed 2–3–06; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2005–21702; Directorate Identifier 2005–NM–024–AD; Amendment 39–14473; AD 2006–03–09]

RIN 2120–AA64

Airworthiness Directives; Airbus Model A330–200 and –300 Series Airplanes, A340–200 and –300 Series Airplanes, and A340–541 and –642 Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Airbus Model A330–200 and –300 series airplanes, A340–200 and –300 series airplanes, and A340–541 and –642 airplanes. This AD requires repetitive borescope inspections of the left and right fuel tanks of the trimmable horizontal stabilizers (trim tanks) for detached or damaged float valves; related investigative/corrective actions if necessary; and the eventual replacement of all float valves in the left and right trim tanks with new, improved float valves, which terminates the need for the repetitive inspections. This AD also requires repetitive replacement of certain new, improved float valves. This AD results from reports of detached and damaged float valves in the trim tanks. We are issuing this AD to prevent, in the event of a lightning strike to the horizontal stabilizer, sparking of metal parts and debris from detached and damaged float valves, or a buildup of static electricity, which could result in ignition of fuel vapors and consequent fire or explosion.

DATES: This AD becomes effective March 13, 2006.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in the AD as of March 13, 2006.

ADDRESSES: You may examine the AD docket on the Internet at *http://dms.dot.gov* or in person at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, Room PL–401, Washington, DC.

Contact Airbus, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France, for service information identified in this AD.

FOR FURTHER INFORMATION CONTACT: Tim Backman, Aerospace Engineer, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2797; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Examining the Docket

You may examine the airworthiness directive (AD) docket on the Internet at *http://dms.dot.gov* or in person at the Docket Management Facility office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Management Facility office (telephone (800) 647–5227) is located on the plaza level of the Nassif Building at the street address stated in the **ADDRESSES** section.

Discussion

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to include an AD that would apply to certain Airbus Model A330 and A340 series airplanes. That NPRM was published in the **Federal Register** on June 29, 2005 (70 FR 37296). That NPRM proposed to require repetitive borescope inspections of the left and right fuel tanks of the trimmable horizontal stabilizers (trim tanks) for detached or damaged float valves; related investigative/corrective actions if necessary; and the eventual replacement of all float valves in the left and right trim tanks with new, improved float valves, which terminates the need for the repetitive inspections. That NPRM also proposed to require repetitive replacement of certain new, improved float valves.

Comments

We provided the public the opportunity to participate in the development of this AD. We have considered the comments received.

Requests That Resulted in a Change to the NPRM

Request To Add Another Service Bulletin

One commenter requests that the NPRM reference an additional service bulletin. The commenter explains that Airbus Service Bulletin A330–28–3093, dated June 16, 2005, installs the same Airbus modification number (53081) as Airbus Service Bulletin A330–28–3094, dated April 7, 2005, which was referenced in the NPRM as an appropriate source of service information. The commenter explains that the effectivity in Airbus Service Bulletin A330–28–3093 includes all of the commenter's airplanes, while Airbus Service Bulletin A330–28–3094 does not.

We agree to add Airbus Service Bulletin A330–28–3093 as another method of compliance to the requirements of the AD. We note that adding this service bulletin is for the convenience of the operator in accomplishing the actions required by this AD, and does not add or remove any airplane listed in the applicability of this AD.

Request To Revise the Costs of Compliance

The same commenter requests that the NPRM be revised to add an estimated cost for access to each of the valves during replacement of the valves, which is a terminating action. The commenter notes that the service information estimates a total of 76 hours of access related labor time. The commenter estimates a more realistic value to be 116 hours. The commenter recognizes that access time is typically not included in the labor estimates of ADs. However, the commenter advises that there are no tasks in the A330 maintenance program that require access to this area. Therefore, the access hours will be driven solely and specifically by the NPRM.

We agree that, in this case, it is appropriate to consider the time necessary for access. We also recognize that different operators may have different access times based on different airplane configurations or other considerations. The estimated cost information for access that is provided by the manufacturer is the latest information that we have, and we have revised the AD to reflect that estimate.

Requests That Did Not Result in a Change to the NPRM

Request To Address Defective Parts Manufacturer Approval (PMA) Parts

One commenter requests that the NPRM be modified to include possible "defective" parts manufactured with a parts manufacturer approval (PMA) that may be installed in lieu of the defective original equipment manufacturer (OEM) part specified in the NPRM. The commenter states that a "known" PMA part exists for the defective OEM part specified in the NPRM, and may contain the same defects as the specified OEM part. The commenter further points out that, if a PMA part is defective and currently installed, the NPRM would not require its removal.

We concur with the commenter's general request that, if we know that an unsafe condition also exists in PMA parts, the AD should address those parts, as well as the original parts. Contrary to the commenter's assertion that the known PMA part is not covered by the wording of the NPRM, the "known" PMA part identified by the commenter does have the same part number as the part number specified in the NPRM. Therefore, it is also subject to the requirements of this AD. We are not aware of other PMA parts that may have a different part number. The commenter's remarks are timely in that the Transport Airplane Directorate currently is in the process of reviewing this issue as it applies to transport category airplanes. We acknowledge that there may be other ways of addressing this issue to ensure that unsafe PMA parts are identified and addressed. Once we have thoroughly examined all aspects of this issue, including input from industry, and have made a final determination, we will consider whether our policy regarding addressing PMA parts in ADs needs to be revised. We consider that to delay this AD action would be inappropriate, since we have determined that an unsafe condition exists and that replacement of certain parts must be accomplished to ensure continued safety. Therefore, no change has been made to the final rule in this regard.

Request to Reference PMA Parts

The same commenter also requests that the language in the NPRM be changed to permit installation of PMA equivalent parts. The commenter states that the mandated installation of a certain part number in the NPRM "is at variance with the higher authority of 14 CFR Section 21.303."

We infer that the commenter would like the AD to permit installation of any equivalent PMA parts so that it is not necessary for an operator to request approval of an alternative method of compliance (AMOC) in order to install an "equivalent" PMA part. Whether an alternative part is "equivalent" in adequately resolving the unsafe condition can only be determined on a case-by-case basis based on a complete understanding of the unsafe condition. We are not currently aware of any such parts. Our policy is that, in order for operators to replace a part with one that is not specified in the AD, they must request an AMOC. This is necessary so that we can make a specific determination that an alternative part is or is not susceptible to the same unsafe condition.

In response to the commenter's statement regarding a "variance with FAR 21.303," under which the FAA issues PMAs, this statement appears to reflect a misunderstanding of the relationship between ADs and the certification procedural regulations of part 21 of the FARs (14 CFR part 21). Those regulations, including section 21.303 of the FARs (14 CFR part 21.303), are intended to ensure that aeronautical products comply with the applicable airworthiness standards. But ADs are issued when, notwithstanding those procedures, we become aware of unsafe conditions in these products or parts. Therefore, an AD takes precedence over design approvals when we identify an unsafe condition, and mandating installation of a certain part number in an AD is not at variance with section § 21.303.

The AD provides a means of compliance for operators to ensure that the identified unsafe condition is addressed appropriately. For an unsafe condition attributable to a part, the AD normally identifies the replacement parts necessary to obtain that compliance. As stated in section 39.7 of the FARs (14 CFR 39.7), "Anyone who operates a product that does not meet the requirements of an applicable airworthiness directive is in violation of this section." Unless an operator obtains approval for an AMOC, replacing a part with one not specified by the AD would make the operator subject to an enforcement action and result in a civil penalty. No change to the AD is necessary in this regard.

Editorial Changes to the AD

Clarification of Alternative Method of Compliance (AMOC) Paragraph

We have revised this action to clarify the appropriate procedure for notifying the principal inspector before using any

approved AMOC on any airplane to which the AMOC applies.

Explanation of Change to Applicability

We have revised the applicability of the existing AD to identify model designations as published in the most recent type certificate data sheet for the affected models.

Conclusion

We have carefully reviewed the available data, including the comments received, and determined that air safety and the public interest require adopting the AD with the changes described previously. We have determined that these changes will neither increase the economic burden on any operator nor increase the scope of the AD.

Costs of Compliance

The following table provides the estimated costs, at an average labor rate per hour of $65, for U.S. operators of Model A330–200 and –300 series airplanes to comply with this AD.

ESTIMATED COSTS

Action	Work hours	Parts	Cost per airplane	Number of U.S. registered airplanes	Fleet cost
Repetitive borescope inspection, per inspection cycle.	2 hours for inspection	None	$130	25	$3,250, per inspection cycle.
Installation of float valves (including access).	4 hours (2 per valve, 2 valves per airplane) plus 76 hours for access.	No charge	5,200	25	$130,000, per installation.
Bonding test (new, improved float valves, left trim tank only).	1	None	65	25	$1,625.

Currently, there are no affected Model A340–200 and –300 series airplanes and A340–541 and –642 airplanes on the U.S. Register. However, should an affected airplane be imported and placed on the U.S. Register in the future, it would be subject to the actions of this AD. The estimated costs would be the same as those listed above for the Model A330–200 and –300 series airplanes.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in subtitle VII, part A, subpart III, section 44701, "General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We have determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a "significant regulatory action" under Executive Order 12866;

(2) Is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this AD and placed it in the AD docket. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

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

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The Federal Aviation Administration (FAA) amends § 39.13 by adding the following new airworthiness directive (AD):

2006–03–09 Airbus: Amendment 39–14473. Docket No. FAA–2005–21702; Directorate Identifier 2005–NM–024–AD.

Effective Date

(a) This AD becomes effective March 13, 2006.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Airbus Model A330–201, –202, –203, –223, –243, –301, –321, –322, –323, –341, –342, and –343 airplanes; and A340–211, –212, –213 –311, –312, –313, –541, and –642 airplanes; certificated in any category, as identified in Table 1 of this AD.

TABLE 1.—APPLICABILITY

Airbus model	Except those modified in production by Airbus modification
A330–201, –202, –203, –223, –243, –301, –321, –322, –323, –341, –342, and –343 airplanes.	51953 and either 52110 or 53081.
A340–211, –212, –213, –311, –312, –313 airplanes	51953 and either 52110 or 53081.
A340–541 and –642 airplanes	51951 and either 52109 or 53081.

Unsafe Condition

(d) This AD was prompted by reports of detached and damaged float valves in the left and right fuel tanks of the trimmable horizontal stabilizers (trim tanks). We are issuing this AD to prevent, in the event of a lightning strike to the horizontal stabilizer, sparking of metal parts and debris from detached and damaged float valves, or a buildup of static electricity, which could result in ignition of fuel vapors and consequent fire or explosion.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Borescope Inspection

(f) At the later of the times specified in paragraph (f)(1) and (f)(2) of this AD: Do a borescope inspection for detached or damaged float valves in the left and right trim tanks, by doing the applicable actions in the Accomplishment Instructions of Airbus Service Bulletins A330–28–3086, dated July 24, 2003, and A330–28–3087, Revision 01, dated August 16, 2004 (for Model A330–201, –202, –203, –223, –243, –301, –321, –322, –323, –341, –342, and –343 airplanes); or A340–28–4100 and A340–28–4101, both Revision 01, both dated August 16, 2004 (for Model A340–211, –212, –213, –311, –312, and –313 airplanes); as applicable.

(1) Prior to the accumulation of 2,500 total flight cycles or 15,000 total flight hours, whichever is first.

(2) Within 7,500 flight hours after the effective date of this AD.

Related Investigative and Corrective Actions

(g) Depending on the results of the inspection required by paragraph (f) of this AD: Do the applicable actions in accordance with the Accomplishment Instructions of the applicable service bulletin identified in Table 2 of this AD, at the times specified in Table 2.

TABLE 2.—INSPECTION RESULTS AND RELATED INVESTIGATIVE/CORRECTIVE ACTIONS

If inspection results reveal—	Then—	In accordance with Airbus service bulletin—
Detached or damaged float valve in the right trim tank.	Before further flight: (1) Remove the detached float and float debris from trim tank and do a detailed tank inspection for structural damage to the affected trim tank. Repair any structural damage to the trim tank or deactivate the trim tank, before further flight, in accordance with the applicable service bulletin, or in accordance with a method approved by the Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate; or the Direction Générale de l'Aviation Civile (DGAC) (or its delegated agent). Where the service bulletin specifies to contact the manufacturer, instead contact the Manager, International Branch, ANM–116, or the DGAC (or its delegated agent)..	A330–28–3086, dated July 24, 2003. A340–28–4100, Revision 01, dated August 16, 2004.
	Before further flight, after doing the detailed inspection and repairing any structural damage: (2) Replace the affected float valve with a new unit having the same part number (P/N), or a new, improved float valve, P/N 62015–1, in accordance with the applicable service bulletin. If a new unit of P/N 61600 is installed, thereafter, do the inspection required by paragraph (f) of this AD at intervals not to exceed 2,500 flight cycles or 15,000 flight hours, whichever is first, after the most recent inspection, until paragraph (h) of this AD is accomplished..	A330–28–3086, dated July 24, 2003. A330–28–3088, dated April 27, 2004. A340–28–4100, Revision 01, dated August 16, 2004. A340–28–4102, dated April 27, 2004.
Detached or damaged float valve in the left trim tank.	Before further flight: (1) Remove the detached float and float debris from the trim tank and do a detailed inspection for structural damage to the affected trim tank. Repair any structural damage to the trim tank or deactivate the trim tank, before further flight, in accordance with the applicable service bulletin, or in accordance with a method approved by the Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate; or the DGAC (or its delegated agent). Where the service bulletin specifies to contact the manufacturer, instead contact the Manager, International Branch, ANM–116, or the DGAC (or its delegated agent)..	A330–28–3087, Revision 01, dated August 16, 2004. A340–28–4101, Revision 01, dated August 16, 2004.
	Before further flight, after doing the detailed inspection and repairing any structural damage: (2) Replace the affected float valve with either a new unit having that same P/N, or a new improved float valve, P/N L87–13–002 or P/N L87–13–003. If a new unit of P/N L87–13–001 is installed, thereafter, do the inspection required by paragraph (f) of this AD at intervals not to exceed 2,500 flight cycles or 15,000 flight hours, whichever is first, after the most recent inspection, until paragraph (h) of this AD is accomplished. For Airbus Model A330–201, –202, –203, –223, –243, –301, –321, –322, –323, –341, –342, and –343 airplanes: If a float valve having P/N L87–13–002 is installed, thereafter, replace that float valve with a float valve having that same P/N at intervals not to exceed those specified in paragraph (h) of this AD. Installation of P/N L87–13–003 on Airbus Model A330–201, –202, –203, –223, –243, –301, –321, –322, –323, –341, –342, and –343 airplanes terminates the repetitive float valve replacement required by paragraph (h) of this AD..	A330–28–3087, Revision 01, dated August 16, 2004. A330–28–3089, Revision 02, dated April 1, 2005. A330–28–3093, dated June 16, 2005. A330–28–3094, dated April 7, 2005. A340–28–4101, Revision 01, dated August 16, 2004. A340–28–4103, Revision 02, dated April 1, 2005. A340–28–4111, dated April 6, 2005.
No damaged or detached float valve in the left trim tank.	Within 10,000 flight hours or 1,500 flight cycles, whichever is first, from the initial inspection done in accordance with paragraph (f) of this AD, replace the existing Argo-Tech float valve, P/N 61600, with either a new unit having that same P/N, or a new, improved float valve, P/N 62015–1. If a new unit of P/N 61600 is installed, thereafter, repeat the inspection required by paragraph (f) of this AD at intervals not to exceed 2,500 flight cycles or 15,000 flight hours, whichever is first, until paragraph (h) of this AD is accomplished..	A330–28–3086, dated July 24, 2003. A330–28–3088, dated April 27, 2004. A340–28–4100, Revision 01, dated August 16, 2004. A340–28–4102, dated April 27, 2004.

TABLE 2.—INSPECTION RESULTS AND RELATED INVESTIGATIVE/CORRECTIVE ACTIONS—Continued

If inspection results reveal—	Then—	In accordance with Airbus service bulletin—
No damaged or detached float valve in the left trim tank.	Within 10,000 flight hours or 1,500 flight cycles, whichever is first, from the initial inspection done in accordance with paragraph (f) of this AD, replace the existing Intertechnique float valve, P/N L87–13–001, with either a new unit having that same P/N, or a new improved float valve, P/N L87–13–002 or P/N L87–13–003. If a new unit of P/N L87–13–001 is installed, thereafter, do the inspection required by paragraph (f) of this AD at intervals not to exceed 2,500 flight cycles or 15,000 flight hours, whichever is first, after the most recent inspection, until paragraph (h) of this AD is accomplished. For Airbus Model A330–201, –202, –203, –223, –243, –301, –321, –322, –323, –341, –342, and –343 airplanes: If a float valve having P/N L87–13–002 is installed, thereafter, replace that float valve with a float valve having that same P/N at intervals not to exceed those specified in paragraph (h) of this AD. Installation of P/N L87–13–003 on Airbus Model A330–201, –202, –203, –223, –243, –301, –321, –322, –323, –341, –342, and –343 airplanes terminates the repetitive float valve replacement required by paragraph (h) of this AD..	A330–28–3087, Revision 01, dated August 16, 2004. A330–28–3089, Revision 02, dated April 1, 2005. A330–28–3093, dated June 16, 2005. A330–28–3094, dated April 7, 2005. A340–28–4101, Revision 01, dated August 16, 2004. A340–28–4103, Revision 02, dated April 1, 2005. A340–28–4111, dated April 6, 2005.

Note 1: For the purposes of this AD, a detailed inspection is: "An intensive examination of a specific item, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at an intensity deemed appropriate. Inspection aids such as mirror, magnifying lenses, etc., may be necessary. Surface cleaning and elaborate procedures may be required."

Installation of New, Improved Float Valves

(h) Within 50 months after the effective date of this AD: Replace any Argo-Tech float valve, P/N 61600, with a new, improved float valve, P/N 62015–1; replace any Intertechnique float valve, P/N L87–13–001, with a new, improved float valve, P/N L87–13–002 or P/N L87–13–003; and do any applicable corrective action; by accomplishing the actions specified in the Accomplishments Instructions of the applicable service bulletin in Table 3 of this AD. Do any applicable corrective action before further flight. For Airbus Model A330–201, –202, –203, –223, —243, –301, –321, –322, –323, –341, –342, and –343 airplanes: If P/N L87–13–002 is installed, replace the float valve thereafter at intervals not to exceed 24,500 flight cycles. Installation of P/N L87–13–003 on Airbus Model A330–201, –202, –203, –223, —243, –301, –321, –322, –323, –341, –342, and –343 airplanes terminates the repetitive float valve replacement required by this paragraph. Installation of either P/N L87–13–002 or P/N L87–13–003 terminates the borescope inspections required by paragraphs (f) and (g) of this AD. Where the service bulletin specifies to contact the manufacturer, instead contact the Manager, International Branch, ANM–116, or the DGAC (or its delegated agent).

TABLE 3.—SERVICE INFORMATION FOR NEW FLOAT VALVES

Airbus model	Float valve P/N	Airbus service bulletin
A330–201, –202, –203, –223, —243, –301, –321, –322, –323, –341, –342, and –343 airplanes.	62015–1 .. L87–13–002. L87–13–003. L87–13–003.	A330–28–3088, dated April 27, 2004. A330–28–3089, Revision 02, dated April 1, 2005. A330–28–3093, dated June 16, 2005. A330–28–3094, dated April 7, 2005.
A340–211, –212, –213, –311, –312, and —313 airplanes.	62015–1 .. L87–13–002. L87–13–003.	A340–28–4102, dated April 27, 2004. A340–28–4103, Revision 02, dated April 1, 2005. A340–28–4111, dated April 6, 2005.
A340–541— and –642 airplanes.	62015–1 .. L87–13–002. L87–13–003.	A340–28–5007, dated May 7, 2004. A340–28–5010, dated may 7, 2004. A340–28–5021, dated April 6, 2005.

Actions Accomplished Previously

(i) Inspections and related investigative and corrective actions accomplished before the effective date of this AD, in accordance with any applicable Airbus service bulletin identified in Table 4 of this AD, are acceptable for compliance with the corresponding actions specified in this AD.

TABLE 4.—SERVICE INFORMATION FOR ACTIONS ACCOMPLISHED PREVIOUSLY

Airbus model	Airbus service bulletin
A330–201, –202, –203, –223, —243, –301, –321, –322, –323, –341, –342, and –343 airplanes.	A330–28–3087, dated July 24, 2003. A330–28–3089, Revision 01, dated May 12, 2004.
A340–211, –212, –213, –311, –312, and —313 airplanes.	A340–28–4100, dated July 24, 2003. A340–28–4101, dated July 24, 2003. A340–28–4103, Revision 01, dated May 12, 2004. A340–28–5010, dated May 7, 2004. A340–28–5021, dated April 6, 2005.

No Submission of Information/Parts

(j) Where any Airbus service bulletin specifies to submit information to Airbus, or send removed float valves to either Argo-Tech or Intertechnique, those actions are not required by this AD.

Alternative Methods of Compliance (AMOCs)

(k)(1) The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

(2) Before using any AMOC approved in accordance with 14 CFR 39.19 on any airplane to which the AMOC applies, notify the appropriate principal inspector in the FAA Flight Standards Certificate Holding District Office.

Related Information

(l) French airworthiness directives F–2005–003, dated January 5, 2005, and F–2005–004 R1 and F–2005–005 R1, both dated April 27, 2005, also address the subject of this AD.

Material Incorporated by Reference

(m) You must use the documents specified in Table 5 of this AD to perform the actions that are required by this AD, unless the AD specifies otherwise. The Director of the Federal Register approved the incorporation by reference of these documents in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Contact Airbus, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France, for a copy of this service information. You may review copies at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street, SW., room PL–401, Nassif Building, Washington, DC; on the Internet at *http://dms.dot.gov*; or at the National Archives and Records Administration (NARA). For information on the availability of this material at the NARA, call (202) 741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

TABLE 5.—MATERIAL INCORPORATED BY REFERENCE

Airbus service bulletin	Revision level	Date
A330–28–3086, excluding Appendix 01	Original	July 24, 2003.
A330–28–3087, excluding Appendix 01	01	August 16, 2004.
A330–28–3088	Original	April 27, 2004.
A330–28–3089	02	April 1, 2005.
A330–28–3093	Original	June 16, 2005.
A330–28–3094	Original	April 7, 2005.
A340–28–4100	01	August 16, 2004.
A340–28–4101, excluding Appendix 01	01	August 16, 2004.
A340–28–4102	Original	April 27, 2004.
A340–28–4103	02	April 1. 2005.
A340–28–4111	Original	April 6, 2005.
A340–28–5007	Original	May 7, 2004.
A340–28–5010	Original	May 7, 2004.
A340–28–5021	Original	April 6, 2005.

Issued in Renton, Washington, on January 27, 2006.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 06–989 Filed 2–3–06; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2003–NM–271–AD; Amendment 39–14470; AD 2006–03–06]

RIN 2120–AA64

Airworthiness Directives; Empresa Brasileira de Aeronautica S.A. (EMBRAER) Model EMB–135 Airplanes and Model EMB–145, –145ER, –145MR, –145LR, –145XR, –145MP, and –145EP Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to all Empresa Brasileira de Aeronautica S.A. (EMBRAER) Model EMB–135 airplanes, and EMB–145, –145ER, –145MR, –145LR, –145XR, –145MP, and –145EP airplanes. This AD requires inspecting the pilot's and co-pilot's seat tracks for proper locking of the seats, and adjusting or replacing the seat tracks if necessary. This AD also requires replacement of the seat locking pin on certain SICMA-brand seats. The actions specified by this AD are intended to prevent uncommanded movement of the pilot's or co-pilot's seat, which could interfere with the

operation of the airplane and consequent temporary loss of airplane control. This action is intended to address the identified unsafe condition.

DATES: Effective March 13, 2006.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the **Federal Register** as of March 13, 2006.

ADDRESSES: The service information referenced in this AD may be obtained from Empresa Brasileira de Aeronautica S.A. (EMBRAER), P.O. Box 343—CEP 12.225, Sao Jose dos Campos—SP, Brazil; or SICMA Aero Seat, 7 Rue Lucien Coupet, 3600 ISSOUDUN, France. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Todd Thompson, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–1175; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an airworthiness directive (AD) that is applicable to certain Empresa Brasileira de Aeronautica S.A. (EMBRAER) Model EMB–135 airplanes, and EMB–145, –145ER, –145MR, –145LR, –145XR, –145MP, and –145EP airplanes, was published as a supplemental notice of proposed rulemaking (NPRM) in the **Federal Register** on November 9, 2005 (70 FR 67935). That action proposed to require inspecting the pilot's and co-pilot's seat tracks for proper locking of the seats, and adjusting or replacing the seat tracks if necessary. That action revised the applicability and also proposed to require replacing the seat locking pin on certain SICMA-brand seats.

Comments

We provided the public the opportunity to participate in the development of this AD. No comments have been received on the supplemental NPRM or on the determination of the cost to the public.

Clarification of Alternative Method of Compliance (AMOC) Paragraph

We revised the supplemental NPRM to clarify the appropriate procedure for notifying the principal inspector before using any approved AMOC on any airplane to which the AMOC applies.

Conclusion

We have carefully reviewed the available data and determined that air safety and the public interest require adopting the AD with the change described previously. We have determined that this change will neither increase the economic burden on any operator nor increase the scope of the AD.

Cost Impact

The FAA estimates that 550 airplanes of U.S. registry are affected by this AD. The following table shows the estimated cost impact for airplanes affected by this AD. The average labor rate is $65 per work hour.

ESTIMATED COSTS

Action	Number of airplanes affected	Work hours	Parts cost	Total fleet cost
Inspection to determine seat and serial numbers	550	1	$0	$35,750, or $65 per airplane
Inspection (Part I of EMBRAER Service Bulletin 145–53–0027, Revision 03, February 5, 2004).	459	4	0	$119,340, or $260 per airplane
Inspection and Alignment (Part III of EMRAER SB145–53–0027, Revision 03, February 5, 2004).	348	4	0	$90,480, or $260 per airplane
Locking Pin and Spring Replacement (SICMA Aero Seat SB 147–25–020, Issue 2, December 22, 2003).	459	1	684	$343,791, or $749 per airplane

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of the requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Authority for this Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in subtitle VII, part A, subpart III, section 44701, "General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Impact

The regulations adopted herein will not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

For the reasons discussed above, I certify that this action (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

■ Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

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

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. Section 39.13 is amended by adding the following new airworthiness directive:

2006–03–06 Empresa Brasileira de Aeronautica S.A. (EMBRAER): Amendment 39–14470. Docket 2003–NM–271–AD.

Applicability: All Model EMB–135BJ, –135ER, –135KE, –135KL, and –135LR airplanes; and Model EMB–145, –145ER, –145MR, –145LR, –145XR, –145MP, and –145EP airplanes; certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

To prevent uncommanded movement of the pilot's or copilot's seat, which could interfere with the operation of the airplane and consequent temporary loss of airplane control, accomplish the following:

Initial Inspection and Corrective Action

(a) Within 500 flight hours after the effective date of this AD, do the actions specified in paragraphs (a)(1), (a)(2), and (a)(3), as applicable.

(1) For all airplanes: Do an inspection of the pilot's and co-pilot's seats for part numbers (P/N) and serial numbers (S/N). A review of airplane maintenance records is acceptable in lieu of this inspection if the P/N and S/N of the seats can be conclusively determined from that review.

(i) If any seat is found to have P/N 1471610–00 or 1471611–00, and the S/N is 000 through 324 inclusive: Before further flight, do general visual and detailed inspection of the seat tracks for proper locking of the seats, and do all applicable related investigative actions and corrective actions, in accordance with Parts I and II, as applicable, of the Accomplishment Instructions of the EMBRAER Service Bulletin 145–53–0027, Revision 03, dated February 5, 2004.

Note 1: For the purposes of this AD, a general visual inspection is: "A visual examination of an interior or exterior area, installation, or assembly to detect obvious damage, failure, or irregularity. This level of inspection is made from within touching distance unless otherwise specified. A mirror may be necessary to ensure visual access to all surfaces in the inspection area. This level of inspection is made under normally available lighting conditions such as daylight, hangar lighting, flashlight, or droplight and may require removal or opening of access panels or doors. Stands, ladders, or platforms may be required to gain proximity to the area being checked."

Note 2: For the purposes of this AD, a detailed inspection is: "An intensive examination of a specific item, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at an intensity deemed appropriate. Inspection aids such as mirror, magnifying lenses, etc., may be necessary. Surface cleaning and elaborate procedures may be required."

Note 3: EMBRAER Service Bulletin 145–53–0027, Revision 03, dated February 5, 2004, refers to EMBRAER EMB–145 Structural Repair Manual, Chapter 53–12–11, dated July 18, 2001, as an additional source of information on the limits of acceptable wear.

(ii) If seats are found not to have P/N 1471610–00 or 1471611–00, and a S/N that is up to and including 324 inclusive: No further action is required by this paragraph.

(2) For airplanes having S/N 145004 through 145290 inclusive, do the actions specified in paragraph (a)(2)(i) or (a)(2)(ii) of this AD, as applicable.

(i) For airplanes with a seat track having P/N 145–33669–001: Do general visual and detailed inspections of the seat track(s) for proper locking of the seat and excessive wear, and do any applicable corrective action, in accordance with Parts I and II, as applicable, of the Accomplishment Instructions of EMBRAER Service Bulletin 145–53–0027, Revision 03, dated February 5, 2004. Replace seat tracks that are found to have excessive wear within 50 flight hours after the inspection with a new seat track having P/N 145–33669–003 or 145–33669–601. Do any other applicable corrective action before further flight. Repeat the general visual and detailed inspections thereafter at intervals not to exceed 500 flight hours until the seat track is replaced by a new seat track having P/N 145–33669–003 or 145–33669–601.

(ii) For airplanes without a seat track having P/N 145–33669–001: No further action is required by this paragraph.

(3) For airplanes having S/N 145002 through 145560 inclusive: If any seat is found during the inspection required by paragraph (a)(1) of this AD that does not have a P/N and S/N specified in paragraph (a)(1)(i) of this AD, within 500 flight hours after the effective date of this AD, do a general visual and detailed inspection of the pilot's and co-pilot's seats for proper locking of the seats, and do all applicable related investigative and corrective actions in accordance with Part III of the Accomplishment Instructions of EMBRAER Service Bulletin 145–53–0027, Revision 03, dated February 5, 2004, except as provided by paragraph (d) of this AD. Do any corrective actions before further flight.

Replacement

(b) For airplanes with a SICMA seat(s) bearing a P/N listed in Table 1 of this AD, within 1,000 flight hours after the effective date of this AD, replace the seat locking pin with a new, improved seat locking pin in accordance with the Accomplishment Instructions of SICMA Aero Seat Service Bulletin 147–25–020, Issue 2, dated December 22, 2003. For airplanes without any SICMA seat bearing a P/N listed in Table 1 of this AD, no further action is required by this paragraph.

TABLE 1.—SICMA SEAT P/NS

Part number
1471610–00
1471610–01
1471610–02
1471610–03
1471611–00
1471611–01
1471611–02
1471611–03

Parts Installation

(c) As of the effective date of this AD, no SICMA seat bearing a P/N listed in Table 1 of this AD may be installed on any airplane unless the seat locking pin has been replaced in accordance with paragraph (b) of this AD.

Certain Repairs

(d) Where the EMBRAER service bulletin recommends contacting EMBRAER for appropriate action: Before further flight, repair per a method approved by either the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the Departamento de Aviacao Civil (or its delegated agent).

Actions Accomplished Per Previous Issue of Service Bulletin

(e) Accomplishment of the actions specified in EMBRAER Service Bulletin 145–53–0027, dated May 31, 2001; Change 01, dated March 12, 2002; or Revision 02, dated January 24, 2003; before the effective date of this AD, is considered acceptable for compliance with the corresponding requirements of paragraph (a) of this AD.

(f) Accomplishment of the actions specified in SICMA Aero Seat Service Bulletin 147–25–020, dated November 17, 2003; or Issue 1, dated December 3, 2003; before the effective date of this AD, is considered acceptable for compliance with the requirements of paragraph (b) of this AD.

Alternative Methods of Compliance

(g)(1) In accordance with 14 CFR 39.19, the Manager, International Branch, ANM–116, FAA, is authorized to approve alternative methods of compliance (AMOCs) for this AD.

(2) Before using any AMOC approved in accordance with 14 CFR 39.19 on any airplane to which the AMOC applies, notify the appropriate principal inspector in the FAA Flight Standards Certificate Holding District Office.

Incorporation by Reference

(h) Unless otherwise specified in this AD, the actions must be done in accordance with EMBRAER Service Bulletin 145–53–0027, Revision 03, dated February 5, 2004; and SICMA Aero Seat Service Bulletin 147–25–020, Issue 2, dated December 22, 2003; as applicable. (Pages 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, and 28 of EMBRAER Service Bulletin 145–53–0027 specify an incomplete document date; the date on those pages should read "05/Feb/2004.") This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. To get copies of this service information, contact Empresa Brasileira de Aeronautica S.A. (EMBRAER), P.O. Box 343—CEP 12.225, Sao Jose dos Campos—SP, Brazil; or SICMA Aero Seat, 7 Rue Lucien Coupet, 36100 ISSOUDUN, France. To inspect copies of this service information, go to the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or to the National Archives and Records Administration (NARA). For information on the availability of this material at the NARA, call (202) 741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Note 4: The subject of this AD is addressed in Brazilian airworthiness directive 2002–09–01R1, effective June 2, 2004.

Effective Date

(i) This amendment becomes effective on March 13, 2006.

Issued in Renton, Washington, on January 24, 2006.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 06–990 Filed 2–3–06; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 17

Change of Address; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to reflect a change in the address for the Departmental Appeals Board (DAB). This action is editorial in nature and is intended to improve the accuracy of the agency's regulations.

DATES: This rule is effective February 6, 2006.

FOR FURTHER INFORMATION CONTACT: Joyce A. Strong, Office of Policy (HF–27), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–31, Rockville, MD 20857, 301–827–7010.

SUPPLEMENTARY INFORMATION: This document amends FDA's regulations to reflect the address change of the DAB by removing the outdated address in § 17.47(a) (21 CFR 17.47(a)) and by adding the new address in its place.

Publication of this document constitutes final action on these changes under the Administrative Procedure Act (5 U.S.C. 553). Notice and public procedures are unnecessary because FDA is merely correcting nonsubstantive errors.

List of Subjects in 21 CFR Part 17

Administrative practice and procedure, Penalties.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 17 is amended as follows:

PART 17—CIVIL MONEY PENALTIES HEARINGS

■ 1. The authority citation for 21 CFR part 17 continues to read as follows:

Authority: 21 U.S.C. 331, 333, 337, 351, 352, 355, 360, 360c, 360f, 360i, 360j, 371; 42 U.S.C. 262, 263b, 300aa–28; 5 U.S.C. 554, 555, 556, 557.

§ 17.47 [Amended]

■ 2. Section 17.47 is amended in paragraph (a) by removing "rm. 637–D, Hubert H. Humphrey Bldg., 200 Independence Ave. SW., Washington, DC 20201" and by adding in its place "Appellate Division MS6127, Departmental Appeals Board, United States Department of Health and Human Services, 330 Independence Ave. SW., Cohen Bldg., rm. G–644, Washington, DC 20201".

Dated: January 30, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 06–1040 Filed 2–3–06; 8:45 am]

BILLING CODE 4160–01–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR PART 52

[EPA–R05–OAR–2005–WI–0003; FRL–8020–1]

Approval and Promulgation of Implementation Plans; Wisconsin; General and Registration Permit Programs

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is taking final action to approve revisions to the Wisconsin State Implementation Plan (SIP) submitted by the State of Wisconsin on July 28, 2005. These revisions include General and Registration permit programs that provide for the issuance of general and registration permits as part of the State's construction permit and operation permit programs. In addition, these permit programs may include the regulation of hazardous air pollutants (HAPs) which may be regulated under section 112 of the Clean Air Act (the Act). Thus, EPA is also approving Wisconsin's general and registration permit program under section 112(l) of the Act.

These SIP revisions also contain changes to definitions related to Wisconsin's air permit program, as well as a minor technical change to provide correct references to the updated chapter NR 445, which was inadvertently omitted in the processing of that rule package. Additionally, these revisions clarify an existing construction permit exemption and operation permit exemption for certain grain storage and drying operations. This clarification is necessary to ensure that column dryers and rack dryers are included in the exemption criteria.

DATES: This final rule is effective on March 8, 2006.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–R05–OAR–2005–WI–0003. All documents in the docket are listed on the *http://www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, *i.e.*, Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *http://www.regulations.gov* or in hard copy at the Environmental Protection

Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. This facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays. We recommend that you telephone Susan Siepkowski, Environmental Engineer, at (312) 353–2654 before visiting the Region 5 office.

FOR FURTHER INFORMATION CONTACT: Susan Siepkowski, Environmental Engineer, Air Permit Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 353–2654, *siepkowski.susan@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document whenever "we," "us," or "our" is used, we mean EPA. This supplementary information section is arranged as follows:

I. Background Information for Today's Action

On September 20, 2005, EPA published a proposal to approve Wisconsin's July 28, 2005 SIP revision request, pertaining to registration and general permits. (70 FR 55062). This revision provides for the issuance of general and registration permits as part of the State's construction permit and operation permit programs. It also proposed to approve Wisconsin's general and registration permit program under section 112(l) of the Act, changes to definitions related to Wisconsin's air permit program, and clarifications to permit exemptions for certain grain storage and drying operations. EPA provided in the proposal a summary of these revisions as well as its analysis for determining whether the revisions complied with Federal requirements.

In the proposal EPA solicited comments, which were due October 20, 2005. EPA received one timely adverse comment on the proposed rule. A copy of this comment letter is available in the RME Docket, both electronically and a hard copy. A summary of the comments received and our responses are discussed in the section below.

II. What Comments Did We Receive and What Are Our Responses?

The comments EPA received on the September 20, 2005, proposal object to giving final approval to Wisconsin's registration and general permit programs. Some of the comments pertain to the draft registration permit templates recently public noticed by WDNR. We will address in this rulemaking only the comments pertaining to the September 20, 2005, proposal. The following is a summary of the comments received and our responses.

Comment: Contrary to EPA's proposed rule, Wisconsin's proposed general and registration permit program is not limited to "Nonmetallic mineral processing plants, asphalt plants, small natural gas fired generators, small heating units, printing presses, and hospital sterilization equipment."

Response: The proposal stated, "Categories of sources that are or could be eligible for general permits include nonmetallic mineral processing plants, asphalt plants, small natural gas fired generators, small heating units, printing presses and hospital sterilization equipment." The proposal did not state that these were the only sources eligible, nor did it state the list was inclusive. The list was only meant to provide examples of source types that WDNR had given as examples in its proposal.

Comment: The proposed changes do not comply with the requirements of 40 CFR Part 51, section 110 of the Act and fail to ensure the protection of the National Ambient Air Quality Standards (NAAQS). 40 CFR 51.160 requires states to have legally enforceable procedures to prevent construction or modification of a source if it would violate any control strategies in the SIP or interfere with attainment or maintenance of the NAAQS. NR 406.11(1)(g), the proposed provision that would prevent coverage for sources that cause or exacerbate a NAAQS (or increment) does not actually include a pre-construction determination of air quality impacts. The air quality review in this provision is retrospective, not prospective pre-construction review.

The general and registration permits being proposed allow construction or modification in areas of the state with very different existing background air pollution concentrations, number of sources, and terrain. There can be no pre-permit air analysis that will determine whether air quality standards will be violated by any specific source that will construct or modify under a general or registration permit. Additionally, there is no limit on the emission rate or the number of sources that can be covered by a general or registration permit. As a result, a large number of relatively-small sources can locate into the same area and, cumulatively, cause a violation of NAAQS, or a facility can emit large quantities of pollutants over a short period of time.

Response: WDNR must assure that these permit programs do not violate the NAAQS. WDNR is requiring the applicant to perform an air dispersion modeling analysis as part of its application for coverage. The analysis must include modeling for all criteria pollutants; however, because there are no increments for volatile organic compounds (VOC) (a pre-curser to ozone), an applicant must submit an analysis for VOC only if the emissions are above the major source threshold for permitting. Regarding ozone, "No significant ambient impact concentration has been established. Instead, any net emissions increase of 100 tons per year of VOC subject to PSD would be required to perform an ambient impact analysis." 1990 New Source Review Workshop Manual, Page C.28, footnote b. However, because the pollutant of concern is ozone and the standard Gaussian models used for PSD (*i.e.*, ISCST3 or AERMOD) don't estimate ozone concentrations, determining ozone impacts from individual sources is difficult. Thus, states often use another type of analysis for VOC.

Upon receipt of the application and analysis, the WDNR has 15 days to determine whether the source is eligible for coverage under a general or registration construction permit, as provided in NR 406.16(3)(c) and 407.17(4)(c).

NR 406.11(1)(g) provides that the source may conduct the air quality determination after the determination that the source is covered under the general or registration construction permit. However, NR 406.16(2)(c) and 406.17(3) also provide that if an emissions unit or units cause or exacerbate, or may cause or exacerbate, a violation of any ambient air quality standard or ambient air increment, a source is ineligible for coverage under the general or registration construction permit. By requiring the permittee to submit a modeling analysis, combined with these provisions in NR 406, WDNR will ensure that a source will not violate the NAAQS.

Further, nothing in the proposed revisions relieves any source from the requirement to submit its yearly emissions for inclusion in the emissions inventory. A note in the rule after section NR 406.17(4)(e) and 407.105(4)(e) states, "**Note:** The permit terms and conditions may include capture and control efficiencies. The Air Emissions Management System (AEMS) requires the owner or operator of a source to calculate actual annual emissions for reporting to the inventory using the terms and conditions in a

permit." The data in the emissions inventory is also used for purposes of determining compliance with NAAQS.

Comment: Even when the WDNR revokes a permit due to a violation of NAAQS or an increment, the violating source is authorized to continue operating under the general or registration permit until a subsequent permit is issued. NR 406.11(1)(g)(2) provides that the permittee is "deemed to be in compliance with the requirement to obtain a construction permit until the department takes final action on a subsequent application for a construction permit. . ."

Section NR 407.105 of the proposed revisions, also allow a facility to be deemed "in compliance" with the SIP for 90 days even if the facility did not determine that a SIP requirement applied and is not in compliance with the limit. Additionally, the "safe harbor" language in the proposed provision is essentially a permit shield, which extends to requirements which were never included specifically in a permit, either as an applicable requirement or in a non-applicability determination.

Response: Since EPA's September 20, 2005, proposed approval of this rule, WDNR has withdrawn provisions NR 406.11(1)(g)(2), 407.105(7), and 407.15(8)(b) for inclusion in its SIP.

Comment: The proposed changes do not comply with the public participation requirements and procedures required by 40 CFR parts 51 and 70. The public notice and comment procedure required by part 51 is not satisfied by merely allowing notice and comment on a generic permit, which WDNR later applies to specific facilities. The required public notice and comment process requires public inspection of the information provided by the applicant and the agency's analysis of the effect on air quality. There is no provision in the proposed general and registration permit program whereby the public gets notice and the ability to comment on "the information submitted by the owner or operator and of the State or local agency's analysis of the effect on air quality." 40 CFR 51.161(b).

Further, proposed section NR 406.16(1)(c) states that "the procedural requirements in s. 285.61(2) to (8), Stats., do not apply to the determination of whether an individual source is covered by a general construction permit for a source category." Proposed section NR 406.17(1)(b) contains similar language for registration permits.

In addition, the general part 70 permits don't comply with the public notice requirements of part 70. The WDNR must provide the public with, *inter alia*: the identity of the affected facility; the name and address of the permittee; the name and address of the permitting authority processing the permit; the activity or activities involved in the permit action; the emissions change involved in any permit modification; the name, address, and telephone number of a person from whom interested persons may obtain additional information, including copies of the permit draft, the application, all relevant supporting materials, and all other materials available to the permitting authority that are relevant to the permit decision. The Act also requires application materials, including compliance certification and compliance plans, to be made public.

Response: As discussed in the proposal, EPA has determined that, in cases where standardized permits have been adopted, EPA and the public need not be involved in their application to individual sources as long as the standard permits themselves have been subject to notice and opportunity to comment. Specifically, EPA's January 25, 1995 memorandum "Guidance on Enforceability Requirements for Limiting Potential to Emit through SIP and § 112 Rules and General Permits" states that "since the rule establishing the program does not provide the specific standards to be met by the source, each general permit, but not each application under each general permit, must be issued pursuant to public and EPA notice and comment." P.10

EPA's April 14, 1998, guidance from John S. Seitz, "Potential to Emit (PTE) Guidance for Specific Source Categories" states, "There are two overall approaches that States and local agencies can use to establish enforceable emission limits* * * Under the second approach, generally appropriate for less complex sources, States and local agencies create a standard set of terms and conditions for many similar sources at the same time. The terms air quality agencies use to describe this approach include "general permits," "prohibitory rules," "exclusionary rules," and "permits-by-rule." (From this point on, rather than to repeat each of these terms, this guidance will use the term "prohibitory rule" for the latter three terms.)" This guidance further states, "State "prohibitory rules" are similar to general permits, but States or local agencies put them in place with a regulation development process rather than a permitting process."

Additionally, EPA's January 25, 1995, Memorandum from John S. Seitz, "Options for Limiting the Potential to Emit (PTE) of a Stationary Source Under Section 112 and Title V of the Clean Air Act", states, "A concept similar to the exclusionary rule is the establishment of a general permit for a given source type. A general permit is a single permit that establishes terms and conditions that must be complied with by all sources subject to that permit. The establishment of a general permit provides for conditions limiting potential to emit in a one-time permitting process, and thus avoids the need to issue separate permits for each source within the covered source type or category."

The State of Massachusetts, "Summary of Comments and Responses to Comments from Public Hearing on Proposed Amendments to 310 CMR 7.00", to which the commenters cite, states, "EPA interprets its regulations at 40 CFR 51.160 to require that all proposed sources undergo full permit review before construction, with the exception of sources constructed pursuant to prohibitory rules."

EPA has stated in guidance that prohibitory rules and general permits are essentially similar, and that neither require individual permit review. Thus, a one-time permit process can be used if the general permit receives full review. While EPA's guidance documents pertaining to general permits generally apply to operation permits, the concept can also be applied to general construction permits, as these are similar to construction pursuant to prohibitory rules. Every general permit issued to a source would not need to go through full review if the general permit did, provided certain materials are still made available to the public.

WDNR must make available to the public all of the permit information listed in parts 51 and 70. Similar to the construction and operation permits WDNR issues, the registration and general permits will also be available on a WDNR Web site. An up-to-date list of sources covered by registration or general permits, with all of the required permittee and facility information, as well the electronic application, will be available to view on-line. In addition, anyone can request to view any permit related materials by contacting the WDNR.

Regarding NR 406.16(1)(c) which states that, "The department may issue the general construction permit if the applicable criteria in s. 285.63, Stats., are met. The procedural requirements in s. 285.61(2) to (8), Stats., do not apply to the determination of whether an individual source is covered by a general construction permit for a source category." There is a note that follows

this section which states, "The statutes cited above require that when issuing a general construction permit, the department distribute a notice of the availability of the proposed general construction permit and of the department's analysis and preliminary determination, a notice of the opportunity for public comment and a notice of the opportunity to request a public hearing. There will be a 30-day public comment period and the department may hold a public hearing within 60 days after the deadline for requesting one."

Wisconsin Stat. 285.63, which contains the criteria for permit approval, requires the source to meet all applicable emission limitations; and prohibits the source from violating or exacerbating an air quality standard or ambient air increment, and from precluding construction or operation of other sources. Wisconsin Stat. 285.61(2) to (8) contains the procedural requirements for construction permit application and review, and requires the WDNR to: prepare an analysis regarding the effect of the proposed construction, distribute and publicize the analysis and a notice of the opportunity to request a public hearing, receive public comments, and hold a public hearing on the construction permit if requested.

As discussed above, because the general permit will go through the procedures in Stat. 285, these procedures will not be required each time the general permit is issued to a specific source.

Comment: The proposed revisions allow the WDNR to determine that the requirements of NR 424.03(2)(a) or (b) are technologically infeasible for every source that will potentially be covered under a general or registration permit. Provision NR 424.03 requires WDNR to determine whether 85% reduction of VOCs is technologically infeasible.

Response: NR 406.16(1)(d) states, "* * * Notwithstanding the requirement in s. NR 424.03(2)(c) to determine the latest available control techniques and operating practices demonstrating best current technology (LACT) for a specific process line, the department may include conditions in the general construction permit that represent LACT, if the requirements of s. NR 424.03(2)(a) or (b) are determined to be technologically infeasible." Similar language is included in and 406.17(1)(d), 407.10(1)(d), and 407.105(1)(c).

Wisconsin Stat. NR 424.03 requires 85% control of VOCs for certain sources. NR 424.03(2)(b)(2) states, "Where 85% control has been demonstrated to be technologically infeasible for a specific process line, control organic compound emissions by the use of the latest available control techniques and operating practices demonstrating best current technology, as approved by the Department." NR 424.03(3) further states, "Surface coating and printing processes subject to the requirements of this section may instead elect, with the approval of the Department, to meet the emission limitations of s. NR 422.01 to 422.155, notwithstanding ss. NR 422.03(1), (2), (3) or (4) and 425.03, provided that: (a) The process line meets the specific applicability requirements of ss. NR 422.05 to 422.155; and (b) The owner or operator submits a written request to the department * * *" (NR 422.01 to 422.155 provides specific conditions for the control of VOC emissions for various types of surface coating, printing and asphalt surfacing operations.)

Wisconsin's rule 424.03(2)(b)(2) does not require a case-by-case or permit-by-permit analysis, and gives the WDNR the authority to made such determinations. The WDNR is making such a determination for the general construction permits. EPA believes this is consistent with Wisconsin's authority under 424.03.

Comment: The proposed rule provides that no construction permit is required if construction, reconstruction, or modification does not violate the term of a general operating permit. However, many requirements in the Wisconsin SIP are triggered, and become more stringent, when a source is modified or reconstructed. The proposed NR 407.10(4) does not prevent construction and modification, but does not require compliance with the more stringent SIP limits, which may become applicable, such as opacity. In fact, it does not require the source to notify the WDNR or EPA that it made the change. Instead, the proposed NR 407.10(4) merely requires the source to comply with the existing SIP limit.

Response: If a source with a general permit becomes subject to an applicable requirement, such as an opacity limit, that is different from the limit included in the general permit, or that is not included in the general permit, then the source no longer qualifies for that general permit. NR 407.10(4)(a)(1) provides, "Notwithstanding the provisions in s. NR 406.04(1) and (2), no construction permit is required prior to commencing construction, reconstruction, replacement, relocation or modification of a stationary source if the source is covered under a general operation permit and all of the following criteria are met: 1. The construction, reconstruction, replacement, relocation or modification will not result in the source violating any term or condition of the general operation permit."

Furthermore, if construction causes a new requirement to become applicable that is not in the general permit, the source would no longer be eligible for the general permit and would need to apply for another permit. NR 407.10(3)(b) provides "(b) An owner or operator of a stationary source who requests or *requires* emission limits, terms or conditions other than, or in addition to, those contained in the general operation permit shall apply for a different type of permit." (Emphasis added.) Further, coverage under a general permit does not preclude a source from complying with Stat. 285.63, which requires sources to comply with all applicable requirements.

Comment: The operating permit program will not require that all emissions, limitations, controls and other requirements imposed by such permits will be at least as stringent as any other applicable imitation or requirement contained in the SIP.

Further, the rules and the draft permits already issued by WDNR under the proposed SIP revision do not identify what limits, controls and requirements apply to a source. Instead, the permit requires the owner or operator to "meet all applicable air pollution requirements in ch. 285, Wis. Stats., and chs. NR 400–NR 499, and therefore, there is no way for the requirement to be enforced.

Response: The registration and general permit rule is not a prohibitory rule and, thus, the permits, not the rule itself, will contain the emissions limitations, controls and other requirements applicable to the source. The rule requires the operation permits to contain these conditions, and NR 407.105(1)(c) provides, "The registration operation permit shall contain applicability criteria, emission caps and limitations, monitoring and record keeping requirements, reporting requirements, compliance demonstration methods and general conditions appropriate for determining compliance with the terms and conditions of the registration operation permit. The permit terms and conditions shall be those required to comply with the Act and those required to assure compliance with applicable provisions in ch. 285, Stats., and chs. NR 400 to 499." NR 407.10(1)(d) also provides, "The general operation permit shall contain applicability criteria, emission limits, monitoring and record keeping requirements, reporting

requirements, compliance demonstration methods and general conditions applicable to the stationary source category. The permit terms and conditions shall be those required to comply with the Act and those required to assure compliance with applicable provisions in ch. 285, Stats., and chs. NR 400 to 499."

As discussed in the previous response, coverage under a general or registration permit does not preclude a source from complying with Stat. 285.63, which requires sources to comply with all applicable requirements. Therefore, the permits must contain conditions that will be at least as stringent as any other applicable imitation or requirement contained in the SIP.

Comment: The proposed permit programs do not ensure that limitations, controls, and requirements are permanent, quantifiable, and otherwise enforceable as a practical matter. The proposed provisions rely on an annual 25 tons per year (TPY) cap on emissions, rather than a production limit. This violates EPA policy that synthetic minor permits must contain a limit on production to be practically enforceable.

Response: The limitations, controls, and requirements in the general and registration construction and minor operation permits are permanent, as these permits do not expire. However, general part 70 permits have a permit term of 5 years as required by 40 CFR 70.6(a)(2). NR 407.10(1)(e) provides, "The term of a general operation permit issued to a part 70 source category, or granted to an individual part 70 source, may not exceed 5 years. General operation permits issued to a non-part 70 source category, or granted to an individual non-part 70 source, shall only expire if an expiration date is requested by the source owner or operator or the department finds that expiring coverage would significantly improve the likelihood of continuing compliance with applicable requirements, compared to coverage that does not expire."

The limitations in the permits must be quantifiable. NR 407.15(2)(a)(1) requires, "The calendar year sum of actual emissions of each air contaminant from the facility may not exceed 25% of any major source threshold in s. NR 407.02(4), except that for lead, emissions may not exceed 0.5 tons per calendar year." The permits must provide a mechanism to demonstrate the source will meet these limitations, and the rule requires the permits to contain emission limits, monitoring and record keeping requirements, reporting requirements, compliance demonstration methods in order to determine compliance with all limits.

Additionally, the limitations, controls, and requirements in the permits must be practically enforceable. EPA has discussed practical enforceability in various guidance documents. EPA's January 25, 1995, John S. Seitz memorandum, "Options for Limiting the Potential to Emit (PTE) of a Stationary Source Under Section 112 and Title V of the Clean Air Act", states,

> Consequently, in all cases, limitations and restrictions must be of sufficient quality and quantity to ensure accountability (see 54 FR 27283). * * * In general, practicable enforceability for a source-specific permit means that the permit's provisions must specify: (1) A technically-accurate limitation and the portions of the source subject to the limitation; (2) the time period for the limitation (hourly, daily, monthly, and annual limits such as rolling annual limits); and (3) the method to determine compliance including appropriate monitoring, record keeping, and reporting. For rules and general permits that apply to categories of sources, practicable enforceability additionally requires that the provisions: (1) Identify the types or categories of sources that are covered by the rule; (2) where coverage is optional, provide for notice to the permitting authority of the source's election to be covered by the rule; and (3) specify the enforcement consequences relevant to the rule.

Wisconsin's rule meets these requirements. The rule at NR 407.105(1)(c) and 407.10(1)(d) requires the permits to contain adequate emission caps and limitations, monitoring and record keeping requirements, reporting requirements, compliance demonstration methods and general conditions for determining compliance. Additionally, the rule at NR 407.10(1)(b) identifies the types or categories of sources that can be covered by the general permit, and coverage is elective, as provided by NR 407.10(3)(a). Further, if a facility covered by a registration or general permit emits more than its permitted cap, or does not comply with a permit term, it will no longer be eligible for the registration or general permit.

III. What Action Is EPA Taking Today?

After carefully reviewing and considering the issues raised by the commenter, EPA is taking final action to approve the proposed SIP revision. EPA is approving all revisions to Wisconsin SIP rules NR 400, 406, 407, and 410 submitted by the State on July 28, 2005, except the sections which Wisconsin later withdrew from consideration. The general construction and operation permit provisions are codified at NR 406.16 and NR 407.10 of the Wisconsin Administrative Code, respectively. Registration construction and operation permit provisions are codified at NR 406.17 and NR 407.105, respectively. EPA is also approving Wisconsin's general permit program under section 112(l) of the Act for the purpose of creating federally enforceable limitations on the potential to emit HAPs regulated under section 112.

This SIP revision amends provisions of Wisconsin's construction and operation permit programs, NR 406.04(1) and NR 407.03(1), respectively, relating to an existing exemption for certain grain storage and processing facilities from needing to obtain a construction or operation permit. Additionally, several sections in NR 406 and NR 407 are renumbered because of the addition of new provisions and definitions, and changes are being made to NR 410.03(1)(a)(5), NR 410.03(1)(a)(6) and (7), Wisconsin's air permit fee rules. EPA is not approving NR 406.11(1)(g)(2), 407.107(7), and 407.15(8)(b) which were included in the State's July 28, 2005, submittal because WDNR has since withdrawn these provisions from inclusion in its SIP. *See* letter from Lloyd L. Eagan, Director, to Thomas Skinner, Regional Administrator, dated November 14, 2005, in which Wisconsin withdrew the cited sections from its July 28, 2005 submission.

Specifically, the approved SIP revision repeals NR 406.04(1)(c) and 407.03(1)(c); renumbers NR 406.02(1) to (4); amends NR 406.04(1)(ce), (cm) and (m)(intro.), 406.11(1)(intro.) and (c), 407.03(1)(ce) and (cm), 407.05(7), 407.15(intro.) and (3), 410.03(1)(a)(5), and 484.05(1); repeals and recreates NR 407.02(3) and 407.10; and creates NR 400.02(73m) and (131m), 406.02(1) and (2), 406.04(2m), 406.11(1)(g)(1), 406.11(3), 406.16, 406.17, 406.18, 407.02(3m), 407.105(1) to (6), 407.107, 407.14 Note, 407.14(4)(c), 407.15(8)(a) and 410.03(1)(a)(6) and (7).

IV. Statutory and Executive Order Reviews

Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866 (*58 FR 51735*, September 30, 1993), this action is not a "significant regulatory action" and therefore is not subject to review by the Office of Management and Budget.

Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

Because it is not a "significant regulatory action" under Executive Order 12866 or a "significant energy action," this action is also not subject to Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (*66 FR 28355*, May 22, 2001).

Regulatory Flexibility Act

This action merely approves state law as meeting federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this rule 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.*).

Unfunded Mandates Reform Act

Because this rule approves pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Public Law 104–4).

Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (*65 FR 67249*, November 9, 2000).

Executive Order 13132: Federalism

This action also does not have Federalism implications because it does not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (*64 FR 43255*, August 10, 1999). This action merely approves a state rule implementing a federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act.

Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

This rule also is not subject to Executive Order 13045 "Protection of Children from Environmental Health Risks and Safety Risks" (*62 FR 19885*, April 23, 1997), because it is not economically significant.

National Technology Transfer Advancement Act

In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. In this context, in the absence of a prior existing requirement for the state to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 *note*) do not apply.

Paperwork Reduction Act

This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

Under Section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by April 7, 2006. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (*See* Section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: December 27, 2005.

Bharat Mathur,

Acting Regional Administrator, Region 5.

■ For the reasons stated in the preamble, part 52, chapter I, of title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

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

Authority: 42 U.S.C. 7401 *et seq.*

Subpart YY—Wisconsin

■ 2. Section 52.2570 is amended by adding paragraph (c)(113) to read as follows:

§ 52.2570 Identification of plan.

* * * * *

(c) * * *

(113) Approval—On July 28, 2005, Wisconsin submitted General and Registration construction and operation permitting programs for EPA approval into the Wisconsin SIP. EPA also is approving these programs under section 112(l) of the Act. EPA has determined that these permitting programs are approvable under the Act, with the exception of sections NR 406.11(1)(g)(2), 407.105(7), and 407.15(8)(b), which Wisconsin withdrew from consideration on November 14, 2005. Finally, EPA is removing from the state SIP NR 406.04(1)(c) and 407.03(1)(c), the exemption for certain grain storage and processing facilities from needing to obtain a construction or operation permit, previously approved in paragraphs (c)(75) and (c)(76) of this section.

(i) Incorporation by reference.

(A) NR 406.02(1) through (4), amended and published in the (Wisconsin) Register, August 2005, No. 596, effective September 1, 2005.

(B) NR 406.04(1) (ce), (cm) and (m) (intro.), 406.11(1) (intro.) and (c), 407.03(1) (ce) and (cm), 407.05(7), 407.15 (intro.) and (3), 410.03(1)(a)(5), and 484.05(1) as amended and

published in the (Wisconsin) Register, August 2005, No. 596, effective September 1, 2005.

(C) NR 407.02(3) and 407.10 as repealed, recreated and published in the (Wisconsin) Register, August 2005, No. 596 effective September 1, 2005.

(D) NR 400.02(73m) and (131m), 406.02(1) and (2), 406.04(2m), 406.11(1)(g)(1), 406.11(3), 406.16, 406.17, 406.18, 407.02(3m), 407.105 (1) through (6), 407.107, 407.14 Note, 407.14(4)(c), 407.15(8)(a), and 410.03(1)(a)(6) and (7) as created and published in the (Wisconsin) Register, August 2005, No. 596, effective September 1, 2005.

[FR Doc. 06–1030 Filed 2–3–06; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 82

[FRL–8028–2]

RIN 2060–AN18

Protection of Stratospheric Ozone: The 2006 Critical Use Exemption From the Phaseout of Methyl Bromide

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is taking final action to exempt methyl bromide production and import for 2006 critical uses. Specifically, EPA is authorizing uses that will qualify for the 2006 critical use exemption, and the amount of methyl bromide that may be produced, imported, or made available from inventory for those uses in 2006. EPA's action is taken under the authority of the Clean Air Act (CAA) and reflects recent consensus Decisions taken by the Parties to the Montreal Protocol on Substances that Deplete the Ozone Layer (Protocol) at the 16th and 17th Meetings of the Parties (MOPs) and the 2nd Extraordinary Meeting of the Parties (ExMOP).

DATES: This final rule is effective on February 1, 2006.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–OAR–2005–0122. All documents in the docket are listed on the *http://www.regulations.gov* web site. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the Air Docket, EPA/DC, EPA West, Room B102, 1301 Constitution Ave., NW., Washington DC. This Docket Facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (202) 566–1742. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Air Docket is (202) 566–1742.

FOR FURTHER INFORMATION CONTACT: Marta Montoro, Office of Atmospheric Programs, Stratospheric Protection Division, Mail Code 6205 J, Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; telephone number: (202) 343–9321; fax number: (202) 343–2337; e-mail address: *mebr.allocation@epa.gov*.

SUPPLEMENTARY INFORMATION: This final rule concerns Clean Air Act restrictions on the consumption, production, and use of methyl bromide (class I, Group VI controlled substance) for critical uses during calendar year 2006. Under the Clean Air Act, methyl bromide consumption and production was phased out on January 1, 2005 apart from certain exemptions, including the critical use exemption and the quarantine and preshipment exemption. With this action, EPA is listing the uses that will qualify for the 2006 critical use exemption, as well as authorizing specific amounts of methyl bromide that may be produced, imported, or made available from inventory for critical uses in 2006.

Section 553(d) of the Administrative Procedure Act (APA), 5 U.S.C. Chapter 5, generally provides that rules may not take effect earlier than 30 days after they are published in the **Federal Register**. EPA is issuing this final rule under section 307(d) of the CAA, which states: "The provisions of section 553 through 557 * * * of Title 5 shall not, except as expressly provided in this subsection, apply to actions to which this subsection applies." CAA section 307(d)(1). Thus, section 553(d) of the APA does not apply to this rule. EPA nevertheless is acting consistently with the policies underlying APA section 553(d) in making this rule effective on February 1, 2006. APA section 553(d) provides an exception for any action that grants or recognizes an exemption or relieves a restriction. This final rule grants an exemption from the phaseout of methyl bromide.

Table of Contents

I. General Information

A. Regulated Entities

Entities potentially regulated by this action are those associated with the production, import, export, sale, application and use of methyl bromide covered by an approved critical use exemption. Potentially regulated categories and entities include:

Category	Examples of regulated entities
Industry	Producers, Importers and Exporters of methyl bromide; Applicators, Distributors of methyl bromide; Users of methyl bromide such as farmers of vegetable crops, fruits and seedlings, owners of stored food commodities and structures such as grain mills and processors, and government and non-government researchers.

The above table is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be regulated by this action. This table lists the types of entities that EPA is aware could be potentially regulated by this action. To determine whether your facility, company, business, or organization is regulated by this action, you should carefully examine the regulations promulgated at 40 CFR Part 82, Subpart A. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** Section.

II. What Is the Background to the Phaseout Regulations for Ozone-Depleting Substances?

The current regulatory requirements of the Stratospheric Ozone Protection Program that limit production and consumption of ozone-depleting substances can be found at 40 CFR Part 82 Subpart A. The regulatory program was originally published in the **Federal Register** on August 12, 1988 (53 FR 30566), in response to the 1987 signing and subsequent ratification of the Montreal Protocol on Substances that Deplete the Ozone Layer (Protocol). The United States was one of the original signatories to the 1987 Montreal Protocol and the U.S. ratified the Protocol on April 12, 1988. Congress then enacted, and President George H.W. Bush signed into law, the Clean Air Act Amendments of 1990 (CAAA of 1990) which included Title VI on Stratospheric Ozone Protection, codified as 42 U.S.C. Chapter 85, Subchapter VI, to ensure that the U.S. could satisfy its obligations under the Protocol. EPA issued new regulations to implement this legislation and has made several amendments to the regulations since that time.

III. What Is Methyl Bromide?

Methyl bromide is an odorless, colorless, toxic gas which is used as a broad-spectrum pesticide and is controlled under the CAA as a Class I ozone-depleting substance (ODS). Methyl bromide is used in the U.S. and throughout the world as a fumigant to control a wide variety of pests such as insects, weeds, rodents, pathogens, and nematodes. Additional characteristics and details about the uses of methyl bromide can be found in the rule on the phaseout schedule for methyl bromide published in the **Federal Register** on March 18, 1993 (58 FR 15014) and the final rule published in the **Federal Register** on December 10, 1993 (58 FR 65018).

The phaseout schedule for methyl bromide production and consumption was revised in a direct final rulemaking on November 28, 2000 (65 FR 70795), which allowed for the phased reduction in methyl bromide consumption and extended the phaseout to 2005. The revised phaseout schedule was again amended to allow for an exemption for quarantine and preshipment purposes with a final rule (68 FR 238) on January 2, 2003. Information on methyl bromide can be found at *http://www.epa.gov/ozone/mbr* and *http://www.unep.org/ozone* or by contacting EPA's Stratospheric Ozone Hotline at 1–800–296–1996.

Because it is a pesticide, methyl bromide is also regulated by EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and other statutes and regulatory authority, as well as by States under their own statutes and regulatory authority. Under FIFRA, methyl bromide is a restricted use pesticide. Because of this status, a restricted use pesticide is subject to certain Federal and State requirements governing its sale, distribution, and use. Nothing in this final rule implementing the Clean Air Act is intended to derogate from provisions in any other Federal, State, or local laws or regulations governing actions including, but not limited to, the sale, distribution, transfer, and use of methyl bromide. All entities that would be affected by provisions of this rule must continue to comply with FIFRA and other pertinent statutory and regulatory requirements for pesticides (including, but not limited to, requirements pertaining to restricted use pesticides) when importing, exporting, acquiring, selling, distributing, transferring, or using methyl bromide for critical uses. The regulations in this action are intended only to implement the CAA restrictions on the production, consumption, and use of methyl bromide for critical uses exempted from the phaseout of methyl bromide.

IV. What Is the Legal Authority for Exempting the Production and Import of Methyl Bromide for Critical Uses Authorized by the Parties to the Montreal Protocol?

Methyl bromide was added to the Protocol as an ozone-depleting substance in 1992 through the Copenhagen Amendment to the Protocol. The Parties authorize critical use exemptions through their Decisions.

The Parties agreed that each industrialized country's level of methyl bromide production and consumption in 1991 should be the baseline for establishing a freeze in the level of methyl bromide production and consumption for industrialized countries. EPA published a final rule in the **Federal Register** on December 10, 1993 (58 FR 65018), listing methyl bromide as a class I, Group VI controlled substance, freezing U.S. production and consumption at this 1991 level, and, in Section 82.7 of the rule, setting forth the percentage of baseline allowances for methyl bromide granted to companies in each control period (each calendar year) until the year 2001, when the complete phaseout would occur. At their 1995 meeting, the Parties made adjustments to the methyl bromide control measures and agreed to reduction steps and a 2010 phaseout date for industrialized countries with exemptions permitted for critical uses. At their 1997 meeting, the Parties agreed to further adjustments to the phaseout schedule for methyl bromide in industrialized countries, with reduction steps leading to a 2005 phaseout for industrialized countries. In October 1998, the U.S. Congress amended the CAA to prohibit the termination of production of methyl bromide prior to January 1, 2005, to require EPA to bring the U.S. phaseout of methyl bromide in line with the schedule specified under the Protocol, and to authorize EPA to provide exemptions for critical uses. On November 28, 2000, EPA issued regulations to amend the phaseout schedule for methyl bromide and extend the complete phaseout of production and consumption to 2005 (65 FR 70795).

On December 23, 2004 (69 FR 76982), EPA published a final rule in the **Federal Register** (the "Framework Rule") that established the framework for the critical use exemption; set forth a list of approved critical uses for 2005; and specified the amount of methyl bromide that could be supplied in 2005 from available inventory and new production or import to meet approved critical uses. With this action, EPA is authorizing the uses that will qualify as approved critical uses in 2006 and the

amount of the 2006 critical use exemption.

This action reflects Decision XVI/2, taken at the Parties' 16th Meeting in November 2004; Decision Ex.II/I, taken at the Second Extraordinary Meeting of the Parties in July 2005; and Decision XVII/9, taken at the Parties' 17th Meeting in December 2005. In accordance with Article 2H(5), the Parties have issued several Decisions pertaining to the critical use exemption. These include Decision IX/6, which sets forth criteria for review of proposed critical uses, as well as the Decisions noted above. For a discussion of the relationship between the relevant provisions of the CAA and Article 2H of the Protocol, and the extent to which EPA takes into account Decisions of the Parties that interpret Article 2H, refer to the December 23, 2004 Framework Rule (69 FR 76984–76985). Briefly, EPA regards certain provisions of Decisions IX/6, XVI/2, Ex.II/1, and XVII/9 as subsequent consensus agreements of the Parties that address the interpretation and application of the critical use provision in Article 2H(5) of the Protocol. In this action, EPA is following the relevant terms of these Decisions. This will ensure consistency with the Montreal Protocol and satisfy the requirements of Section 604(d)(6) and Section 614(b) of the Clean Air Act.

In Decision XVI/2, taken in November 2004, the Parties to the Protocol agreed as follows: "for the agreed critical-use categories for 2006, set forth in section IIA to the annex to the present Decision for each Party, to permit, subject to the conditions set forth in Decision Ex.I/4, to the extent those conditions are applicable, the levels of production and consumption for 2006 set forth in section IIB to the annex to the present Decision which are necessary to satisfy critical uses, with the understanding that additional levels of production and consumption and categories of uses may be approved by the Meeting of the Parties to the Montreal Protocol in accordance with Decision IX/6." Section IIA of the Annex to Decision XVI/2 lists the following critical use categories for the U.S.: Cucurbits—field; dried fruit and nuts; forest nursery seedlings; nursery stock—fruit trees, raspberries, roses; strawberry runners; turfgrass; dry commodities/cocoa beans; dry commodities/structures; eggplant/field; mills and processors; peppers/field; strawberry fruit/field; tomato/field; and orchard replant with a total agreed critical-use level of 6,897,680 kilograms, which is equivalent to 27% of the U.S. 1991 methyl bromide consumption baseline.

In Decision Ex.II/1, taken in July 2005, the Parties to the Protocol agreed as follows: "for the agreed critical uses for 2006, set forth in table A of the annex to the present Decision, to permit, subject to the conditions set forth in the present Decision and in Decision Ex. I/4, to the extent those conditions are applicable, the supplementary levels of production and consumption for 2006 set forth in table B of the annex to the present Decision which are necessary to satisfy critical uses, with the understanding that additional levels and categories of uses may be approved by the Seventeenth Meeting of the Parties in accordance with Decision IX/6." Table A of the Annex to Decision Ex.II/1 lists the following critical use categories for the U.S.: Ornamentals; dry-cured ham; dry commodities/structures (cocoa beans); dry commodities/structures (processed foods, herbs and spices, dried milk and cheese processing facilities); eggplant—field, for research only; mills and processors; peppers—field; strawberry fruit—field; tomato—field with a total agreed critical-use level of 1,117,003 kilograms, which is equivalent to 5% of the U.S. 1991 methyl bromide consumption baseline. When combined, the agreed critical use levels for 2006 from Decision XVI/2 and Decision Ex.II/1 total 8,074,683 kilograms, which is equivalent to 32% of the U.S. 1991 methyl bromide consumption baseline. Decision XVII/9, taken at the 17th Meeting of the Parties in December 2005, authorizes an additional 26.4% of baseline for 6,749,000 kilograms for 2007, and an additional supplemental request of 7,070 kilograms for 2006. This supplemental amount is discussed more fully in Section J below. Based, in part, on the applications underlying the U.S. 2006 nomination, the extensive review of those applications culminating in the preparation of that nomination, and the Decisions noted above, EPA is modifying Columns B and C of Appendix L to 40 CFR Part 82, Subpart A to reflect agreed critical use categories, locations of use, and limiting critical conditions applicable to the 2006 control period.

The question of whether, and to what extent, EPA should adjust the total critical use level agreed by the Parties for 2006 is addressed in Section E below. The question of what amount of the total should come from new production or import, and what amount should come from pre-phaseout inventories, is addressed in Section F below. For the reasons given in those sections, and based, in part, on the applications underlying the U.S. 2006 nomination, the extensive review of those applications culminating in the preparation of that nomination, and the Decisions noted above, EPA is modifying the table in 40 CFR 82.8 to reflect the amount of methyl bromide that may be produced or imported, and sold from pre-phaseout inventories, for the 2006 control period.

V. What Is the Critical Use Exemption Process?

A. Background of the Process

Starting in 2002, EPA began notifying applicants as to the availability of an application process for a critical use exemption to the methyl bromide phaseout. On May 8, 2003, the Agency published a notice in the **Federal Register** (68 FR 24737) announcing the deadline to apply for critical uses for the 2006 calendar year, and directing applicants to announcements posted on EPA's methyl bromide Web site at *http://www.epa.gov/ozone/mbr.* Applicants were told they could apply as individuals or as part of a group of users (a "consortium") who face the same limiting critical conditions (i.e., specific conditions which establish a critical need for methyl bromide). This process has been repeated on an annual basis since then. The critical use exemption is designed to meet the needs of methyl bromide users who do not have technically and economically feasible alternatives available.

The criteria for the exemption are delineated in Decision IX/6 of the Parties to the Protocol. In that Decision, the Parties agreed that "a use of methyl bromide should qualify as 'critical' only if the nominating Party determines that: (i) The specific use is critical because the lack of availability of methyl bromide for that use would result in a significant market disruption; and (ii) there are no technically and economically feasible alternatives or substitutes available to the user that are acceptable from the standpoint of environment and public health and are suitable to the crops and circumstances of the nomination." These criteria are reflected in EPA's definition of "critical use" at 40 CFR 82.3.

In response to the annual requests for critical use exemption applications published in the **Federal Register**, applicants have provided information supporting their position that they have no technically and economically feasible alternatives to methyl bromide available to them. Applicants for the exemption have submitted information on their use of methyl bromide, on research into the use of alternatives to methyl bromide, on efforts to minimize

use of methyl bromide and reduce emissions, and on the specific technical and economic research results of testing alternatives to methyl bromide.

EPA's December 23, 2004, Framework Rule describing the operational framework for the critical use exemption (69 FR 76982) established the majority of critical uses for the 2005 calendar year. Today's action authorizes exemptions for 2006 reflecting information that the U.S. Government submitted to the Protocol's Ozone Secretariat in its annual nomination submission in February 2004, as approved by the Parties in November 2004, July 2005, and December 2005. The domestic review process is discussed in detail in a memo titled "Development of 2003 Nomination for a Critical Use Exemption for Methyl Bromide for the United States of America" on Docket ID OAR–2005–0122. Briefly, the U.S. Government reviews applications using the criteria in Decision IX/6 and creates a package for submission to the Ozone Secretariat of the Protocol (the "critical use nomination" or CUN). The CUNs of various countries are then reviewed by the Methyl Bromide Technical Options Committee (MBTOC) and the Technical and Economic Assessment Panel (TEAP), which are independent advisory bodies to the Parties. These bodies make recommendations to the Parties regarding the nominations.

On February 7, 2004, the U.S. Government submitted the second U.S. Nomination for a Critical Use Exemption for Methyl Bromide to the Ozone Secretariat of the United Nations Environment Programme. This second nomination contained a supplemental request for critical use methyl bromide for 2005 and the initial request for 2006. In June 2004, MBTOC sent questions to the U.S. Government concerning technical and economic issues in the nomination. The U.S. Government transmitted its response on August 12, 2004. The U.S. submitted a revised request in conjunction with "The U.S. Nomination for Critical Uses for Methyl Bromide in 2007 and Beyond." This revised request was for an additional amount of 622,053 kilograms of methyl bromide for a total of 2,844,985 kilograms of methyl bromide for the year 2006. This revised request was included in the U.S. rebuttal to MBTOC's recommendation issued in its October 2004 report. These documents, together with reports by the advisory bodies noted above, can be accessed on Docket ID OAR–2005–0122.

EPA received five comments requesting the Agency not to exempt any methyl bromide for critical uses. The CAA allows the Agency to create an exemption for critical uses from the production and consumption phaseout of methyl bromide. In Decisions XVI/2, Ex II/1, and XVII/9, the Parties decided to authorize an exemption for uses nominated by the United States. EPA, in conjunction with other U.S. Government entities, spent substantial time reviewing applications for critical use exemptions and preparing a nomination due to the lack of technically and economically feasible alternatives for the nominated uses. Although the Act does not require EPA to establish an exemption, EPA believes the lack of suitable alternatives for the uses listed as approved critical uses in this rulemaking warrants the continuation of the exemption process begun in 2005.

The history of ozone protection programs has been the transition of industries away from production, import, and use of ozone-depleting substances to alternatives. In some instances a successful transition was possible within the allotted time. In other instances, additional time has been required to allow for the development and market penetration of alternatives. In fact, more than ten years after the phaseout of chlorofluorocarbons (CFCs), the U.S. Government is still exempting the production of CFCs for essential uses in metered dose inhalers. In the instance of critical uses where suitable alternatives are not yet available for all uses, EPA believes it would be inconsistent with the history and the goals of the ozone protection program not to allow for a safety valve in accordance with the provisions of both international and domestic law.

B. How Does This Final Rulemaking Relate to Previous Rulemakings Regarding the Critical Use Exemption?

EPA's December 23, 2004 Framework Rule (69 FR 76982) established the framework for the critical use exemption in the U.S., including trading provisions and recordkeeping and reporting obligations. The Framework Rule defines the terms "critical use allowances" (CUAs) and "critical stock allowances" (CSAs) at 40 CFR 82.3. Each allowance represents the right to produce or import, or to sell from inventory, respectively, one kilogram of methyl bromide for an approved critical use. For example, a distributor with 100 CSAs may sell 100 kilograms of pre-phaseout methyl bromide from inventory for an approved critical use. Today's action authorizes the uses that will qualify as approved critical uses for 2006 and allocates CUAs and CSAs for those uses. In the future, EPA will continue to undertake rulemakings that address both the approved critical uses and the amounts of methyl bromide to be allocated for critical uses in specific control periods.

On August 30, 2005, EPA published a direct final rule and concurrent proposal relating to supplemental critical use exemptions for 2005 (70 FR 51270). These recent notices in the **Federal Register** addressed three additional uses as well as additional CSAs for supplementary amounts of critical use methyl bromide in 2005. EPA received adverse comments on the direct final rule and published a withdrawal notice in the **Federal Register** on October 18, 2005 (70 FR 60443), which stopped the rule from going into effect. EPA addressed the comments and published a final rule for supplemental 2005 CSAs and uses in the **Federal Register** on December 13, 2005 (70 FR 73604). In this action, the Agency is finalizing: (1) The list of uses that qualify for the critical use exemption in 2006; and (2) the amounts of methyl bromide that may be produced or imported, or supplied from pre-phaseout inventories, for those uses in 2006.

In the proposed rulemaking, published on October 27, 2005 (70 FR 62030), EPA sought comment on critical use exemptions for the 2006 calendar year. Only discrete, specific changes to the operational framework were proposed. Some commenters, however, requested that EPA re-examine significant portions of the operational framework identified in the December 23, 2004 Framework Rule. In this action, EPA is only addressing comments within the scope of the proposal, but may consider additional suggestions pertaining to other areas in future critical use exemption rulemakings. With respect to many of the comments on the operational framework, EPA has already addressed similar points in the Response to Comments document for the Framework Rule, accessible on Docket ID OAR–2005–0122.

With respect to the critical use exemption regulatory process generally, EPA received eight comments expressing concern about the late publication of the proposed rule. EPA understands this concern but notes that the Second Extraordinary Meeting of the Parties, where the final 2006 amounts for critical uses in the U.S. were authorized by the Parties, did not take place until July 1, 2005.

EPA received one comment asking how the critical use exemption process will be affected by the enforcement of ISPM 15 (the international standard for

trade in wood packaging material, including dunnage). EPA notes that ISPM 15 is unrelated to the critical use exemption process.

EPA received two comments concerning the term significant market disruption, as described in Decision IX/6. One commenter stated that the proposal was flawed because EPA does not define significant market disruption. A description of EPA's application of this concept is available in the memo titled "Development of the 2003 Nomination for a Critical Use Exemption for Methyl Bromide for the United States of America," on E-Dockets OAR–2003–0017, OAR–2004–0506, and OAR–2005–0122. The commenter states that a "significant market disruption" refers to "a decrease or delay in supply or an increase in price of a commodity produced with methyl bromide." EPA views this as one possible type of market disruption. As stated in the memo available on E-docket OAR–2004–0506, "markets are partially defined by the interaction between supply and demand, which determines the price and quantity of a good traded in a market. EPA's position is that a disruption to either side of a commodity market, demand or supply, would result in market disruption." That is, a significant market disruption could be experienced on the demand side as an increase in price, as noted by the commenter, or on the supply side if growers or processors experience a loss of production or delays in production. For example, if the loss of methyl bromide in strawberry production resulted in significant production decreases—and loss of grower income—EPA could determine that it constitutes a significant market disruption.

In determining whether a change in supply or demand is significant, EPA considers several dimensions of which two are key: (1) Individual versus aggregate and (2) absolute versus relative. EPA typically evaluates losses at the individual level, e.g., on a per-acre basis. We then extrapolate to the aggregate loss by multiplying this representative loss by the number of acres affected, using crop budgets and other relevant information. EPA balances the two measures to determine whether impacts are significant. For example, if the loss of methyl bromide in Michigan for vegetable production results in shortages and high prices in the upper Midwest, EPA may determine that it constitutes a significant market disruption, even if producers and consumers in the rest of the country are unaffected.

The other key dimension is absolute versus relative impacts. The loss of a single processing plant may not seem significant. However, if there are only three such plants, the loss of one could still result in significant market disruption. EPA relies on detailed crop budgets and other sources of information for data on production costs, gross revenues, and other measures.

One commenter, in requesting a clearer definition of significant market disruption, provided an example of a situation that it did not believe would constitute a significant market disruption. The example was a price increase of less than 1 cent per pound of flour as a result of the use of a methyl bromide alternative. In analyzing this example, however, EPA would look not only at the market price, but also at the effects on users, bearing in mind the dimensions explained above.

C. What Are the Approved Critical Uses?

In Decision XVI/2, taken in November 2004, the Parties to the Protocol agreed as follows: "for the agreed critical-use categories for 2006, set forth in section IIA to the annex to the present Decision for each Party, to permit, subject to the conditions set forth in Decision Ex.I/4, to the extent those conditions are applicable, the levels of production and consumption for 2006 set forth in section IIB to the annex to the present Decision which are necessary to satisfy critical uses, with the understanding that additional levels of production and consumption and categories of uses may be approved by the Meeting of the Parties to the Montreal Protocol in accordance with Decision IX/6." Section IIA of the Annex to Decision XVI/2 lists the following critical use categories for the U.S.: Cucurbits—field; dried fruit and nuts; forest nursery seedlings; nursery stock—fruit trees, raspberries, roses; strawberry runners; turfgrass; dry commodities/cocoa beans; dry commodities/structures; eggplant field; mills and processors; peppers field; strawberry fruit field; tomato field; and orchard replant. These categories represent a total agreed critical-use level for 2006 of 6,897,680 kilograms, which is equivalent to 27% of the U.S. 1991 methyl bromide consumption baseline.

In Decision Ex.II/1, taken in July 2005, the Parties to the Protocol agreed as follows: "for the agreed critical uses for 2006, set forth in table A of the annex to the present Decision, to permit, subject to the conditions set forth in the present Decision and in Decision Ex. I/4, to the extent those conditions are applicable, the supplementary levels of production and consumption for 2006 set forth in table B of the annex to the present Decision which are necessary to satisfy critical uses, with the understanding that additional levels and categories of uses may be approved by the Seventeenth Meeting of the Parties in accordance with Decision IX/6." Table A of the Annex to Decision Ex.II/1 lists the following critical use categories for the U.S.: Ornamentals; dry-cured ham; dry commodities/structures (cocoa beans); dry commodities/structures (processed foods, herbs and spices, dried milk and cheese processing facilities); eggplant—field, for research only; mills and processors; peppers—field; strawberry fruit—field; tomato—field. These categories represent an additional agreed critical-use level for 2006 of 1,117,003 kilograms, which is equivalent to 5% of the U.S. 1991 methyl bromide consumption baseline. When combined, the agreed critical-use levels for 2006 from Decision XVI/2 and from Decision Ex.II/1 total 8,074,683 kilograms, which is equivalent to 32% of the U.S. 1991 methyl bromide consumption baseline. Based, in part, on the applications underlying the U.S. 2006 nomination, the extensive review of those applications culminating in the preparation of that nomination, and the Decisions noted above, EPA is modifying Columns B and C of Appendix L to 40 CFR Part 82, Subpart A to reflect agreed critical-use categories.

Under the December 23, 2004, Framework Rule (69 FR 76982), an approved critical user may obtain access to exempted production/import and limited inventories of pre-phaseout methyl bromide inventory, the combination of which constitute the supply of "critical use methyl bromide" intended to meet the needs of agreed critical uses.

As set out in the Framework Rule, an approved critical user is a self-identified entity who meets the following requirements:

(1) For the applicable control period, applied to EPA for a critical use exemption or is a member of a consortium that applied to EPA for a critical use exemption for a use and location of use that was included in the U.S. nomination, authorized by a Decision of the Parties to the Montreal Protocol, and then finally determined by EPA in a notice-and-comment rulemaking to be an approved critical use, and

(2) Has an area in the applicable location of use that requires methyl bromide fumigation because the user reasonably expects that the area will be subject to a limiting critical condition during the applicable control period.

Using these criteria, an approved critical user could be a tomato farmer in Florida whose farm is over karst topography, but would not include a tomato farmer in Oklahoma even if he too has a farm over karst topography because no exemption application was filed on behalf of Oklahoma tomato farmers. Similarly, a Florida tomato farmer who did not have a field with karst topography, or one of the other limiting critical conditions specified in this rule, would not be an approved critical user because the circumstance of the use is not an approved critical use.

A "limiting critical condition" is the basis on which the critical need for methyl bromide is demonstrated and authorized. It is defined as "the regulatory, technical, and economic circumstances * * * that establish conditions of critical use of methyl bromide in a fumigation area." 40 CFR 82.3. The limiting critical condition placed on a use category reflects certain regulatory, technical, or economic factors that either prohibit the use of alternatives or represent the lack of a technically or economically feasible alternative for that use or circumstance. For example, EPA may determine that a critical use exemption for tomatoes is only necessary for areas of tomato production in karst topography even if the EPA received applications for all of U.S. fresh market tomato production. In this example, not all tomato growers would be eligible to acquire exempted critical use methyl bromide. Only those growers with production in an area with the limiting critical condition of karst topography would have access to critical use methyl bromide. Another example is as follows: EPA received applications for exemptions for all U.S. grain milling companies that are members of the North American Milling Association (NAMA). The Parties authorized the exemption because grain milling companies have a critical need for methyl bromide because the alternatives can not be used, in part, due to corrosivity to electronic equipment. Thus, one of the limiting critical conditions for this critical use category is the presence of sensitive electronic equipment subject to corrosion associated with fumigation with the alternative. All grain mills that are members of NAMA that have sensitive electronic equipment would be eligible to acquire and use critical use methyl bromide.

EPA is authorizing the critical uses and limiting critical conditions for the year 2006 based on its assessment of the technical and economic feasibility of alternatives and the potential for a significant market disruption if methyl bromide were not available for the uses authorized for 2006. This authorization is based on the information submitted by CUE applicants, as well as public and proprietary data sources. The CUE applications (except to the extent claimed confidential), the U.S. nomination, the questions and answers between the MBTOC and the U.S. Government about the nomination, and procedural memos are all available on Docket ID OAR–2005–0122. Data submitted by the CUE applicants served as a basis for the nomination. EPA and other government experts also sought data from multiple other sources, including but not limited to the National Agricultural Statistics Service of the U.S. Department of Agriculture, the State of California Department of Pesticide Regulation, and proprietary agricultural databases available to EPA. All of the CUE applications underwent a rigorous review by highly qualified technical experts. A detailed explanation of the nomination process, including the criteria used by expert reviewers, is available in a memo titled "Development of the 2003 Nomination for a Critical Use Exemption for Methyl Bromide from the United States of America" on Docket ID OAR–2005–0122. The memo was originally written to describe the process leading to the 2005 critical use exemption rules, but it applies generally to the process leading to this action.

The U.S. Government, in developing the nomination, defined the limiting critical conditions for which exempted methyl bromide was being sought. The U.S. Government used the information referenced above to determine: (a) Whether the lack of availability of methyl bromide for a particular use would result in significant market disruption, and (b) whether there were any technically and economically feasible methyl bromide alternatives available to the user. The analysis was described in the U.S. critical use nomination. The nomination was then sent to the Parties to the Protocol, and the Parties used the information in the nomination and the report from the MBTOC (which was based in part on the iterative exchange of questions and answers with the U.S. Government) as the basis for the Decisions that authorized critical uses.

Based on the information described above, EPA determined that the uses in Table I, with the limiting critical conditions specified, qualify to obtain and use critical use methyl bromide in 2006, as discussed in Section E. However, as discussed in Section E, some of the circumstances for some of the critical use categories have changed due to recent registrations of an alternative and therefore EPA is decreasing the total CUE level for 2006. EPA has determined, based on the U.S. nomination and its supporting documents, that users who are in a specific geographic location, identified below, or who are members of a specific industry consortium, identified below, or companies specifically identified below, are approved critical users provided that such users are subject to the specified limiting critical condition(s).

EPA notes the endorsement of emission minimization techniques in paragraph 6 of Decision Ex.II/1 and urges the users listed in Table I to use "emission minimization techniques such as virtually impermeable films, barrier film technologies, deep shank injection and/or other techniques that promote environmental protection, whenever technically and economically feasible." Indeed, many emissions minimization techniques are already being applied, some of which are required in accordance with methyl bromide label requirements. Users should make every effort to decrease overall emissions of methyl bromide by implementing such measures, to the extent consistent with state and local laws and regulations. EPA notes that research continues to be conducted on the potential to reduce application rates and emissions using high-barrier films.

TABLE I.—APPROVED CRITICAL USES

Column A Approved critical uses	Column B Approved critical user and location of use	Column C Limiting critical conditions
Pre-Plant Uses:		

TABLE I.—APPROVED CRITICAL USES—Continued

Column A Approved critical uses	Column B Approved critical user and location of use	Column C Limiting critical conditions
Cucurbits	(a) Michigan growers	with a reasonable expectation that one or more of the following limiting critical conditions either already exist or could occur without methyl bromide fumigation: moderate to severe soilborne fungal disease infestation, or moderate to severe disease infestation could occur without methyl bromide fumigation; or with a need for methyl bromide for research purposes.
	(b) Southeastern U.S. except Georgia limited to growing locations in Alabama, Arkansas, Kentucky, Louisiana, North Carolina, South Carolina, Tennessee, and Virginia.	with a reasonable expectation that one or more of the following limiting critical conditions either already exist or could occur without methyl bromide fumigation: moderate to severe yellow or purple nutsedge infestation, or to a lesser extent: fungal disease infestation and root knot nematodes; or with a need for methyl bromide for research purposes.
	(c) Georgia growers	with a reasonable expectation that one or more of the following limiting critical conditions either already exist or could occur without methyl bromide fumigation: moderate to severe yellow or purple nutsedge infestation, moderate to severe fungal disease infestation, or to a lesser extent: root knot nematodes; or with a need for methyl bromide for research purposes.
Eggplant	(a) Florida growers	with a reasonable expectation that one or more of the following limiting critical conditions either already exist or could occur without methyl bromide fumigation: moderate to severe yellow or purple nutsedge infestation, or moderate to severe nematodes, or moderate to severe disease infestation, or restrictions on alternatives due to karst geology; or with a need for methyl bromide for research purposes.
	(b) Georgia growers	with a reasonable expectation that one or more of the following limiting critical conditions either already exist or could occur without methyl bromide fumigation: moderate to severe yellow or purple nutsedge infestation, or moderate to severe nematodes, or moderate to severe pythium root and collar rots, or moderate to severe southern blight infestation, and to a lesser extent: crown and root rot; or with a need for methyl bromide for research purposes.
	(c) Michigan growers	with a reasonable expectation that moderate to severe soilborne fungal disease infestation could occur without methyl bromide fumigation; or with a need for methyl bromide for research purposes.
Forest Nursery Seedlings	(a) Members of the Southern Forest Nursery Management Cooperative limited to growing locations in Alabama, Arkansas, Florida, Georgia, Louisiana, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas and Virginia.	with a reasonable expectation that one or more of the following limiting critical conditions already either exist or could occur without methyl bromide fumigation: moderate to severe yellow or purple nutsedge infestation, or moderate to severe disease infestation.
	(b) International Paper and its subsidiaries limited to growing locations in Alabama, Arkansas, Georgia, South Carolina and Texas.	with a reasonable expectation that one or more of the following limiting critical conditions already either exist or could occur without methyl bromide fumigation: moderate to severe yellow or purple nutsedge infestation, or moderate to severe disease infestation.
	(c) Public (government-owned) seeding nurseries in the states of Illinois, Indiana, Kentucky, Maryland, Missouri, New Jersey, Ohio, Pennsylvania, West Virginia and Wisconsin.	with a reasonable expectation that one or more of the following limiting critical conditions either already exist or could occur without methyl bromide fumigation: moderate to severe weed infestation including purple and yellow nutsedge infestation, or moderate to severe Canada thistle infestation, or moderate to severe nematodes, and to a lesser extent: fungal disease infestation.
	(d) Weyerhaeuser Company and its subsidiaries limited to growing locations in Alabama, Arkansas, North Carolina and South Carolina.	with a reasonable expectation that one or more of the following limiting critical conditions already either exist or could occur without methyl bromide fumigation: moderate to severe yellow or purple nutsedge infestation, moderate to severe disease infestation, and to a lesser extent: nematodes and worms.
	(e) Weyerhaeuser Company and its subsidiaries limited to growing locations in Washington and Oregon.	with a reasonable expectation that one or more of the following limiting critical conditions already either exist or could occur without methyl bromide fumigation: moderate to severe yellow nutsedge infestation, or moderate to severe fungal disease infestation.
	(f) Michigan growers	with a reasonable expectation that one or more of the following limiting critical conditions already either exist or could occur without methyl bromide fumigation: moderate to severe disease infestation, moderate to severe Canada thistle infestation, moderate to severe nutsedge infestation, and to a lesser extent: nematodes.

TABLE I.—APPROVED CRITICAL USES—Continued

Column A Approved critical uses	Column B Approved critical user and location of use	Column C Limiting critical conditions
	(g) Michigan herbaceous perennials growers.	with a reasonable expectation that one or more of the following limiting critical conditions already exist or could occur without methyl bromide fumigation: moderate to severe nematodes, moderate to severe fungal disease infestation, and to a lesser extent: yellow nutsedge and other weeds infestation.
Orchard Nursery Seedlings	(a) Members of the Western Raspberry Nursery Consortium limited to growing locations in California and Washington (Driscoll's Raspberries and their contract growers in California and Washington).	with a reasonable expectation that one or more of the following limiting critical conditions already either exists or could occur without methyl bromide fumigation: moderate to severe nematode infestation, medium to heavy clay soils, or a prohibition on the use of 1,3-dichloropropene products due to reaching local township limits on the use of this alternative; or with a need for methyl bromide for research purposes.
	(b) Members of the California Association of Nurserymen-Deciduous Fruit and Nut Tree Growers.	with a reasonable expectation that one or more of the following limiting critical conditions already either exists or could occur without methyl bromide fumigation: moderate to severe nematodes, medium to heavy clay soils, or a prohibition on the use of 1,3-dichloropropene products due to reaching local township limits on the use of this alternative; or with a need for methyl bromide for research purposes.
	(c) California rose nurseries	with a reasonable expectation that one or more of the following limiting critical conditions already either exists or could occur without methyl bromide fumigation: moderate to severe nematodes, or user may be prohibited from using 1,3-dichloropropene products because local township limits for this alternative have been reached; or with a need for methyl bromide for research purposes.
Strawberry Nurseries	(a) California growers	with a reasonable expectation that one or more of the following limiting critical conditions already either exists or could occur without methyl bromide fumigation: moderate to severe disease infestation, or moderate to severe yellow or purple nutsedge infestation, or moderate to severe nematodes; or with a need for methyl bromide for research purposes.
	(b) North Carolina, Tennessee and Maryland growers.	with a reasonable expectation that one or more of the following limiting critical conditions already either exists or could occur without methyl bromide fumigation: moderate to severe black root rot, or moderate to severe root-knot nematodes, or moderate to severe yellow and purple nutsedge infestation, and to a lesser extent: crown rot; or with a need for methyl bromide for research purposes.
Orchard Replant	(a) California stone fruit growers ...	with a reasonable expectation that one or more of the following limiting critical conditions already either exists or could occur without methyl bromide fumigation: moderate to severe nematodes, or moderate to severe fungal disease infestation, or replanted (non-virgin) orchard soils to prevent orchard replant disease, or medium to heavy soils, or a prohibition on the use of 1,3-dichloropropene products because local township limits for this alternative have been reached; or with a need for methyl bromide for research purposes.
	(b) California table and raisin grape growers.	with a reasonable expectation that one or more of the following limiting critical conditions already either exists or could occur without methyl bromide fumigation: moderate to severe nematodes, or moderate to severe fungal disease infestation, or replanted (non-virgin) orchard soils to prevent orchard replant disease, or medium to heavy soils, or a prohibition on the use of 1,3-dichloropropene products because local township limits for this alternative have been reached; or with a need for methyl bromide for research purposes.
	(c) California walnut growers	with a reasonable expectation that one or more of the following limiting critical conditions already either exists or could occur without methyl bromide fumigation: moderate to severe nematodes, or replanted (non-virgin) orchard soils to prevent orchard replant disease, or medium to heavy soils, or a prohibition on the use of 1,3-dichloropropene products because local township limits for this alternative have been reached; or with a need for methyl bromide for research purposes.

TABLE I.—APPROVED CRITICAL USES—Continued

Column A Approved critical uses	Column B Approved critical user and location of use	Column C Limiting critical conditions
	(d) California almond growers	with a reasonable expectation that one or more of the following limiting critical conditions already either exists or could occur without methyl bromide fumigation: moderate to severe nematodes, or replanted (non-virgin) orchard soils to prevent orchard replant disease, or medium to heavy soils, or a prohibition on the use of 1,3-dichloropropene products because local township limits for this alternative have been reached; or with a need for methyl bromide for research purposes.
Ornamentals	(a) California growers	with a reasonable expectation that one or more of the following limiting critical conditions already either exists or could occur without methyl bromide fumigation: moderate to severe disease infestation, or moderate to severe nematodes, or a prohibition on the use of 1,3-dichloropropene products because local township limits for this alternative have been reached; or with a need for methyl bromide for research purposes.
	(b) Florida growers	with a reasonable expectation that one or more of the following limiting critical conditions already either exists or could occur without methyl bromide fumigation: moderate to severe weed infestation, or moderate to severe disease infestation, or moderate to severe nematodes, or karst topography; or with a need for methyl bromide for research purposes.
Peppers	(a) California growers	with a reasonable expectation that one or more of the following limiting critical conditions already either exists or could occur without methyl bromide fumigation: moderate to severe disease infestation, or moderate to severe nematodes, or a prohibition on the use of 1,3-dichloropropene products because local township limits for this alternative have been reached; or with a need for methyl bromide for research purposes.
	(b) Alabama, Arkansas, Kentucky, Louisiana, North Carolina, South Carolina, Tennessee and Virginia growers.	with a reasonable expectation that one or more of the following limiting critical and conditions already either exists or could occur without methyl bromide fumigation: moderate to severe yellow or purple nutsedge infestation, or moderate to severe nematodes, or moderate to severe pythium root, collar, crown and root rots, or the presence of an occupied structure within 100 feet of a grower's field the size of 100 acres or less; or with a need for methyl bromide for research purposes.
	(c) Florida growers	with a reasonable expectation that one or more of the following limiting critical conditions already either exists or could occur without methyl bromide fumigation: moderate to severe yellow or purple nutsedge infestation, or moderate to severe disease infestation, or moderate to severe nematodes, or karst topography; or with a need for methyl bromide for research purposes.
	(d) Georgia growers	with a reasonable expectation that one or more of the following limiting critical conditions either already exist or could occur without methyl bromide fumigation: moderate to severe yellow or purple nutsedge infestation, or moderate to severe nematodes, or moderate to severe pythium root and collar rots, or moderate to severe southern blight infestation, and to a lesser extent: crown and root rot; or with a need for methyl bromide for research purposes.
	(e) Michigan growers	with a reasonable expectation that moderate to severe fungal disease infestation would occur without methyl bromide fumigation; or with a need for methyl bromide for research purposes.
Strawberry Fruit	(a) California growers	with a reasonable expectation that one or more of the following limiting critical conditions already either exists or could occur without methyl bromide fumigation: moderate to severe black root rot or crown rot, or moderate to severe yellow or purple nutsedge infestation, or moderate to severe nematodes, or a prohibition of the use of 1,3-dichloropropene products because local township limits for this alternative have been reached, time to transition to an alternative; or with a need for methyl bromide for research purposes.
	(b) Florida growers	with a reasonable expectation that one or more of the following limiting critical conditions already either exists or could occur without methyl bromide fumigation: moderate to severe yellow or purple nutsedge, or moderate to severe nematodes, or moderate to severe disease infestation, or karst topography and to a lesser extent: carolina geranium or cut-leaf evening primrose infestation; or with a need for methyl bromide for research purposes.

TABLE I.—APPROVED CRITICAL USES—Continued

Column A Approved critical uses	Column B Approved critical user and location of use	Column C Limiting critical conditions
	(c) Alabama, Arkansas, Georgia, Illinois, Kentucky, Louisiana, Maryland, New Jersey, North Carolina, Ohio, South Carolina, Tennessee and Virginia growers.	with a reasonable expectation that one or more of the following limiting critical conditions already either exists or could occur without methyl bromide fumigation: moderate to severe yellow or purple nutsedge, or moderate to severe nematodes, or moderate to severe black root and crown rot, or the presence of an occupied structure within 100 feet of a grower's field the size of 100 acres or less; or with a need for methyl bromide for research purposes.
Tomatoes	(a) Michigan growers	with a reasonable expectation that one or more of the following limiting critical conditions already either exists or could occur without methyl bromide fumigation: moderate to severe disease infestation, or moderate to severe fungal pathogen infestation; or with a need for methyl bromide for research purposes.
	(b) Alabama, Arkansas, Florida, Georgia, Kentucky, Louisiana, North Carolina, South Carolina, and Tennessee growers.	with a reasonable expectation that one or more of the following limiting critical conditions already either exists or could occur without methyl bromide fumigation: moderate to severe yellow or purple nutsedge infestation, or moderate to severe disease infestation, or moderate to severe nematodes, or the presence of an occupied structure within 100 feet of a grower's field the size of 100 acres or less, or karst topography; or with a need for methyl bromide for research purposes.
	(c) California growers	with a reasonable expectation that one or more of the following limiting critical conditions already either exists or could occur without methyl bromide fumigation: moderate to severe disease infestation, or moderate to severe nematodes; or with a need for methyl bromide for research purposes.
Turfgrass	(a) U.S. turfgrass sod nursery producers who are members of Turfgrass Producers International (TPI).	for the production of industry certified pure sod; with a reasonable expectation that one or more of the following limiting critical conditions already either exists or could occur without methyl bromide fumigation: moderate to severe bermudagrass, nutsedge and off-type perennial grass infestation, or moderate to severe white grub infestation; or with a need for methyl bromide for research purposes.
Post-Harvest Uses:		
Food Processing	(a) Rice millers in all locations in the U.S. who are members of the USA Rice Millers' Association.	with a reasonable expectation that one or more of the following limiting critical conditions exists: moderate to severe infestation of beetles, weevils or moths, or older structures that can not be properly sealed to use an alternative to methyl bromide, or the presence of sensitive electronic equipment subject to corrosivity, time to transition to an alternative.
	(b) Pet food manufacturing facilities in the U.S. who are active members of the Pet Food Institute. (For this rule, "pet food" refers to domestic dog and cat food).	with a reasonable expectation that one or more of the following limiting critical conditions exists: moderate to severe infestation or beetles, moths, or cockroaches, or older structures that can not be properly sealed to use an alternative to methyl bromide, or the presence of sensitive electronic equipment subject to corrosivity, time to transition to an alternative.
	(c) Kraft Foods in the U.S.	with a reasonable expectation that one or more of the following limiting critical conditions exists: older structures that can not be properly sealed to use an alternative to methyl bromide, or the presence of sensitive electronic equipment subject to corrosivity, time to transition to an alternative.
	(d) Members of North American Millers' Association in the U.S.	with a reasonable expectation that one or more of the following limiting critical conditions already exists or could occur without methyl bromide fumigation: moderate to severe beetle infestation, or older structures that can not be properly sealed to use an alternative to methyl bromide, or the presence of sensitive electronic equipment subject to corrosivity, time to transition to an alternative.
	(e) Members of the National Pest Management Association treating cocoa beans in storage and associated spaces and equipment in processed food, cheese, dried milk, herbs and spices and spaces in equipment in associated processing facilities.	with a reasonable expectation that one or more of the following limiting critical conditions already exists or could occur without methyl bromide fumigation: moderate to severe pest infestation, or older structures that can not be properly sealed to use an alternative to methyl bromide, or the presence of sensitive electronic equipment subject to corrosivity, time to transition to an alternative.

TABLE I.—APPROVED CRITICAL USES—Continued

Column A Approved critical uses	Column B Approved critical user and location of use	Column C Limiting critical conditions
Commodity Storage	(a) California entities storing walnuts, beans, dried plums, figs, raisins, dates and pistachios in California.	with a reasonable expectation that one or more of the following limiting critical conditions exists: rapid fumigation is required to meet a critical market window, such as during the holiday season, rapid fumigation is required when a buyer provides short (2 working days or less) notification for a purchase, or there is a short period after harvest in which to fumigate and there is limited silo availability for using alternatives; or with a need for methyl bromide for research purposes.
Dry Cured Pork Products	(a) Members of the National Country Ham Association.	with a reasonable expectation that one or more of the following limiting critical conditions already exists or could occur without methyl bromide fumigation: moderate to severe red legged ham beetle, cheese/ham skipper, dermestid beetle or ham mite infestation.
	(b) Members of the American Association of Meat Processors.	with a reasonable expectation that one or more of the following limiting critical conditions already exists or could occur without methyl bromide fumigation: moderate to severe red legged ham beetle, cheese/ham skipper, dermestid beetle or ham mite infestation.
	(c) Nahunta Pork Center (North Carolina).	with a reasonable expectation that one or more of the following limiting critical conditions already exists or could occur without methyl bromide fumigation: moderate to severe red legged ham beetle, cheese/ham skipper, dermestid beetle or ham mite infestation.

EPA received seven comments on the proposed critical uses. Four commenters stated that the "Southern Forest Nursery Management Cooperative" should have been explicitly identified as an approved critical user. EPA has corrected this omission from the proposed rule. Another commenter proposed revised language describing the National Pest Management Association, discussed the inclusion of dried milk as an approved critical use, and noted that the spelling of the scientific name of a pest described in the corresponding "Limiting Critical Conditions" column was incorrect. EPA has changed the incorrect spelling of "dermisted" beetle to "dermestid" beetle, in the last three paragraphs of the "Limiting Critical Conditions" table. In Decision Ex.II/1, issued by the Parties on July 1, 2005, in Table A of the Annex, "dry commodities/structures (processed foods, herbs, and spices, dried milk and cheese processing facilities)" are noted as "agreed critical-use categories." Since dried milk was authorized by the Parties, EPA is including dried milk, as well as cheese processing facilities, in the Approved Critical Uses table. EPA has incorporated this revised language describing the National Pest Management Association because it clarifies that commodities will be fumigated as part of space fumigations.

EPA received one set of comments pertaining to the proposed limiting critical conditions. These comments are addressed in the Response to Comments document for this action, accessible on Docket ID OAR–2005–0122.

EPA notes that an additional error was made in Column B of the Table of Approved Critical Uses concerning the Forest Nursery sector. The states of Idaho, Kansas, Nebraska, Oregon, Utah, and Washington should not have been included as states where publicly owned nurseries are exempted. The corresponding consortia did not apply to EPA for a critical use exemption for 2006 and as a result, were not approved by the Parties and are not approved critical users. Therefore, EPA is not exempting these uses.

D. What Are the Uses That May Obtain Methyl Bromide for Research?

The categories listed in Section C above were approved for critical uses for 2006 in Decisions XVI, Ex.II/1, and XVII/9 of the Parties. The amount of methyl bromide approved for research purposes is included in the amount of methyl bromide approved by the Parties for the commodities for which "research" is indicated as a limiting critical condition in Table I above. However, the Agency is not setting aside a specific quantity of methyl bromide to be associated with research activities. Methyl bromide is needed for research purposes including experiments that require methyl bromide as a control chemical with which to compare the trial alternatives' results. EPA is allowing the following sectors to use critical use methyl bromide for research purposes: Cucurbits, dried fruit and nuts, nursery stock, strawberry nurseries, turfgrass, eggplant, peppers, strawberry fruit, tomatoes, ornamentals, and orchard replant. These are the sectors that requested methyl bromide for research in their applications to EPA. In Decision XVII/9, the Parties requested that Parties "endeavor to use stocks, where available, to meet any demand for methyl bromide for the purposes of research and development." Although we read this Decision to apply prospectively to amounts authorized by that Decision, for the above 2006 research uses, we nonetheless encourage all relevant research users to use pre-phaseout inventory, where available, for research purposes.

E. What Amount of Methyl Bromide Is Necessary for Critical Uses?

In this section, EPA authorizes the amount of methyl bromide that may be produced or imported for critical uses in 2006, and the amount that may be sold for critical uses from pre-phaseout inventories. Section IIB of the Annex to Decision XVI/2 lists a "permitted level of production and consumption" for the United States in 2006 of 6,897,680 kilograms, which is equivalent to 27% of the 1991 baseline. Table B of the Annex to Decision Ex.II/1 lists a "permitted level of production and consumption" for the United States in 2006 of 760,585 kilograms, which is equivalent to 3% of the 1991 baseline. When combined, the permitted level of production and consumption from the two Decisions is 7,658,265 kilograms, which is equivalent to 30% of the 1991 baseline. Paragraph 2 of Decision Ex.II/1 states, "that a Party with a critical-use exemption level in excess of permitted levels of exempted production and consumption for critical uses is to make up any such difference between those levels by using quantities of methyl

bromide available from existing stocks." The difference between the agreed 2006 critical-use exemption level of 8,074,683 kilograms and the permitted level of exempted production and consumption of 7,658,265 kilograms is 416,418 kilograms, which is equivalent to 2% of the 1991 baseline. In accordance with paragraph 2 of Decision Ex.II/1, this amount is to come from inventory. The supplemental amount for 2006, authorized in Decision XVII/9, is also to come from inventory. In this final rule, EPA is determining that an additional amount should come from inventory. A further elaboration of the amounts that EPA is authorizing to come from inventory and from new exempted production or import in 2006 is found below in Sections F and H.

With this action, the Agency is authorizing critical use levels of methyl bromide for 2006 that are slightly less than the amount authorized by the Parties because of recent registrations of an alternative to methyl bromide, sulfuryl fluoride. As noted above, the U.S. Government submitted the nomination for 2006 critical use exemptions on February 7, 2004. The information in the U.S. nomination reflected the most up-to-date information on alternatives to methyl bromide that was available at that time of submission to the Ozone Secretariat in February 2004. In addition, through an iterative process of questions and answers with the MBTOC, the U.S. Government was able to provide new information about the status of methyl bromide alternatives in the United States for the nominated sectors up until the time the MBTOC issued its final report in the weeks prior to the 2nd Extraordinary Meeting of the Parties in July 2005. Since the MBTOC's final review and report on the 2006 nomination there have been several new actions in the U.S. relevant to uses included in Decision XVI/2 and Decision Ex.II/1. The most recent Federal action, on July 15, 2005, was the issuance of an EPA rule establishing new federal tolerance levels for residues of sulfuryl fluoride in or on commodities in food processing facilities (70 FR 40899). On July 15 EPA also issued a Federal registration for these new uses of sulfuryl fluoride. The Agency received comments confirming that as many as 48 of 50 states subsequently issued state registrations allowing the use of sulfuryl fluoride for these new uses. In addition, on May 18, 2005, the state of California registered sulfuryl fluoride for use in mills, warehouses, stationary transportation vehicles (railcars, trucks, etc.), temporary and permanent fumigation chambers, and storage structures containing commodities listed on the state-approved label (cereal and small grains, dried fruit, and nuts). The state of California has not approved the label issued by EPA on July 15, 2005. The Federal label permits sulfuryl fluoride use for a wide range of food commodities, such as dried fruits, tree nuts, cereals and small grains, and processed food products. Prior to these registration actions, EPA did not consider sulfuryl fluoride as a technically and economically feasible alternative for these uses. In this action, EPA's determination of critical amounts of methyl bromide for 2006 reflects these changes in the circumstances of the use sectors for which sulfuryl fluoride is a newly registered alternative.

In the Notice of Proposed Rulemaking, EPA estimated that approximately 15% of the post-harvest sectors, for which sulfuryl fluoride is a newly registered alternative, would transition to sulfuryl fluoride during 2006. EPA proposed a 15% reduction in the amount of critical use methyl bromide for the newly registered uses in California, such as mills, dried fruit, and nuts, as well as a 15% reduction in the amount of critical use methyl bromide for the sectors in the U.S. nomination that include food processing facilities, such as mills and processors. EPA's proposed uptake estimate was based on information from a MBTOC report regarding projected uptake of sulfuryl fluoride for previously-registered uses, as well as information in the U.S. nomination for 2007 critical use exemptions. The uptake estimate in the MBTOC report was 10% for the 2005 calendar year for uses for which sulfuryl fluoride was registered in early 2004 (not including the most recent registration in California or the new Federal registration for food processing facilities). EPA also stated in the proposal that the 2007 nomination contained a projection that the specific uses associated with the new registrations and tolerances would uptake sulfuryl fluoride at a rate of 25% per year. However, the 25% projected uptake rate was projected over a longer period of time and referred to those facilities that would be able to transition at a certain rate. The 2007 Bromide Usage Numerical Index contained an adoption rate of 14% for two sub-sectors of the structures/food facilities sector, which is more comparable to the 2008 Bromide Usage Newer Numerical Index (BUNNI) range of 12%–18%. EPA recognizes that the proposed uptake rate is not necessarily comparable to the MBTOC projection, because the MBTOC's estimate was a reduction factor for all facilities included in the Nomination. The rates in the current 2008 BUNNI analysis reflect the percentage of each structural/food facilities and National Pest Management Association (NPMA) sub-sector that is able to transition per year.

EPA received 13 comments on the estimated uptake of sulfuryl fluoride. Six commenters stated that EPA did not provide a sufficient rationale to justify the 15% reduction in critical use methyl bromide for the uses for which sulfuryl fluoride is now a registered alternative. Three indicated their belief that there was no factual basis for the 15% reduction. Some commenters pointed out that in the 2005 CUE rulemaking, EPA stated that it lacked data to determine market uptake of sulfuryl fluoride. Other commenters noted that actual 2005 data would be available in early 2006, and that the Agency could then propose adequate reductions, based on consumption patterns, when allocating exemptions for 2007. Four commenters noted that the U.S. nomination for 2007 was reviewed and approved by two panels of experts (EPA and the MBTOC) and stated that therefore the uptake estimate should not vary from the percentage identified in that nomination without sufficient review. Another group of commenters expressed concerns that the estimate did not take into account their inability to use sulfuryl fluoride in situations where all finished products and the majority of the facility's bagged ingredients could not be removed from the premises. Two commenters indicated that the pace of transition to an alternative should not be left wholly up to the market to determine, in view of the environmental benefits from the transition.

As explained below, for purposes of this final rule, EPA is relying on the assessment performed for the U.S. nomination for 2008, rather than arriving at an estimate based on the figures in the MBTOC Report and U.S. nomination for 2007, since the U.S. nomination for 2008 reflects recent information. While EPA indicated in the December 23, 2004 Framework Rule that there was insufficient data at that time to conduct an adequate analysis of the uptake of sulfuryl fluoride, EPA now possesses additional data on sulfuryl fluoride, as reflected in the assessment performed for the U.S. nomination for 2008. This assessment also takes into account the concern raised by the commenter regarding inability to use sulfuryl fluoride in situations where all

specified items cannot be removed from the premises.

In the final rule, EPA is reducing post-harvest critical use allowances from the amount that was proposed by 13.66 kilograms to account for an uptake of sulfuryl fluoride for certain post-harvest sectors, including food processing and structures and sub-sectors of the National Pest Management Association (NPMA), of 12–18%. This reduction is equal to less than 0.5% of the 1991 baseline. These sectors are those for which sulfuryl fluoride is registered, and where there are data demonstrating that key pests are controlled by sulfuryl fluoride. Although sulfuryl fluoride is registered for certain commodities, EPA is not making a reduction based on transitions in the commodity sector at this time due to the lack of sulfuryl fluoride food tolerances in countries where the commodities are exported, such as the European Union and Canada. Because of the complications associated with separating quantities of commodities designated for export markets for which sulfuryl fluoride is not a registered alternative, there is no way to determine at harvest which portion of the commodity will be exported. This issue is further discussed in the "Methyl Bromide CUN for Post-Harvest Use for Commodites" chapter of the 2008 U.S. nomination, available on Docket ID OAR–2005–0122.

Based on the assessment performed for the BUNNI of the 2008 CUN, which is available on Docket ID OAR–2005–0122, a transition rate of between 12%–18% reflects the best available data on the feasible uptake of sulfuryl fluoride in the affected portions of the industry. The 2008 assessment was conducted in January 2006 and reflects current market conditions. The 12%–18% range is based on available data and on professional judgment about the uptake of a new chemical in the market. EPA believes that the projected uptake in 2008 under a business-as-usual scenario can be achieved in 2006 by removing the corresponding amount of methyl bromide from the approved critical use level, for the affected sectors. This is consistent with the environmental goals of EPA's stratospheric ozone program and the definition of "critical uses" in Section 82.3 as uses for which there are no technically and economically feasible alternatives. In the proposed rule, EPA noted that uptake can be relatively slow in the initial period following new registrations. The Agency is only applying this projected uptake factor to the structures-food facilities use areas, as well as sub-sectors of NPMA, as the Agency has determined that regulatory and/or technical and economic barriers exist to the adoption of sulfuryl fluoride in other post-harvest critical use areas. (For an additional discussion of economic barriers, please see the 2008 CUN, available on Docket ID OAR–2005–0122). Some technical and/or economic conditions may exist, preventing the full adoption of sulfuryl fluoride in the structures-food facilities sector. For instance, no transition was projected for cheese processing plants because there is no information to show that sulfuryl fluoride is effective on mites. The Agency will continue to review data to better evaluate the potential for sulfuryl fluoride to more broadly penetrate the post-harvest market in the future. Such data would include studies that encompass multiple years and multiple locations, and compare sulfuryl fluoride with methyl bromide. Several studies, with similar pests (at high pest pressures), different locations, with similar collection data (trap catch/bioassays) would be needed in order to conduct such an analysis. Therefore, the best available information for the 2006 rule would suggest a rate of adoption of between 12% and 18%, depending on the sector.

During a notice-and-comment rulemaking, EPA responds, in part, to evolving market conditions between the time of the nomination and the applicable control period. The Agency is taking new registrations of sulfuryl fluoride into account in determining the amount of methyl bromide needed for critical uses in 2006. In the notice of proposed rulemaking, the Agency also recognized that the status of other alternatives to methyl bromide could have changed since the finalization of the May 2005 MBTOC report and there could be updated comparative information regarding alternatives and methyl bromide, as well as new data on emission minimization techniques that would allow a user to obtain the same results with smaller quantities of methyl bromide. The Agency invited the public to submit any such updated information.

EPA received three comments on the issue of post-hoc review. One commenter stated concern over the length of the three-year CUE process, during which time many technical and regulatory changes may change the capacity of methyl bromide alternatives. The commenter requested that EPA provide a post-hoc evaluation of alternatives for the pre-plant sector, as well as the post-harvest sector. EPA is not providing a post-hoc assessment of pre-plant alternatives in this rulemaking but may do so in future critical use exemption rulemakings, should the situation in pre-plant sectors warrant a post-hoc assessment. In this rulemaking, EPA did not receive adequate data to support such an assessment. One commenter provided additional information for the post-harvest sector. An additional commenter suggested that EPA wait until all information about methyl bromide use and inventories is available in early 2006 before deciding to reduce methyl bromide beyond the 30% of baseline. EPA believes sufficient information is available at this time to project the uptake of sulfuryl fluoride during 2006. Comments regarding the amount to come from inventory are addressed in a separate section of this preamble.

EPA received eight comments concerning the barriers to adopting other alternatives to methyl bromide. Two commenters discussed the mandated cap on 1,3-Dichloropropene in township caps in California. EPA is aware of this situation and accounted for township cap barriers when developing the 2006 nomination. Five commenters noted several barriers to the adoption of alternatives, such as narrow ranges of climate conditions, plant-back delay, and lack of comprehensive pest control. EPA considered all of these factors when developing the nomination, and also discussed barriers to adoption in the nomination for 2006. In addition, EPA's Office of Pesticide Programs is currently evaluating all soil fumigants together. More detailed responses to each individual comment are available in the Response to Comments document for this rule, on Docket ID OAR–2005–0122.

EPA received one comment expressing concern that EPA is promoting various alternatives to methyl bromide which are widely known to have severe negative health and environmental impacts. The commenter expressed concern about several alternatives and noted that the environmental risks must be examined before EPA further promotes their use. EPA's Office of Pesticide Programs has a comprehensive registration program in place in order to carefully evaluate the safety of all chemicals, including alternatives to methyl bromide, prior to registration. The Office of Pesticide Programs is currently assessing risks and developing risk management decisions for several soil fumigants, including methyl bromide, to ensure that human health risk assessment approaches are consistent and that the relative risks and benefits of each chemical are considered.

F. What Are the Sources of Critical Use Methyl Bromide?

As discussed above and in the December 23, 2004 Framework Rule, an approved critical user may obtain access to exempted production/import of methyl bromide and to limited inventories of pre-phaseout methyl bromide, the combination of which constitute the supply of "critical use methyl bromide" intended to meet the needs of agreed critical uses. In Decision XVI/2, Decision Ex.II/1, and Decision XVII/9, the Parties to the Protocol authorized agreed critical-use levels for 2006 of 8,081,753 kilograms, which is equivalent to 32% of the U.S. 1991 methyl bromide consumption baseline and includes the supplemental amount. As noted above, paragraph 2 of Decision Ex.II/1 states, "that a Party with a critical-use exemption level in excess of permitted levels of production and consumption for critical uses is to make up any such difference between those levels by using quantities of methyl bromide available from existing stocks." The permitted level of production and consumption of critical use methyl bromide in Decision XVI/2 and Decision Ex.II/1 is 7,658,265 kilograms, or 30% of the U.S. 1991 consumption baseline, leaving approximately 2% to come from inventory.

In developing this action, the Agency notes that Decision XVI/2 (para. 4) states that: "each Party which has an agreed critical use should ensure that the criteria in paragraph 1 of Decision IX/6 are applied when licensing, permitting or authorizing critical use of methyl bromide and that such procedures take into account available stocks of banked or recycled methyl bromide," and Decision Ex.II/1 (para. 5) states that: "each Party which has an agreed critical use renews its commitment to ensure that the criteria in paragraph 1 of Decision IX/6 are applied when licensing, permitting or authorizing critical use of methyl bromide and that such procedures take into account quantities of methyl bromide available from existing stocks."

The language in these Decisions is similar to language in Decision Ex I/3, paragraph 5. In the December 23, 2004 Framework Rule, EPA interpreted paragraph 5 of Decision Ex I/3 "as meaning that the U.S. should not authorize critical use exemptions without including provisions addressing drawdown from stocks for critical uses" (69 FR 76987). The December 23, 2004 rule established provisions governing the sale of pre-phaseout inventories for critical uses, including the concept of critical stock allowances (CSAs) and a prohibition on sale of pre-phaseout inventories in excess of the amount of CSAs held by the seller for critical uses. In addition, EPA noted that inventory was further taken into account through the trading provisions that allow critical use allowances to be converted into critical stock allowances. Under today's final action, no significant changes have been made to those provisions, which remain part of the framework for the critical use exemption and which continue to be in accordance with Decisions of the Parties. Bearing in mind the United States' "renewed commitment" as stated in Decision Ex II/1, and its experience with the 2005 critical use nomination, EPA is, however, exercising its discretion to adjust the portion of critical use methyl bromide to come from exempted production or import as compared to the portion to come from inventory. This action authorizes 6,821,487 kilograms of methyl bromide (27% of baseline) to come from exempted new production or import and 1,136,008 kilograms (5% of baseline) to be made available from pre-phaseout methyl bromide inventories. The percentage of baseline to be taken from pre-phaseout inventories (5%) is the same as that authorized in the Framework Rule for 2005.

EPA received 12 comments on the proportion of critical use methyl bromide coming from pre-phaseout inventories and from new production or import. Eight commenters were concerned with taking only 27% from exempt new production, when the Decisions allow for up to 30%. The commenters said EPA's assumptions about users' ability to obtain methyl bromide from inventory during 2005 were incorrect and indicated that the increased depletion of inventory will increase the cost of the material. Additional comments are detailed below.

With regard to authorizing new production, EPA agrees that Decision Ex II/1 allows up to 30% of the 1991 baseline to come from new production. EPA disagrees, however, that the effect of Decisions XVI/2 and Ex. II/1 is that "7658.28 MT must be allowed to be produced and imported." The Parties agreed to "permit" this level of production and consumption; they did not—and could not—mandate that the U.S. authorize this level of production and consumption domestically. Nor does the CAA require EPA to exempt the full amount permitted by the Parties. Section 604(d)(6) of the CAA does not require EPA to exempt any amount of production and consumption for critical uses ("the Administrator * * * may exempt * * *").

As explained above, EPA is continuing to take inventory into account in the same manner as set forth in the Framework Rule. However, EPA has discretion to take additional actions; such actions would be in line with the United States' "renewed commitment." In response to the Notice of Proposed Rulemaking, the commenters did not provide a reason why the amount of critical use methyl bromide to be taken from inventory in 2006 should be less than the amount authorized to be taken from inventory during the bulk of the prior control period. The commenters believe that Decision Ex II/1 suggests a continuation of the commitment previously made, not a new commitment to reduce levels of production and consumption. While we agree, EPA views continued drawdown of inventory for critical uses at the level authorized in the Framework Rule for 2005 as an appropriate means this year of continuing the commitment previously made, in light of our understanding of current inventory and our analysis of the current needs of users. EPA understands that some commenters object to any regulation of pre-phaseout inventory. The reasons for EPA's limited regulation of such inventory are explained in the Framework Rule and the accompanying Response to Comments document, on Docket ID OAR–2005–0122. That Response to Comments document also responds to the commenters' conclusion that the Parties have implicitly accepted the environmental effects of the full 30%. As explained in the preamble to the Framework Rule, EPA recognizes that certain users elected not to apply for a critical use exemption because they reasonably believed they could meet their limited transitional needs for methyl bromide from inventory. However, during 2005, EPA was not made aware of any evidence that such users encountered problems as a result of EPA's allocating CSAs equal to 7.5% of baseline. Nor have the commenters provided any compelling evidence that such users would be unable to meet their limited transitional needs during 2006 due to a continuation of the same policy. One commenter stated that it did not have enough CUE pounds of methyl bromide to supply customers, so that users had to access existing inventory previously purchased. However, the commenter did not state that it would not be able to meet their customers' needs during 2006. Other commenters did state that EPA had no basis to assume that critical users have had no difficultly obtaining methyl bromide because most users would have

experienced difficulty during the last quarter of the year, after the publication of the proposed rule. Again, EPA is not aware of users having difficulty obtaining methyl bromide from inventory through December, 2005.

Nine commenters stated that it is important to preserve sufficient existing inventory for use in the event of catastrophic loss or an unexpected pest outbreak. EPA agrees with this statement. EPA does recognize that natural disasters may cause disruptions in inventory supply and distribution, and may address this issue in future rulemakings.

Two commenters noted that the accelerated use of inventory will result in inventory being concentrated in the hands of a few large entities and may cause market disruption. EPA recognizes that inventory may not be uniformly distributed and that at some locations, inventory have already been depleted. However, if a particular distributor holds CSAs but no longer holds pre-phaseout inventories, that distributor can sell the CSAs to another entity that does hold such inventories. Depletion of inventory in a particular geographic area does not mean that approved critical users in that geographic area will necessarily lack access to methyl bromide, as they may be able to obtain methyl bromide produced through the expenditure of CUAs.

Two commenters stated that there may be errors in the amount of methyl bromide that was nominated for each sector, and that as a result, shifting the source of 3% of baseline from new production and import to pre-phaseout inventory may result in insufficient supplies. EPA notes that allocating on a universal basis, with a split between the pre-plant and post-harvest sectors, allows the market to correct for any errors in the amount of methyl bromide estimated to be needed in each sector.

Nine commenters stated a belief that no downward adjustment should be made until EPA has fully evaluated actual data for 2005. These commenters stated that EPA must have a rational basis for its actions. EPA's action is based on its experience with inventory drawdown in 2005 and on data regarding inventory holdings that has been claimed as confidential.

One commenter stated that increased depletion of inventory will increase the cost of methyl bromide. EPA notes that rising costs help encourage the transition to non-ozone-depleting substitutes. In the Response to Comments document for the December 23, 2004 Framework Rule, EPA also stated that economic theory would suggest that an increase in the price of critical use methyl bromide would occur should demand for critical use methyl bromide exceed supply. However, EPA believes critical use demand is not likely to exceed the 32% of baseline authorized by the Parties.

One commenter stated that no CUAs should be permitted if sufficient inventory is available for critical uses. Another commenter stated that EPA's proposal does not comply with the CAA or the Protocol, specifically Decisions XVI/2, Ex II/1, and IX/6, with regard to accounting for inventory. The commenter stated that in promulgating the Framework Rule, EPA undertook no analysis of how much critical need could be met with existing inventory and refused to disclose the total amount. As a result, according to the commenter, EPA cannot rely in the 2006 rule on its assessment of inventory in the 2005 rules. In addition, the commenter states that the phrase "renews its commitment to ensure" in Decision Ex. II/1 clarifies that the language regarding accounting for inventory in that Decision constitutes a commitment and that similar language in earlier Decisions also constituted a commitment.

To the extent the commenter questions the determinations made as part of the Framework Rule, EPA refers the commenter to the preamble to that rule and the accompanying Response to Comments document. The briefs filed in the litigation concerning the Framework Rule have also been placed in Docket ID OAR–2005–0122. Although EPA disagrees with the commenter's suggestion that the commitment reflected in Decision Ex. II/1 has the legal consequences the commenter suggests, EPA's actions in today's rule are an expression of this U.S. "renewed commitment." In addition, EPA disagrees with the commenter's assumption that the phrase "take into account quantities of methyl bromide available from existing stocks" is susceptible to only one interpretation. EPA has taken available inventory into account both by including stock-related provisions in the Framework Rule and by continuing the allocation of CSAs at a level equal to 5% of baseline in the CUE allocation for 2006. Finally, EPA notes that the earlier Decisions provide some context for understanding this "renewed commitment"; contrary to the commenter's suggestion, the more recent Decision does not affect the meaning of the earlier ones.

EPA received one comment stating that reporting requirements are being evaded through transfer of legal title to the end users. EPA did not specifically solicit comment on this point but may consider the issue in future rulemakings. In addition, EPA is now requiring that inventory drawdown be reported on an annual basis. This amendment to the regulatory text was made in the 2005 supplemental rule.

Ten commenters stated that EPA has no basis to assume that critical users have had no difficulty obtaining methyl bromide from inventory during 2005 because most users would only be in need of additional methyl bromide after the proposal was issued. However, it does not appear that critical users have had difficulty in obtaining methyl bromide from inventory during the 2005 control period. While the commenters stated that any such difficulty would arise after the issuance of the proposed rule, this final rule is based on a full calendar year's experience. Up until December 9th approved critical users were authorized to obtain up to 30% of baseline from new production and import and up to 5% from inventory. As of December 9th, approved critical users were authorized to obtain an additional 2.5% of baseline from inventory. We recognize that some users might not have had time to purchase the material prior to the end of the 2005 control period. Therefore, we are relying on the full year's experience with the stock amount authorized for approved critical uses in the Framework Rule. Drawing on this experience, EPA is granting CSAs equivalent to 5% of baseline for the 2006 control period, on the basis that users will continue to be able to access this level of inventory during 2006. In the proposed rule, we indicated that there was some uncertainty in this determination because the 2005 control period had not yet ended. However, the 2005 control period has now ended. In the proposed rule, we also stated that we anticipated that inventory levels would be lower in 2006. While we continue to anticipate a decline in inventory levels, we do not anticipate that critical users will be unable to obtain needed quantities. We have placed data on inventory holdings in the confidential portion of the docket.

On December 23, 2005, EPA received a letter concerning the impact of the Decision of the Parties taken at their 17th Meeting, concerning critical uses for 2007 and the impact of this Decision on critical uses for the 2006 control period. While this letter did not arrive during the comment period, EPA is addressing it in this final rule because of the subject matter. The letter stated that in light of the Decisions taken at the 17th Meeting, EPA should grant the full 30% of baseline in the form of CUAs for the 2006 control period. The industry group that wrote the letter observed that

at the 17th Meeting of the Parties, the Parties authorized up to approximately 20% from new production and 6.25% from inventory for 2007. The letter expressed concerns that taking 5% of baseline from inventory in 2006 and 6.25% in 2007 would result in shortages. EPA has re-examined the available inventory data and has projected multiple scenarios concerning levels of consumption of existing inventory. Based on these efforts, EPA believes that critical users will continue to be able to meet their needs throughout 2006 and 2007 through the anticipated combination of new production and import and inventory drawdown. EPA's analysis is based on data that has been claimed as confidential and therefore has not been included in the public portion of the docket for this rule. While EPA previously determined that aggregate inventory information for a prior year was not confidential business information, EPA has not made that information public due to the filing of complaints by affected businesses. EPA will continue to monitor CUA and CSA data very closely. If an inventory shortage occurs, EPA may consider various options, including but not limited to promulgating a final version of the proposed petition process, taking into account comments received; proposing a different administrative mechanism to serve the same purpose; or authorizing conversion of a limited number of CSAs to CUAs through rulemaking, bearing in mind the upper limit on U.S. production for critical uses. EPA may also address consideration of inventory to satisfy critical uses for the 2007 control period in a future rulemaking.

In the proposed rule, EPA requested comment on a petition process that would allow an approved critical user to demonstrate inability to acquire sufficient methyl bromide from inventory. Upon receipt of a petition that met the specified criteria, EPA would review the petition and consider converting a limited number of CSAs to CUAs (up to the 30% limit agreed by the Parties).

EPA received 11 on-time comments opposed to the proposed petition process, and one on-time comment in favor. The comments in opposition stated that the petition process was cumbersome and would cause significant additional burden to end-users. Other commenters stated that the October 1 deadline proposed for submittal of a petition would be too early in the calendar year, as most potential CSA shortages are expected to occur during the latest months of the year. One commenter was opposed to the petition process in general but suggested revisions, such as reducing EPA's review period from 30 days to 7 days. One additional commenter objected to the proposed petition process and stated that EPA had no justification for a process that would lead to increased production, and that a much greater reduction in production and import would be required to comply with Decisions IX/6, XVI/2 and Ex. II/1. The one comment in favor of the petitions noted that the proposed process would prevent unneeded methyl bromide from entering the market, but also stated that the situation would be unlikely to occur. Having considered the comments, EPA concludes that approved critical users do not view the petition process as providing a significant benefit. The petition process was designed to assist approved critical users in the unlikely event that they were unable to obtain a quantity from inventory equal to the number of CSAs allocated in this rulemaking. EPA has received no indication that such a shortage will occur during 2006. Therefore, EPA is not finalizing the proposed petition process and is withdrawing the information collection request (ICR) for this provision that it submitted to OMB under the Paperwork Reduction Act.

G. What Are the Critical Use Allowance Allocations?

For 2006, EPA is authorizing production and import of 6,821,487 kilograms of critical use methyl bromide, as shown in Table II below. With this action, EPA is allocating critical use allowances (CUAs) to producers and importers on a pro-rata basis based on their 1991 consumption baseline levels. Each CUA is equivalent to 1 kilogram of critical use methyl bromide. These allowances expire at the end of the control period and, as stated in the Framework Rule, are not bankable from one year to the next. This action allocates the following number of pre-plant and post-harvest critical use allowances (CUAs) to the entities listed below. They will be subject to the trading provisions at 40 CFR 82.12, which are discussed in section V.(G) of the preamble to the Framework Rule (69 FR 76982).

As discussed in section V.(E) of the preamble to the Framework Rule (69 FR 76990), EPA issues CUEs once a year except in the instance where the Parties authorize supplemental amounts or uses for CUEs.

EPA has modified the CUAs and CSAs that were listed in the October 27, 2005 Notice of Proposed Rulemaking due to the revised adjustment for uptake of sulfuryl fluoride, as well as EPA's determination to allow 27% of baseline for new production and 5% of baseline for CSAs. These adjustments result in a total of 6,315,237 kilograms for pre-plant CUAs and 506,250 kilograms for post-harvest CUAs.

TABLE II.—ALLOCATION OF CRITICAL USE ALLOWANCES

Company	2006 Critical use allowances for pre-plant uses* (kilograms)	2006 Critical use allowances for post-harvest uses* (kilograms)
Great Lakes Chemical Corp.	3,838,070	307,673
Albemarle Corp.	1,578,274	126,520
Ameribrom, Inc.	871,872	69,892
TriCal, Inc.	27,020	2,166
Total	6,315,237	506,250

* For production or import of class I, Group VI controlled substance exclusively for the Pre-Plant or Post-Harvest uses specified in Appendix L to 40 CFR Part 82.

EPA received eight comments identifying a duplication error in the proposed critical use allocations for 2006 (70 FR 62030). EPA unintentionally duplicated the amount of post-harvest CUAs as "129,934 kilograms" for both Albemarle and Ameribrom. However, the revised post-harvest calculations in this final rule

authorize 126,520 post-harvest CUAs for Albemarle and 69,892 for Ameribrom. The revised overall total of post-harvest CUAs is 506,250 kilograms.

Paragraph four of Decision Ex. I/3, taken at the 1st Extraordinary Meeting of the Parties, stated "that Parties should endeavor to allocate the quantities of methyl bromide recommended by the Technology and Economic Assessment Panel as listed in annex II A to the report of the First Extraordinary Meeting of the Parties." Similarly, paragraph four of Decision Ex. II/1 states, "that Parties that have an agreed critical use shall endeavor to license, permit, authorize or allocate the quantities of methyl bromide recommended by the Technology and Economic Assessment Panel to the specific categories of use shown in table A of the annex to the present Decision." In accordance with Decision Ex.I/3, paragraph four, and consistent with the more recent Decision, the Agency endeavored to allocate directly on a sector-by-sector basis by analyzing this option, among others, in August 2004. In the final Framework Rule, the Agency made a reasoned decision as to the economic, environmental and practical effects of implementing the various proposed approaches, after considering public comment. In the August 25, 2004 proposed rulemaking for the allocation framework (69 FR 52366), EPA solicited comment on both universal and sector-based allocation of critical use allowances, as well as more flexible methods for determining allocations. EPA determined in the final Framework Rule (69 FR 76989) that a lump-sum, or universal, allocation, modified to include distinct caps for pre-plant and post-harvest uses, was the most efficient and least burdensome approach that would achieve the desired environmental results, and that there would be significant administrative and practical difficulties associated with a sector-specific approach.

EPA received two on-time comments concerning use-specific allocations. One commenter stated that CSAs and CUAs should be allocated specifically to each of the sectors as authorized by the Parties, and that the current "lump sum" allocation system delays the transition to alternatives. However, the commenter also stated that if EPA does not implement a use-specific allocation system, the Agency should maintain the current system that differentiates "pre-plant" and "post-harvest" uses. EPA intends to continue differentiating between "pre-plant" and "post-harvest" uses as defined in the Framework Rule (69 FR 76982) for the 2006 control period. EPA's consideration of a use-specific allocation system is summarized below.

In developing the Framework Rule and allocating CUAs for 2005, EPA examined the economic, environmental and administrative effects of various allocation options over the projected life of the CUE exemption program. The Agency found that a universal approach would offer equal environmental protection, at less cost and with easier implementation, than other options such as sector-specific allocation. The Agency adopted a modified universal approach, separating pre-plant from post-harvest uses in order to address concerns raised by smaller, less frequent, and end-of-year uses.

In addition, although the approach adopted in the Framework Rule does not directly allocate allowances to each category of use, the Agency anticipates that reliance on market mechanisms will achieve similar results indirectly. As described in the August 25, 2004 proposed rulemaking and accompanying regulatory impact analysis (E-Docket OAR–2003–0230), the Agency believes that under the universal approach, as divided into pre-plant and post-harvest sectors, the actual critical use will closely follow the sector breakout listed by the TEAP and incorporated into the Parties' Decision. EPA will continue to monitor use sector by sector. A market-based lump sum system will likely operate to mirror a sector-specific allocation over time, and should not therefore delay the transition to alternatives. For the reasons stated above, and consistent with our current analysis of this issue as it relates to 2006, EPA is not changing the approach previously adopted in the Framework Rule for the allocation of CUAs.

EPA notes that the U.S. Government has spent over $150 million on alternatives research, and continues to develop research priorities. In addition, all critical use exemption applicants are required to have a research plan in order for their requests to be included in the annual nomination.

The other commenter supported the allocation of CUAs to the same pre-plant and post-harvest groupings because critical users require consistency from year to year. EPA is continuing to implement this allocation mechanism.

H. What Are the Critical Stock Allowance Allocations?

EPA is allocating 1,136,008 kilograms of critical stock allowances (CSAs) to the entities listed below in Table III for the 2006 control period. The amounts are apportioned to each entity in proportion to inventory held.

EPA addressed the issue of access to inventory for approved critical uses in the October 27, 2005 Notice of Proposed Rulemaking for 2006 allocations (70 FR 62044) and in the December 23, 2004 Framework Rule. EPA is not changing this aspect of the critical use exemption framework through this action.

EPA currently possesses information on existing inventory of methyl bromide that has been claimed as confidential. With regard to data for 2003, EPA has determined that the aggregate inventory information is not confidential business information and may be disclosed but is currently withholding that information due to the filing of complaints by affected businesses seeking to enjoin the Agency from its release (40 CFR 2.205). EPA will continue to follow its own regulations with respect to the treatment of this information. EPA received one comment requesting that it disclose the amount of inventory held by private sector entities on the grounds that the information is relevant to the outcome of the rule and should therefore be available for public comment under Section 307(d) of the CAA: The commenter refers to arguments made in comments on the framework rule and in legal briefs. EPA's position on these issues is explained in the preamble to the Framework Rule and the responses to comments received on that rule. The comment responses, and legal briefs in the case to which the commenter refers, are available in Docket ID OAR–2005–0122.

TABLE III.—ALLOCATION OF CRITICAL STOCK ALLOWANCES

Company
Albemarle
Ameribrom, Inc.
Bill Clark Pest Control, Inc.
Blair Soil Fumigation
Burnside Services, Inc.
Cardinal Professional Products
Carolina Eastern, Inc.
Degesch America, Inc.
Dodson Bros.
Great Lakes Chemical Corp.
Harvey Fertilizer & Gas
Helena Chemical Co.
Hendrix & Dail
Hy Yield Bromine
Industrial Fumigation Company
J.C. Ehrlich Co.
Pacific Ag
Pest Fog Sales Corp.
Prosource One
Reddick Fumigants
Royster-Clark, Inc.
Southern State Cooperative, Inc.
Trical Inc.
Trident Agricultural Products
UAP Southeast (NC)
UAP Southeast (SC)

TABLE III.—ALLOCATION OF CRITICAL STOCK ALLOWANCES—Continued

Company
Univar
Vanguard Fumigation Co.
Western Fumigation
TOTAL—1,136,008 kilograms

I. Clarifications to the Framework Rule

EPA is clarifying the Framework Rule regarding consecutive use of non-critical use methyl bromide and critical use methyl bromide. Under 40 CFR 82.13(dd), an approved critical user who purchases a quantity of critical use methyl bromide is required to certify, in part: "I will not use this quantity of methyl bromide for a treatment chamber, facility, or field that I previously fumigated with non-critical use methyl bromide purchased during the same control period" unless certain exceptions apply. This certification, by itself, would not preclude the user from using the critical-use methyl bromide for a treatment chamber, facility, or field that he or she had fumigated earlier that year with non-critical use methyl bromide purchased during an earlier control period. However, the prohibition at § 82.4(p)(2)(vi) states: "No person who purchases critical use methyl bromide during the control period shall use that methyl bromide on a field or structure for which that person has used non-critical use methyl bromide for the same use (as defined in Columns A and B of Appendix L) in the same control period" unless certain exceptions apply. That prohibition does not distinguish between non-critical use methyl bromide purchased during the current control period and carryover amounts purchased during earlier control periods.

In deciding how to reconcile these two provisions, EPA considered the effect of an amendment contained in the December 13, 2005 **Federal Register** notice concerning the supplemental allocation for 2005. There, EPA amended § 82.4(p)(2)(vi) and the certification language in § 82.13(dd) so that end users who had been using non-critical use methyl bromide during the first part of 2005 would not be prevented from using critical use methyl bromide on the same field or structure for the same use if they became approved critical users as a result of that supplemental rulemaking (70 FR 73604). That change would also prevent adverse consequences for end users if the main allocation rule for a particular calendar year were delayed. EPA is reconciling the language in § 82.4(p)(2)(vi) and § 82.13(dd) by changing the language of the certification to omit the word "purchased" from the sentence that begins "I will not use this quantity of methyl bromide for a treatment chamber, facility, or field that I previously fumigated with non-critical use methyl bromide purchased during the same control period * * * ". This approach puts the focus on actions taken during the current control period and provides greater clarity and simplicity by eliminating the date of purchase of non-critical use methyl bromide as an issue.

EPA received eight comments on how to reconcile these two provisions. One commenter was confused about how the proposed change related to the change included in the supplemental rule for 2005. The change included in the supplemental rule addressed situations in which EPA authorizes critical uses during a control period. That change was made because the general prohibition on changing from non-critical-use methyl bromide to critical-use methyl bromide during a control period would otherwise have prevented access to critical-use methyl bromide for the newly authorized uses. The October 27, 2005 proposed rule for 2006 critical uses focused on a separate issue: Whether critical users were barred from using critical-use methyl bromide on a field or structure previously fumigated, during the same control period, with any non-critical-use methyl bromide, or only a field or structure previously fumigated, during the same control period, with non-critical-use methyl bromide purchased during that same control period. The commenter states that EPA did not explain why the change was necessary. EPA is making the change to make the prohibition in section § 82.4(p) consistent with the certification language in § 82.13(dd). The change made in the supplemental rule ensures that users who have uses that will be designated as critical uses upon the effective date of this rule will not be prevented from using critical-use methyl bromide as a result of having used non-critical-use-inventory of methyl bromide prior to the critical use designation.

This commenter stated that the proposed rule did not include relevant regulatory text on this issue. Because the change described in the supplemental rule was pending at the time of the proposed rule for this action, EPA chose not to include relevant regulatory text in the proposal, as doing so could have caused additional confusion. The change was adequately described in the preamble. This final rule includes the text of § 82.13(dd) as amended through the supplemental rule and through this action.

One commenter states that the Framework Rule allows users to "double-dip" by dividing fields or structures under common ownership into two parts, in order to apply critical-use methyl bromide to the first part and non-critical-use methyl bromide to the second part. However, EPA is not aware of such double-dipping taking place. In this rulemaking for the 2006 control period, we are not revisiting all aspects of the Framework Rule. We proposed a small change to reconcile language in two different sections of that rule. We welcome specific suggestions for improvements to the critical use regulations for consideration in future rulemakings. In this action, however, we are addressing only the aspects of this comment that relate to the specific change proposed. The commenter appears to believe that removing the word "purchased" from § 82.13(dd) would allow greater overall usage of methyl bromide. This is not the case. This change simply conforms the language of the end-user certification with the language of the prohibition in § 82.4(p)(2)(vi). It clarifies that, except in the instances noted in the rule, end-users may not use non-critical-use methyl bromide on a particular field or structure and then switch to critical-use methyl bromide for that same field or structure, regardless of when the non-critical-use methyl bromide was purchased.

EPA received two comments stating that methyl bromide in pre-phaseout inventory should not be accessed by those without critical needs. While EPA has previously discussed this issue in the Framework Rule, in summary, Decision Ex. II/1 does not require that individual Parties prohibit use of inventory by users whose uses fall outside the categories of agreed critical uses. Nothing in the Protocol or CAA mandates that EPA limit drawdown from existing inventory for such uses. Further details are available in the Response to Comments document for the Framework Rule.

J. Supplemental Critical Use Exemptions for 2006

On January 31, 2005, the U.S. Government submitted a supplemental nomination for 2006 critical use exemptions equivalent to 0.03% of the 1991 U.S. baseline. The supplemental nomination for 7,070 kilograms for California dried beans was considered "unable to assess" by the MBTOC in its May 2005 report because of a need for clarification about the label for phosphine and the principal pest, the

cowpea weevil. The U.S. submitted additional information in August 2005 to the MBTOC, responding to various questions on critical use nominations, including a clarification of the status of the phosphine label with regard to its use for dried beans. In December 2005, the Parties approved the supplemental nomination for 2006 at their 17th Meeting in Dakar, Senegal. In light of the Parties' approval of the supplemental 2006 nomination, EPA is including this quantity in the critical use levels for 2006.

EPA received one on-time comment concerning the supplemental request for 2006. The commenter objected to granting domestic approval to a critical use category not yet fully reviewed or authorized by the Parties, and was concerned that the public would not have a second opportunity to comment on the supplemental request. EPA was as specific as possible in the October 27, 2005 proposed rule regarding the size and nature of the supplemental request in order to provide the public a full opportunity to comment. There is no significant new information to put before the public at this time. Therefore, a second comment period is unnecessary. The commenter suggests that EPA take a second look at the supplemental amount on the basis of the most up-to-date information. However, in this instance the information that formed the basis of the Parties' Decision is the most up-to-date information available. That information included the U.S. responses to questions from MBTOC in August of 2005. The supplemental request is being authorized through the allocation of additional CSAs.

VI. Statutory and Executive Order Reviews

A. Executive Order No. 12866: Regulatory Planning and Review

Under Executive Order No. 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether the regulatory action is "significant" and therefore subject to OMB review and the requirements of the Executive Order. The Order defines "significant regulatory action" as one that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Pursuant to the terms of Executive Order 12866, OMB has notified EPA that it considers this a "significant regulatory action" within the meaning of the Executive Order. EPA has submitted this action to OMB for review. Changes made in response to OMB suggestions or recommendations will be documented in the public record.

B. Paperwork Reduction Act

EPA submitted an information collection request (control number 2179.04) for OMB approval that pertains to the petitioning requirements described in Section E, under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* However, as described in that section, EPA is not finalizing the petitioning requirements in this action and has withdrawn 2179.04 from OMB consideration. The information collection under this final rule is authorized under Sections 603(b), 603(d) and 614(b) of the Clean Air Act (CAA).

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9.

C. Regulatory Flexibility

EPA has determined that it is not necessary to prepare a regulatory flexibility analysis in connection with this final rule. For purposes of assessing the impacts of today's rule on small entities, small entity is defined as: (1) A small business that is identified by the North American Industry Classification System (NAICS) Code in the Table below; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

Category	NAICS code	SIC code	NAICS small business size standard (in number of employees or millions of dollars)
Agricultural Production ...	1112—Vegetable and Melon farming	0171—Berry	0.75
	1114—Greenhouse, Nursery, and Floriculture Production.	0171—Berry Crops	
		0181—Ornamental Floriculture and Nursery products.	
Storage Uses	115114—Post-harvest crop activities (except Cotton Ginning).	4221—Farm Product Warehousing and Storage ..	21.5
	493110—General Warehousing and Storage	4225—General Warehousing and Storage	
	493130—Farm product Warehousing Storage		

Agricultural producers of minor crops and entities that store agricultural commodities are categories of affected entities that contain small entities. This rule only affects entities that applied to EPA for a de-regulatory exemption. In most cases, EPA received aggregated requests for exemptions from industry consortia. On the exemption application, EPA asked consortia to describe the number and size distribution of entities their application covered. Based on the data provided, EPA estimates that 3,218 entities petitioned EPA for an exemption. Since many applicants did not provide information on the distribution of sizes of entities covered in their applications, EPA estimated that between one-fourth and one-third of the entities may be small businesses based on the definition given above. In addition, other categories of affected entities do not contain small businesses based on the above description.

After considering the economic impacts of today's rule on small entities, EPA has concluded that this action will not have a significant economic impact on a substantial number of small entities. The small entities directly regulated by this rule are primarily agricultural entities, producers, importers, and distributors of methyl bromide, as well as any entities holding inventory of methyl bromide.

In determining whether a rule has a significant economic impact on a substantial number of small entities, the impact of concern is any significant adverse economic impact on small entities, since the primary purpose of the regulatory flexibility analyses is to identify and address regulatory alternatives "which minimize any significant economic impact of the rule on small entities." (5 U.S.C. 603–604). Thus, an Agency may conclude that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves a regulatory burden, or otherwise has a positive economic effect on all of the small entities subject to the rule. Since this rule will make additional methyl bromide available for approved critical uses after the phaseout date of January 1, 2005, this is a de-regulatory action which will confer a benefit to users of methyl bromide. EPA believes the estimated de-regulatory value for users of methyl bromide is between $20 million to $30 million annually, as a result of the entire critical use exemption program over its projected duration. We have therefore concluded that today's final rule will relieve regulatory burden for all small entities.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with "Federal mandates" that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

EPA has determined that this final rule does not contain a Federal mandate that may result in expenditures of $100 million or more by State, local and tribal governments, in the aggregate, or by the private sector in any one year. The recordkeeping and reporting burden on the private sector associated with this rule is estimated to be under $200,000 on an annual basis. Thus, this rule is not subject to the requirements of Sections 202 and 205 of the UMRA. Further, EPA has determined that this rule contains no regulatory requirements that might significantly or uniquely affect small governments because it does not create any requirements on any State, local, or tribal government.

E. Executive Order No. 13132: Federalism

Executive Order No. 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

This final rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order No. 13132. This final rule is expected to primarily affect producers, suppliers, importers, and exporters and users of methyl bromide. Thus, Executive Order 13132 does not apply to this rule.

In the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and State and local governments, EPA specifically solicited comment on this rule from State and local officials. EPA did not receive comment on this rule from State or local officials.

F. Executive Order No. 13175: Consultation and Coordination With Indian Tribal Governments

Executive Order No. 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000), requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." This final rule does not have tribal implications, as specified in Executive Order No. 13175. This rule does not significantly or uniquely affect the communities of Indian tribal governments, nor does it impose any enforceable duties on communities of Indian tribal governments. Thus, Executive Order No. 13175 does not apply to this rule.

G. Executive Order No. 13045: Protection of Children From Environmental Health & Safety Risks

Executive Order No. 13045: "Protection of Children From

Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997) applies to any rule that: (1) Is determined to be "economically significant" as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

EPA interprets Executive Order 13045 as applying only to those regulatory actions that are based on health or safety risks, such that the analysis required under Section 5–501 of the Order has the potential to influence the regulation. This final rule is not subject to Executive Order 13045 because it does not establish an environmental standard intended to mitigate health or safety risks.

H. Executive Order No. 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This final rule is not a "significant energy action" as defined in Executive Order No. 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355 (May 22, 2001)) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. This rule does not pertain to any segment of the energy production economy nor does it regulate any manner of energy use. Therefore, we have concluded that this rule is not likely to have any adverse energy effects.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 ("NTTAA"), Public Law 104–113, Section 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards. This rulemaking does not involve technical standards. Therefore, EPA did not consider the use of any voluntary consensus standards.

J. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2). This rule will be effective on February 1, 2006.

List of Subjects in 40 CFR Part 82

Environmental protection; Environmental treaty; Montreal Protocol on Substances that Deplete the Ozone Layer; Ozone depletion; Methyl bromide; Chemicals; Exports, Imports, Production, Reporting and recordkeeping requirements.

Dated: January 30, 2006.

Stephen L. Johnson,

Administrator.

■ For the reasons set out in the preamble, 40 CFR part 82 is amended as follows:

PART 82—PROTECTION OF STRATOSPHERIC OZONE

■ 1. The authority citation for part 82 continues to read as follows:

Authority: 42 U.S.C. 7414, 7601, 7671–7671q.

■ 2. Section 82.8 is amended by revising paragraphs (c)(1) and (c)(2) to read as follows:

§ 82.8 Grant of essential use allowances and critical use allowances.

* * * * *

(c) * * *

(1) Allocated critical use allowances granted for specified control period.

Company	2006 Critical use allowances for pre-plant uses* (kilograms)	2006 Critical use allowances for post-harvest uses* (kilograms)
Great Lakes Chemical Corp.	3,838,070	307,673
Albemarle Corp.	1,578,274	126,520
Ameribrom, Inc.	871,872	69,892
TriCal, Inc.	27,020	2,166
Total	6,315,237	506,250

* For production or import of class I, Group VI controlled substance exclusively for the Pre-Plant or Post-Harvest uses specified in Appendix L to this subpart.

(2) Allocated critical stock allowances granted for specified control period. The following companies are allocated critical stock allowances for 2006 on a pro-rata basis in relation to the inventory held by each.

Company
Albemarle
Ameribrom, Inc.
Bill Clark Pest Control, Inc.
Blair Soil Fumigation
Burnside Services, Inc.
Cardinal Professional Products
Carolina Eastern, Inc.
Degesch America, Inc.
Dodson Bros. Trical Inc.
Great Lakes Chemical Corp.
Harvey Fertilizer & Gas
Helena Chemical Co.
Hendrix & Dail
Hy Yield Bromine
Industrial Fumigation Company
J.C. Ehrlich Co.
Pacific Ag
Pest Fog Sales Corp.
Prosource One
Reddick Fumigants

Company
Royster-Clark, Inc.
Southern State Cooperative, Inc.
Trident Agricultural Products
UAP Southeast (NC)
UAP Southeast (SC)
Univar
Vanguard Fumigation Co.
Western Fumigation
TOTAL—1,136,008 kilograms

■ 3. Section 82.13 is amended by revising paragraph (dd) to read as follows:

§ 82.13 Recordkeeping and Reporting Requirements for Class I Controlled Substances.

* * * * *

(dd) Every approved critical user purchasing an amount of critical use methyl bromide or purchasing fumigation services with critical use methyl bromide must, for each request, identify the use as a critical use and certify being an approved critical user. The approved critical user certification will state, in part: "I certify, under penalty of law, I am an approved critical user and I will use this quantity of methyl bromide for an approved critical use. My action conforms to the requirements associated with the critical use exemption published in 40 CFR part 82. I am aware that any agricultural commodity within a treatment chamber, facility or field I fumigate with critical use methyl bromide cannot subsequently or concurrently be fumigated with non-critical use methyl bromide during the same control period, excepting a QPS treatment or a treatment for a different use (*e.g.*, a different crop or commodity). I will not use this quantity of methyl bromide for a treatment chamber, facility, or field that I previously fumigated with non-critical use methyl bromide during the same control period, excepting a QPS treatment or a treatment for a different use (*e.g.*, a different crop or commodity), unless a local township limit now prevents me from using methyl bromide alternatives or I have now become an approved critical user as a result of rulemaking." The certification will also identify the type of critical use methyl bromide purchased, the location of the treatment, the crop or commodity treated, the quantity of critical use methyl bromide purchased, and the acreage/square footage treated, and will be signed and dated by the approved critical user.

■ 4. Appendix L to Subpart A is revised to read as follows:

Appendix L to Part 82 Subpart A—Approved Critical Uses, and Limiting Critical Conditions for Those Uses for the 2006 Control Period

Column A Approved critical uses	Column B Approved critical user and location of use	Column C Limiting critical conditions
Pre-Plant Uses:		
Cucurbits	(a) Michigan growers	with a reasonable expectation that moderate to severe soilborne fungal disease infestation, or moderate to severe disease infestation could occur without methyl bromide fumigation; or with a need for methyl bromide for research purposes.
	(b) Southeastern U.S. except Georgia limited to growing locations in Alabama, Arkansas, Kentucky, Louisiana, North Carolina, South Carolina, Tennessee, and Virginia.	with a reasonable expectation that one or more of the following limiting critical conditions either already exist or could occur without methyl bromide fumigation: moderate to severe yellow or purple nutsedge infestation, or to a lesser extent: fungal disease infestation and root knot nematodes; or with a need for methyl bromide for research purposes.
	(c) Georgia growers	with a reasonable expectation that one or more of the following limiting critical conditions either already exist or could occur without methyl bromide fumigation: moderate to severe yellow or purple nutsedge infestation, moderate to severe fungal disease infestation, or to a lesser extent: root knot nematodes; or with a need for methyl bromide for research purposes.
Eggplant	(a) Florida growers	with a reasonable expectation that one or more of the following limiting critical conditions either already exist or could occur without methyl bromide fumigation: moderate to severe yellow or purple nutsedge infestation, or moderate to severe nematodes, or moderate to severe disease infestation, or restrictions on alternatives due to karst geology; or with a need for methyl bromide for research purposes.
	(b) Georgia growers	with a reasonable expectation that one or more of the following limiting critical conditions either already exist or could occur without methyl bromide fumigation: moderate to severe yellow or purple nutsedge infestation, or moderate to severe nematodes, or moderate to severe pythium root and collar rots, or moderate to severe southern blight infestation, and to a lesser extent: crown and root rot; or with a need for methyl bromide for research purposes.
	(c) Michigan growers	with a reasonable expectation that moderate to severe soilborne fungal disease infestation could occur without methyl bromide fumigation; or with a need for methyl bromide for research purposes.
Forest Nursery Seedlings	(a) Members of the Southern Forest Nursery Management Cooperative limited to growing locations in Alabama, Arkansas, Florida, Georgia, Louisiana, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas and Virginia.	with a reasonable expectation that one or more of the following limiting critical conditions already either exist or could occur without methyl bromide fumigation: moderate to severe yellow or purple nutsedge infestation, or moderate to severe disease infestation.

Column A Approved critical uses	Column B Approved critical user and location of use	Column C Limiting critical conditions
	(b) International Paper and its subsidiaries limited to growing locations in Alabama, Arkansas, Georgia, South Carolina and Texas.	with a reasonable expectation that one or more of the following limiting critical conditions already either exist or could occur without methyl bromide fumigation: moderate to severe yellow or purple nutsedge infestation, or moderate to severe disease infestation.
	(c) Public (government owned) seedling nurseries in the states of Illinois, Indiana, Kentucky, Maryland, Missouri, New Jersey, Ohio, Pennsylvania, West Virginia and Wisconsin.	with a reasonable expectation that one or more of the following limiting critical conditions either already exist or could occur without methyl bromide fumigation: moderate to severe weed infestation including purple and yellow nutsedge infestation, or moderate to severe Canada thistle infestation, or moderate to severe nematodes, and to a lesser extent: fungal disease infestation.
	(d) Weyerhaeuser Company and its subsidiaries limited to growing locations in Alabama, Arkansas, North Carolina and South Carolina.	with a reasonable expectation that one or more of the following limiting critical conditions already either exist or could occur without methyl bromide fumigation: moderate to severe yellow or purple nutsedge infestation, moderate to severe disease infestation, and to a lesser extent: nematodes and worms.
	(e) Weyerhaeuser Company and its subsidiaries limited to growing locations in Washington and Oregon.	with a reasonable expectation that one or more of the following limiting critical conditions already either exist or could occur without methyl bromide fumigation: moderate to severe yellow nutsedge infestation, or moderate to severe fungal disease infestation.
	(f) Michigan growers	with a reasonable expectation that one or more of the following limiting critical conditions already either exist or could occur without methyl bromide fumigation: moderate to severe disease infestation, moderate to severe Canada thistle infestation, moderate to severe nutsedge infestation, and to a lesser extent: nematodes.
	(g) Michigan herbaceous perennials growers.	with a reasonable expectation that one or more of the following limiting critical conditions already exist or could occur without methyl bromide fumigation: moderate to severe nematodes, moderate to severe fungal disease infestation, and to a lesser extent: yellow nutsedge and other weeds infestation.
Orchard Nursery Seedlings	(a) Members of the Western Raspberry Nursery Consortium limited to growing locations in California and Washington (Driscoll's Raspberries and their contract growers in California and Washington).	with a reasonable expectation that one or more of the following limiting critical conditions already either exists or could occur without methyl bromide fumigation: moderate to severe nematode infestation, medium to heavy clay soils, or a prohibition on the use of 1,3-dichloropropene products due to reaching local township limits on the use of this alternative, or with a need for methyl bromide for research purposes.
	(b) Members of the California Association of Nurserymen-Deciduous Fruit and Nut Tree Growers.	with a reasonable expectation that one or more of the following limiting critical conditions already either exists or could occur without methyl bromide fumigation: moderate to severe nematodes, medium to heavy clay soils, or a prohibition on the use of 1,3-dichloropropene products due to reaching local township limits on the use of this alternative, or with a need for methyl bromide for research purposes.
	(c) California rose nurseries	with a reasonable expectation that one or more of the following limiting critical conditions already either exists or could occur without methyl bromide fumigation: moderate to severe nematodes, or user may be prohibited from using 1,3-dichloropropene products because local township limits for this alternative have been reached, or with a need for methyl bromide for research purposes.
Strawberry Nurseries	(a) California growers	with a reasonable expectation that one or more of the following limiting critical conditions already either exists or could occur without methyl bromide fumigation: moderate to severe disease infestation, or moderate to severe yellow or purple nutsedge infestation, or moderate to severe nematodes; or with a need for methyl bromide for research purposes.
	(b) North Carolina, Tennessee and Maryland growers.	with a reasonable expectation that one or more of the following limiting critical conditions already either exists or could occur without methyl bromide fumigation: moderate to severe black root rot, or moderate to severe root-knot nematodes, or moderate to severe yellow and purple nutsedge infestation, and to a lesser extent: crown rot; or with a need for methyl bromide for research purposes.

Column A Approved critical uses	Column B Approved critical user and location of use	Column C Limiting critical conditions
Orchard Replant	(a) California stone fruit growers	with a reasonable expectation that one or more of the following limiting critical conditions already either exists or could occur without methyl bromide fumigation: moderate to severe nematodes, or moderate to severe fungal disease infestation, or replanted (non virgin) orchard soils to prevent orchard replant disease, or medium to heavy soils, or a prohibition on the use of 1,3-dichloropropene products because local township limits for this alternative have been reached; or with a need for methyl bromide for research purposes.
	(b) California table and raisin grape growers.	with a reasonable expectation that one or more of the following limiting critical conditions already either exists or could occur without methyl bromide fumigation: moderate to severe nematodes, or moderate to severe fungal disease infestation, or replanted (non-virgin) orchard soils to prevent orchard replant disease, or medium to heavy soils, or a prohibition on the use of 1,3-dichloropropene products because local township limits for this alternative have been reached; or with a need for methyl bromide for research purposes.
	(c) California walnut growers	with a reasonable expectation that one or more of the following limiting critical conditions already either exists or could occur without methyl bromide fumigation: moderate to severe nematodes, or replanted (non-virgin) orchard soils to prevent orchard replant disease, or medium to heavy soils, or a prohibition on the use of 1,3-dichloropropene products because local township limits for this alternative have been reached; or with a need for methyl bromide for research purposes.
	(d) California almond growers	with a reasonable expectation that one or more of the following limiting critical conditions already either exists or could occur without methyl bromide fumigation: moderate to severe nematodes, or replanted (non-virgin) orchard soils to prevent orchard replant disease, or medium to heavy soils, or a prohibition on the use of 1,3-dichloropropene products because local township limits for this alternative have been reached; or with a need for methyl bromide for research purposes.
Ornamentals	(a) California growers	with a reasonable expectation that one or more of the following limiting critical conditions already either exists or could occur without methyl bromide fumigation: moderate to severe disease infestation, or moderate to severe nematodes, or a prohibition on the use of 1,3-dichloropropene products because local township limits for this alternative have been reached; or with a need for methyl bromide for research purposes.
	(b) Florida growers	with a reasonable expectation that one or more of the following limiting critical conditions already either exists or could occur without methyl bromide fumigation: moderate to severe weed infestation, or moderate to severe disease infestation, or moderate to severe nematodes, or karst topography; or with a need for methyl bromide for research purposes.
Peppers	(a) California growers	with a reasonable expectation that one or more of the following limiting critical conditions already either exists or could occur without methyl bromide fumigation: moderate to severe disease infestation, or moderate to severe nematodes, or a prohibition on the use of 1,3-dichloropropene products because local township limits for this alternative have been reached; or with a need for methyl bromide for research purposes.
	(b) Alabama, Arkansas, Kentucky, Louisiana, North Carolina, South Carolina, Tennessee and Virginia growers.	with a reasonable expectation that one or more of the following limiting critical conditions already either exists or could occur without methyl bromide fumigation: moderate to severe yellow or purple nutsedge infestation, or moderate to severe nematodes, or moderate to severe pythium root, collar, crown and root rots, or the presence of an occupied structure within 100 feet of a grower's field the size of 100 acres or less; or with a need for methyl bromide for research purposes.
	(c) Florida growers	with a reasonable expectation that one or more of the following limiting critical conditions already either exists or could occur without methyl bromide fumigation: moderate to severe yellow or purple nutsedge infestation, or moderate to severe disease infestation, or moderate to severe nematodes, or karst topography; or with a need for methyl bromide for research purposes.

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	(d) Georgia growers	with a reasonable expectation that one or more of the following limiting critical conditions either already exist or could occur without methyl bromide fumigation: moderate to severe yellow or purple nutsedge infestation, or moderate to severe nematodes, or moderate to severe pythium root and collar rots, or moderate to severe southern blight infestation, and to a lesser extent: crown and root rot; or with a need for methyl bromide for research purposes.
	(e) Michigan growers	with a reasonable expectation that moderate to severe fungal disease infestation would occur without methyl bromide fumigation; or with a need for methyl bromide for research purposes.
Strawberry Fruit	(a) California growers	with a reasonable expectation that one or more of the following limiting critical conditions already either exists or could occur without methyl bromide fumigation: moderate to severe black root rot or crown rot, or moderate to severe yellow or purple nutsedge infestation, or moderate to severe nematodes, or a prohibition of the use of 1,3-dichloropropene products because local township limits for this alternative have been reached, time to transition to an alternative; or with a need for methyl bromide for research purposes.
	(b) Florida growers	with a reasonable expectation that one or more of the following limiting critical conditions already either exists or could occur without methyl bromide fumigation: moderate to severe yellow or purple nutsedge, or moderate to severe nematodes, or moderate to severe disease infestation, or karst topography and to a lesser extent: carolina geranium or cut-leaf evening primrose infestation; or with a need for methyl bromide for research purposes.
	(c) Alabama, Arkansas, Georgia, Illinois, Kentucky, Louisiana, Maryland, New Jersey, North Carolina, Ohio, South Carolina, Tennessee and Virginia growers.	with a reasonable expectation that one or more of the following limiting critical conditions already either exists or could occur without methyl bromide fumigation: moderate to severe yellow or purple nutsedge, or moderate to severe nematodes, or moderate to severe black root and crown rot, or the presence of an occupied structure within 100 feet of a grower's field the size of 100 acres or less; or with a need for methyl bromide for research purposes.
Tomatoes	(a) Michigan growers	with a reasonable expectation that one or more of the following limiting critical conditions already either exists or could occur without methyl bromide fumigation: moderate to severe disease infestation, or moderate to severe fungal pathogen infestation; or with a need for methyl bromide for research purposes.
	(b) Alabama, Arkansas, Florida, Georgia, Kentucky, Louisiana, North Carolina, South Carolina, and Tennessee.	with a reasonable expectation that one or more of the following limiting critical conditions already either exists or could occur without methyl growers bromide fumigation: moderate to severe yellow or purple nutsedge infestation, or moderate to severe disease infestation, or moderate to severe nematodes, or the presence of an occupied structure within 100 feet of a grower's field the size of 100 acres or less, or karst topography; or with a need for methyl bromide for research purposes.
	(c) California growers	with a reasonable expectation that one or more of the following limiting critical conditions already either exists or could occur without methyl bromide fumigation: moderate to severe disease infestation, or moderate to severe nematodes; or with a need for methyl bromide for research purposes.
Turfgrass	(a) U.S. turfgrass sod nursery producers who are members of Turfgrass Producers International (TPI).	for the production of industry certified pure sod; with a reasonable expectation that one or more of the following limiting critical conditions already either exists or could occur without methyl bromide fumigation: moderate to severe bermudagrass, nutsedge and off-type perennial grass infestation, or moderate to severe white grub infestation; or with a need for methyl bromide for research purposes.
Post-Harvest Uses:		
Food Processing	(a) Rice millers in all locations in the U.S. who are members of the USA Rice Millers' Association.	with a reasonable expectation that one or more of the following limiting critical conditions exists: moderate to severe infestation of beetles, weevils or moths, or older structures that can not be properly sealed to use an alternative to methyl bromide, or the presence of sensitive electronic equipment subject to corrosivity, time to transition to an alternative.
	(b) Pet food manufacturing facilities in the U.S. who are active members of the Pet Food Institute. (For this rule, "pet food" refers to domestic dog and cat food).	with a reasonable expectation that one or more of the following limiting critical conditions exists: moderate to severe infestation or beetles, moths, or cockroaches, or older structures that can not be properly sealed to use an alternative to methyl bromide, or the presence of sensitive electronic equipment subject to corrosivity, time to transition to an alternative.

Column A Approved critical uses	Column B Approved critical user and location of use	Column C Limiting critical conditions
	(c) Kraft Foods in the U.S	with a reasonable expectation that one or more of the following limiting critical conditions exists: older structures that can not be properly sealed to use an alternative to methyl bromide, or the presence of sensitive electronic equipment subject to corrosivity, time to transition to an alternative.
	(d) Members of the North American Millers' Association in the U.S.	with a reasonable expectation that one or more of the following limiting critical conditions already exists or could occur without methyl bromide fumigation: moderate to severe beetle infestation, or older structures that can not be properly sealed to use an alternative to methyl bromide, or the presence of sensitive electronic equipment subject to corrosivity, time to transition to an alternative.
	(e) Members of the National Pest Management Association treating cocoa beans in storage and associated spaces and equipment in processed food, cheese, dried milk, herbs and spices and spaces and equipment in associated processing facilities.	with a reasonable expectation that one or more of the following limiting critical conditions already exists or could occur without methyl brornide fumigation: moderate to severe pest infestation, or older structures that can not be properly sealed to use an alternative to methyl spaces and bromide, or the presence of sensitive equipment in electronic equipment subject to corrosivity, time to transition to an alternative.
Commodity Storage	(a) California entities storing walnuts, beans, dried plums, figs, raisins, dates and pistachios in California.	with a reasonable expectation that one or more of the following limiting critical conditions exists: rapid fumigation is required to meet a critical market window, such as during the holiday season, rapid fumigation is required when a buyer provides short (2 working days or less) notification for a purchase, or there is a short period after harvest in which to fumigate and there is limited silo availability for using alternatives; or with a need for methyl bromide for research purposes.
Dry Cured Pork Products	(a) Members of the National Country Ham Association.	with a reasonable expectation that one or more of the following limiting critical conditions already exists or could occur without methyl bromide fumigation: moderate to severe red legged ham beetle, cheese/ham skipper, dermestid beetle or ham mite infestation.
	(b) Members of the American Association of Meat Processors.	with a reasonable expectation that one or more of the following limiting critical conditions already exists or could occur without methyl bromide fumigation: moderate to severe red legged ham beetle, cheese/ham skipper, dermestid beetle or ham mite infestation.
	(c) Nahunta Pork Center (North Carolina).	with a reasonable expectation that one or more of the following limiting critical conditions already exists or could occur without methyl bromide fumigation: moderate to severe red legged ham beetle, cheese/ham skipper, dermestid beetle or ham mite infestation.

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Proposed Rules

Federal Register
Vol. 71, No. 24
Monday, February 6, 2006

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.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 319

[Docket No. APHIS–2006–0009]

Importation of Tomatoes From Certain Central American Countries

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the regulations governing the importation of fruits and vegetables in order to allow pink and red tomatoes grown in approved registered production sites in Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua, and Panama to be imported into the United States without treatment. The conditions to which the proposed importation of tomatoes would be subject, including trapping, pre-harvest inspection, and shipping procedures, are designed to prevent the introduction of quarantine pests into the United States. This action would allow for the importation of pink and red tomatoes from those countries in Central America while continuing to provide protection against the introduction of quarantine pests into the United States.

DATES: We will consider all comments that we receive on or before April 7, 2006.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and, in the "Search for Open Regulations" box, select "Animal and Plant Health Inspection Service" from the agency drop-down menu, then click on "Submit." In the Docket ID column, select APHIS–2006–0009 to submit or view public comments and to view supporting and related materials available electronically. After the close of the comment period, the docket can be viewed using the "Advanced Search" function in Regulations.gov.
- *Postal Mail/Commercial Delivery:* Please send four copies of your comment (an original and three copies) to Docket No. APHIS–2006–0009, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. APHIS–2006–0009.

Reading Room: You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue, SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

Other Information: Additional information about APHIS and its programs is available on the Internet at *http://www.aphis.usda.gov*.

FOR FURTHER INFORMATION CONTACT: Ms. Donna L. West, Senior Import Specialist, Commodity Import Analysis and Operations, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737–1231; (301) 734–8758.

SUPPLEMENTARY INFORMATION:

Background

The regulations in "Subpart—Fruits and Vegetables" (7 CFR 319.56 though 319.56–8, referred to below as the regulations) prohibit or restrict the importation of fruits and vegetables into the United States from certain parts of the world to prevent the introduction and dissemination of plant pests that are new to or not widely distributed within the United States.

Section 319.56–2dd of the regulations contains administrative instructions allowing the importation of tomatoes from various countries where the Mediterranean fruit fly (Medfly, *Ceratitis capitata*) is present. In this document, we are proposing to amend that section by adding a new paragraph (f) that would set forth administrative instructions concerning the importation of pink and red tomatoes from Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua, and Panama.

In a decision sheet [1] dated December 28, 1934, we authorized the importation of tomatoes from Central America and Mexico. However, in a subsequent set of decision sheets dated April 15, 1982, and January 27, 1983, we identified red tomatoes from Ecuador, Costa Rica, and Panama as an occasional Medfly host. Given the similar pest situations in the other Central American countries, we changed the conditions of the permits issued for Central American tomatoes to allow only green tomatoes to be imported, since they are not a Medfly host. Pink tomatoes were prohibited in order to reduce confusion between pink and red tomatoes during port-of-entry inspections.

The Government of El Salvador has requested the reauthorization of the importation of pink and red tomatoes from that country. In response, the Animal and Plant Health Inspection Service (APHIS) developed a systems approach, described below, under which tomatoes could be imported into the United States without treatment. We have determined that the systems approach could also be used by producers throughout Costa Rica, Guatemala, Honduras, Nicaragua, and Panama because of the similar pest risks present in these countries. Therefore, we are proposing to allow tomatoes to be imported into the United States from those six Central American countries under conditions very similar to current requirements for importing tomatoes from France, Morocco and Western Sahara, and Spain. Currently, tomatoes are being shipped from over 200 greenhouses in Europe using this systems approach. Since the start of the tomato systems approach in France and Spain, the number of pest interceptions has been very low, with an approximate shipment infestation rate of 0.005 percent in Spain and 0.06 percent in France.

We have prepared a document in which we examine the risks of importing tomatoes from the six Central America countries that was based on an examination of relevant information (e.g., pest risk assessments, decisions

[1] Before we routinely prepared pest risk assessments according to the guidelines provided by the Food and Agriculture Organization and the North American Plant Protection Organization we prepared decision sheets. Decision sheets contain relatively the same information that is contained in modern pest risk assessments, but without the standardized format.

sheets, pest interception data, etc.) regarding this commodity. The document may be viewed on the Regulations.gov Web site (see **ADDRESSES** above for instructions for accessing Regulations.gov) or on the APHIS Web site at *http://www.aphis.usda.gov/ppq/pra/draft/*. The quarantine pests of concern in Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua, and Panama, as identified in the document prepared for this proposed rule, are Medfly, the tomato fruit borer (*Neoleucinodes elegantalis*), the pea leafminer (*Liriomyza huidobrensis*), and the potato spindle tuber viroid.

With the exception of Medfly, for which we have developed the specific systems approach described below as mitigation, the pests of concern (tomato fruit borer, the pea leafminer, and the potato spindle tuber viroid) exhibit symptoms that are macroscopic and detectable upon visual inspection in the production areas or during pre-export or port-of-entry inspections. Specifically:

- Tomato fruit borer larvae penetrate the fruit and may cause the fruit to fall or become otherwise unmarketable. More mature larvae create large exit holes in the fruit that can be easily detected. In addition, the screen size required by the systems approach described below is too small to allow the entry of adult tomato fruit borers.
- Pea leafminers spend a majority of their lifecycle in larval form, mining host leaves. These mines are easily detectable via visual inspection.
- Potato spindle tuber viroid is primarily a pest of potatoes, but may also affect tomatoes. Symptoms of the viroid, except for mild strains, would be readily detected with the naked eye. Recent data on the potato spindle tuber viroid indicate there has only been one interception of the viroid from one country in Central America, Costa Rica. The interception was on potatoes, not tomatoes, and was easily detected by inspectors. This evidence suggests that it is unlikely that the potato spindle tuber viroid will be found on tomatoes from Central America, and we believe that inspections throughout the growing season will provide sufficient mitigation.

Thus, we would utilize inspection as the primary mitigation measure for tomato fruit borer, pea leafminer, and potato spindle tuber viroid, and the specific systems approach described in this document would serve to mitigate the risks associated with Medfly. The systems approach, outlined below, utilizes pest exclusionary greenhouses and packinghouses. As stated previously, we believe this approach could be used by producers throughout Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua, and Panama, given the similar pest risks present in these countries. We are confident that these measures would effectively mitigate the risk posed by Medfly while production site, pre-export, and port-of-entry inspections would continue to provide mitigation for any additional pests. Green tomatoes could continue to be imported as before, but the systems approach would provide importers with alternative sources of tomatoes at a more advanced stage of ripeness. In addition, we would also allow the importation of pink or red field-grown tomatoes from areas certified free of Medfly. The proposed conditions for the importation of greenhouse-grown and field-grown tomatoes are explained in the following paragraphs.

Areas Where Medfly Is Present

Tomatoes grown in an area that has not been determined to be free of Medfly would be required to be grown in approved production sites registered with the national plant protection organization (NPPO) of the exporting country and would be subject to the systems approach detailed below. Initial approval of the production sites would be completed jointly by the exporting country's NPPO and APHIS. Representatives of the exporting country's NPPO would have to visit and inspect the production sites monthly, starting 2 months before harvest and continuing through until the end of the shipping season. APHIS could monitor the production sites at any time during this period.

Tomato production sites would have to consist of pest exclusionary greenhouses with self-closing double doors. All additional openings would be required to be covered with 1.6 (or less) millimeter screening. Registered sites would have to contain traps with an approved protein bait for the detection of Medfly within the greenhouses at a density of four traps per hectare, with a minimum of at least two traps per greenhouse. Traps would have to be serviced on a weekly basis. Medfly traps with an approved protein bait would also have to be placed inside a buffer area 500 meters wide around the registered production site, at a density of 1 trap per 10 hectares. These traps would have to be checked at least once every 7 days. At least one trap would have to be near the greenhouse. Traps would have to be set for at least 2 months prior to export, and trapping would have to continue to the end of harvest. Capture of 0.7 or more Medflies per trap per week within the buffer zone would suspend or delay the harvest, depending on whether the harvest had begun, for consignments of tomatoes from that production site until APHIS and the exporting country's NPPO determine that the pest risk has been mitigated.

If a single Medfly is detected inside a registered production site or in a consignment, the registered production site would lose its ability to export tomatoes to the United States until APHIS and the exporting country's NPPO mutually determine that risk mitigation has been achieved. For the other pests of concern listed above, the greenhouse would have to be inspected prior to harvest, and if any of these pests or any other quarantine pests is found to be generally infesting the greenhouse, the NPPO would not allow export from that production site until APHIS and the NPPO agree that risk mitigation has been achieved. If the NPPO detected any quarantine pests in the consignment, the shipment would be deemed ineligible for export to the United States.

The exporting country's NPPO would have to maintain records of trap placement, checking of traps, and any Medfly captures, as well as production site and packinghouse inspection results. In addition, the exporting country's NPPO would have to maintain an APHIS-approved quality control program to monitor or audit the trapping program. The trapping records would have to be maintained for APHIS's review.

We would require that tomatoes be packed within 24 hours of harvest in a pest-exclusionary packinghouse. The tomatoes would have to be safeguarded by an insect-proof mesh screen or plastic tarpaulin while in transit from the production site to the packinghouse and while awaiting packing. The tomatoes would have to be packed in insect-proof cartons or containers, or covered with insect-proof mesh or plastic tarpaulin, for transit into the United States. These safeguards would have to remain intact until arrival in the United States or the shipment would not be allowed to enter the United States.

During the time the packinghouse is in use for exporting fruit to the United States, the packinghouse could accept fruit only from registered approved production sites.

The exporting country's NPPO would be responsible for export certification, inspection, and issuance of phytosanitary certificates. Each shipment of tomatoes would have to be accompanied by a phytosanitary certificate issued by the NPPO and bearing the declaration, "These

tomatoes were grown in an approved production site and the shipment has been inspected and found free of the pests listed in the requirements." The shipping box would have to be labeled with the identity of the production site.

Medfly-Free Areas

We would allow tomatoes grown in a Medfly-free area to be imported under conditions less stringent than those described above for tomatoes grown in areas where Medfly is present. The tomatoes would have to be grown and packed in an area that APHIS has determined to be free of Medfly in accordance with the procedures described in § 319.56–2(f); currently, the Department of Peten in Guatemala is the only Medfly-free area in the Central American countries covered by this proposed rule.

For the tomato fruit borer, pea leafminer, and potato spindle tuber viroid, the production site would have to be inspected prior to harvest and if any of these pests or any other quarantine pests are found to be generally infesting the production site, the NPPO would not allow export from that production site until APHIS and the NPPO agree that risk mitigation has been achieved. If the NPPO detects any quarantine pests in the consignment, the shipment would be deemed ineligible for export to the United States.

We would require that the tomatoes be packed in insect-proof cartons or containers, or covered with insect-proof mesh or plastic tarpaulin, for transit into the United States. These safeguards would have to remain intact until arrival in the United States or the shipment would not be allowed to enter the United States. These measures would be necessary since, although the production area is Medfly-free, the tomatoes would need to be protected against infestation while in transit.

The exporting country's NPPO would be responsible for export certification, inspection, and issuance of phytosanitary certificates. Each shipment of tomatoes would have to be accompanied by a phytosanitary certificate issued by the NPPO and bearing the declaration, "These tomatoes were grown in an area recognized to be free of Medfly and the shipment has been inspected and found free of the pests listed in the requirements." The shipping box would have to be labeled with the identity of the production site.

Executive Order 12866 and Regulatory Flexibility Act

This proposed rule has been reviewed under Executive Order 12866. The rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

The Regulatory Flexibility Act (RFA) requires that agencies consider the economic impact of their rules on small businesses, organizations, and governmental jurisdictions. In accordance with section 603 of the RFA, we have prepared an initial regulatory flexibility analysis describing the expected impact of the changes proposed in this document on small entities.

Under the Plant Protection Act (7 U.S.C. 7701 *et seq.*), the Secretary of Agriculture is authorized to regulate the importation of plants, plant products, and other articles to prevent the introduction of plant pests and noxious weeds.

We are proposing to amend the regulations governing the importation of fruits and vegetables in order to allow pink and red tomatoes grown in approved registered production sites in Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua, and Panama to be imported into the United States without treatment. The conditions to which the proposed importation of tomatoes would be subject, including trapping, pre-harvest inspection, and shipping procedures, are designed to prevent the introduction of quarantine pests into the United States. This action would allow for the importation of pink and red tomatoes from those countries in Central America while continuing to provide protection against the introduction of quarantine pests into the United States.

Central American Production and Exports

While agriculture is an important industry in the countries that would be affected by this rule, it does not account for the largest share of gross domestic product in any of the countries. Tomatoes do not appear to be major crops in those Central American countries. However, production and exports of tomatoes are following upward trends.

Tomato production in Central America has been steadily increasing since the early 1960s. Over this period, production has increased almost 300 percent. In conjunction with this increase in production, exports of tomatoes from the region have also increased. Exports in 2003 were 42 times the exports in 1962. Between 1980 and 2003, exports increased by 45 percent. From 1962 to 2003, exports of tomatoes to countries within Central America accounted for 96 percent of total exports. In more recent times, specifically the period between 1980 and 2003, this percentage has increased by 99 percent. Thus, the vast majority of the tomatoes exported from any Central American country are destined for another country within the same region.

U.S. Import Levels

U.S. imports of Central American tomatoes have fluctuated greatly over the last 15 years.[2] In fact, 2003 was the end of a 10-year period during which the United States did not import tomatoes from any Central American country. U.S. imports of fresh tomatoes principally originate in Mexico, Canada, and the Netherlands, with Mexico being by far the largest supplier.

Although this proposed rule would allow for more liberal importation of tomatoes from certain Central American countries, it is unlikely that the proposed changes would lead to dramatic increases in U.S. import levels from this region.

Effects on Small Entities

This proposed rule would affect domestic producers of tomatoes as well as importers that deal with these commodities. It is likely that the entities affected would be small according to Small Business Administration (SBA) guidelines. As detailed below, information available to APHIS indicates that the effects on these small entities would not be significant.

Two alternatives to the proposed course of action are as follows: Maintaining the status quo with respect to the importation of tomatoes from these Central American countries (i.e., green tomatoes only) or allowing importation without establishing the proposed risk mitigations.

The first alternative would maintain current safeguards against the entry of quarantine pests. However, this option would also mean that those specified Central American countries as well as the United States would forgo the economic benefits expected to be afforded by the proposed trade.

Allowing the importation of fresh tomatoes from certain Central American countries under phytosanitary requirements less restrictive than are proposed could potentially lead to the introduction of pests not currently found in the United States. This option could result in significant damage and costs to domestic production and is not desirable for those reasons.

[2] It is important to note here that this discussion refers to imports of all varieties of tomatoes. Disaggregated data were not available for this analysis.

Affected U.S. tomato producers are expected to be small based on the 2002 Census of Agriculture data and SBA guidelines for entities in two farm categories: Other Vegetable (except Potato) and Melon Farming (North American Industry Classification System [NAICS] code 111219) and Other Food Crops Grown Under Cover (NAICS code 111419). The SBA classifies producers in these farm categories as small entities if their total annual sales are $750,000 or less. APHIS does not have information on the size distribution of domestic tomato producers, but according to 2002 Census data, there were a total of 2,128,892 farms in the United States.[3] Of this number, approximately 97 percent had total annual sales of less than $500,000 in 2002, which is well below the SBA's small entity threshold for commodity farms.[4] This indicates that the majority of farms are considered small by SBA standards, and it is reasonable to assume that most of the 19,539 tomato farms that could be affected by the proposed rule would also qualify as small. In the case of fruit and vegetable wholesalers (NAICS code 422480),[5] those entities with fewer than 100 employees are considered small by SBA standards.[6] In 1997, there were a total of 4,811 fruit and vegetable wholesale trade farms in the United States.[7] Of these farms, 4,610 or 95.8 percent employed fewer than 100 employees and were considered small by SBA standards. Between 1997 and 2002, there is not likely to have been substantial changes in the industry. Therefore, domestic producers and importers that may be affected by this proposed rule are predominantly small entities.

Economic analysis of the expected increase in imports of tomatoes from Central America shows that the proposed importation of this commodity would lead to negligible changes in domestic prices. APHIS estimates that an additional 13,092 metric tons of tomatoes may be imported from Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua, and Panama on a yearly basis. Using historical consumption data to estimate an elasticity of demand for tomatoes, an increase in imports of this size would result in a price decrease of $0.50 per hundredweight (cwt) overall.

TABLE 1.—U.S. SUPPLY, UTILIZATION, AND FARM WEIGHT PRICE OF FRESH TOMATOES, 2000–2005

Year	Supply			Utilization			Season-average price	
	Production	Imports	Total	Exports	Domestic	Per capita use	Current dollars	Constant 2000 dollars
	(Million pounds)					(Pounds)	($/cwt)	
2000	4,162.0	1,609.5	5,771.5	410.4	5,361.2	19.0	$30.70	$30.70
2001	4,061.1	1,815.6	5,876.7	398.2	5,478.5	19.2	30.00	29.30
2002	4,289.3	1,896.2	6,185.5	332.1	5,853.4	20.3	31.60	30.36
2003	3,909.8	2,070.7	5,980.5	314.1	5,666.4	19.5	36.70	34.62
2004	3,975.7	2,054.6	6,030.3	367.5	5,662.8	19.3	36.70	33.92
2005[f]	4,086.0	2,000.0	6,086.0	360.0	5,726.0	19.4	—	—

Notes: —= not available, f = ERS forecast.
Source: USDA/ERS, "Vegetables and Melons Yearbook," *http://usda.mannlib.cornell.edu/data-sets/specialty/89011/.*

For this analysis, it is assumed that imports of tomatoes from Central America would compete with all fresh tomatoes produced domestically. In 2004, U.S. fresh tomato production totaled 3,976 million pounds (table 1). APHIS estimates that an additional 13,092 metric tons (28.7 million pounds) of tomatoes would be imported from Central America. These imports would account for only 0.7 percent of domestic production in 2004 and 1.4 percent of 2004 imports. Given the additional imports, it is possible that the domestic price would fall by as much as $0.50 per cwt. In 2004, the average producer price was $36.70 per cwt. Thus, the expected price decline would represent a 1.4 percent decline. However, this percentage is likely overstated because the new imports would be close substitutes for tomatoes from other countries. Imports from Central America would probably displace at least some of those imports from other countries. This likely substitution is not taken into account in the analysis.

In order to put this price change into perspective, we consider it in terms of average revenue for small-entity tomato producers. Due to the lack of data on tomato farming, it is difficult to determine an accurate potential change in revenues for all producers. Averaging the total drop in revenues across all firms would overstate the loss to small producers while understating that for the larger ones. Data from the 2002 Census of Agriculture were used to estimate tomato production by small and large firms. This, in turn, was used to estimate revenues for these two categories. An average revenue per firm was then calculated. We conclude that any producer with fewer than 80 acres of tomatoes may be considered small, based on industry yields and revenues and the small-entity definition of not more than $750,000 in annual revenue. For small-entity producers with fewer than 100 acres (the reported category closest to 80 acres), a price change of $0.50 per cwt would lead to an estimated per firm decline in annual revenue of $293, or 1.6 percent. Given this small change and recalling that these effects are likely overstated, domestic producers are not likely to be significantly impacted by the proposed rule.

Although domestic producers may face slightly lower prices as a result of the potential increase in the tomato supply, these price changes are expected to be negligible. APHIS welcomes public comment on these preliminary estimates. Domestic import firms, on the other hand, may actually

[3] This number represents the total number of farms in the United States, thus including barley, buckwheat, corn, millet, oats, rice, soybean, and sugarcane farms.

[4] Source: SBA and 2002 Census of Agriculture.

[5] Note that this NAICS code relates to the 1997 Economic Census. The 2002 NAICS code for this group is 424480.

[6] For NAICS 424480, SBA guidelines state that an entity with not more than 100 employees should be considered small unless that entity is a Government contractor. In this case, the size standard increases to 500 employees. However, in this instance, it is fair to assume that fruit and vegetable importers will not be under Government contract since it is against regulations for imports to be used in relevant Government programs (*e.g.* school lunch programs).

[7] Source: SBA and 1997 Economic Census.

benefit from more open trade with Central America resulting from increased opportunities that could be made available as a result of establishing new sources of tomatoes at a more advanced stage of ripeness. In both instances, changes of the magnitude presented here should not have large repercussions for either domestic producers or importers of tomatoes.

This proposed rule contains information collection or recordkeeping requirements (see "Paperwork Reduction Act" below).

Executive Order 12988

This proposed rule would allow pink and red tomatoes grown in approved registered production sites in Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua, and Panama to be imported into the United States. If this proposed rule is adopted, State and local laws and regulations regarding tomatoes imported under this rule would be preempted while the fruit is in foreign commerce. Fresh fruits and vegetables are generally imported for immediate distribution and sale to the consuming public and would remain in foreign commerce until sold to the ultimate consumer. The question of when foreign commerce ceases in other cases must be addressed on a case-by-case basis. If this proposed rule is adopted, no retroactive effect will be given to this rule, and this rule will not require administrative proceedings before parties may file suit in court challenging this rule.

National Environmental Policy Act

To provide the public with documentation of APHIS' review and analysis of the potential environmental impacts associated with the importation of tomatoes from Central America, we have prepared an environmental assessment. The environmental assessment, entitled "Proposed Rule for the Importation of Tomatoes from Central America," was prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

The environmental assessment may be viewed on the Regulations.gov Web site or in our reading room (see **ADDRESSES** above for instructions for accessing Regulations.gov and information on the location and hours of the reading room). You may request paper copies of the environmental assessment by calling or writing to the person listed under **FOR FURTHER INFORMATION CONTACT.** Please refer to the title of the environmental assessment when requesting copies.

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB). Please send written comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for APHIS, Washington, DC 20503. Please state that your comments refer to Docket No. APHIS–2006–0009. Please send a copy of your comments to: (1) Docket No. APHIS–2006–0009, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238, and (2) Clearance Officer, OCIO, USDA, room 404–W, 14th Street and Independence Avenue, SW., Washington, DC 20250. A comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication of this proposed rule.

In this document, we are proposing to allow certain types of tomatoes grown in approved registered production sites in Costa Rica, El Salvador, Guatemala, Honduras, and Nicaragua to be imported into the United States without treatment, under certain conditions. Those conditions include trapping, pre-harvest inspection, and shipping procedures designed to prevent the introduction of quarantine pests into the United States. These precautions, along with other requirements, would allow for the importation of tomatoes from those countries in Central America while continuing to provide protection against the introduction of quarantine pests into the United States.

Allowing tomatoes to be imported would necessitate the use of certain information collection activities, including the completion of pre-harvest inspections, phytosanitary certificates, and fruit fly monitoring records.

We are soliciting comments from the public (as well as affected agencies) concerning our proposed information collection and recordkeeping requirements. These comments will help us:

(1) Evaluate whether the proposed information collection is necessary for the proper performance of our agency's functions, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the information collection on those who are to respond (such as through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology; e.g., permitting electronic submission of responses).

Estimate of burden: Public reporting burden for this collection of information is estimated to average 0.0061148 hours per response.

Respondents: National plant protection organizations and growers.

Estimated annual number of respondents: 172.

Estimated annual number of responses per respondent: 26,081.

Estimated annual number of responses: 4,485,992.

Estimated total annual burden on respondents: 27,431 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

Copies of this information collection can be obtained from Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 734–7477.

Government Paperwork Elimination Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the Government Paperwork Elimination Act (GPEA), which requires Government agencies in general to provide the public the option of submitting information or transacting business electronically to the maximum extent possible. For information pertinent to GPEA compliance related to this proposed rule, please contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 734–7477.

List of Subjects in 7 CFR Part 319

Coffee, Cotton, Fruits, Imports, Logs, Nursery stock, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Rice, Vegetables.

Accordingly, we propose to amend 7 CFR part 319 as follows:

PART 319—FOREIGN QUARANTINE NOTICES

1. The authority citation for part 319 would continue to read as follows:

Authority: 7 U.S.C. 450, 7701–7772, and 7781–7786; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.

2. Section 319.56–2dd would be amended by adding a new paragraph (f) to read as follows:

§ 319.56–2dd Administrative instructions: conditions governing the entry of tomatoes.

* * * * *

(f) *Tomatoes (fruit) (Lycopersicon esculentum) from certain countries in Central America.* Pink or red tomatoes may be imported into the United States from Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua, and Panama only under the following conditions:

(1) From areas free of Mediterranean fruit fly:

(i) The tomatoes must be grown and packed in an area that has been determined by APHIS to be free of Mediterranean fruit fly (Medfly) in accordance with the procedures described in § 319.56–2(f) of this subpart.

(ii) A pre-harvest inspection of the production site must be conducted by the national plant protection organization (NPPO) of the exporting country for pea leafminer, tomato fruit borer, and potato spindle tuber viroid. If any of these pests are found to be generally infesting the production site, the NPPO may not allow export from that production site until the NPPO and APHIS have determined that risk mitigation has been achieved.

(iii) The tomatoes must be packed in insect-proof cartons or containers or covered with insect-proof mesh or plastic tarpaulin at the packinghouse for transit to the United States. These safeguards must remain intact until arrival in the United States.

(iv) The exporting country's NPPO is responsible for export certification, inspection, and issuance of phytosanitary certificates. Each shipment of tomatoes must be accompanied by a phytosanitary certificate issued by the NPPO and bearing the declaration, "These tomatoes were grown in an area recognized to be free of Medfly and the shipment has been inspected and found free of the pests listed in the requirements."

(2) From areas where Medfly is considered to exist:

(i) The tomatoes must be grown in approved registered production sites. Initial approval of the production sites will be completed jointly by the exporting country's NPPO and APHIS. The exporting country's NPPO must visit and inspect the production sites monthly starting 2 months before harvest and continuing through until the end of the shipping season. APHIS may monitor the production sites at any time during this period.

(ii) Tomato production sites must consist of pest-exclusionary greenhouses, which must have self-closing double doors and have all other openings and vents covered with 1.6 (or less) mm screening.

(iii) Registered sites must contain traps for the detection of Medfly both within and around the production site as follows:

(A) Traps with an approved protein bait for Medfly must be placed inside the greenhouses at a density of four traps per hectare, with a minimum of two traps per greenhouse. Traps must be serviced on a weekly basis.

(B) If a single Medfly is detected inside a registered production site or in a consignment, the registered production site will lose its ability to export tomatoes to the United States until APHIS and the exporting country's NPPO mutually determine that risk mitigation is achieved.

(C) Medfly traps with an approved protein bait must be placed inside a buffer area 500 meters wide around the registered production site, at a density of 1 trap per 10 hectares and a minimum of 10 traps. These traps must be checked at least every 7 days. At least one of these traps must be near the greenhouse. Traps must be set for at least 2 months before export and trapping must continue to the end of the harvest.

(D) Capture of 0.7 or more Medflies per trap per week will delay or suspend the harvest, depending on whether harvest has begun, for consignments of tomatoes from that production site until APHIS and the exporting country's NPPO can agree that the pest risk has been mitigated.

(E) The greenhouse must be inspected prior to harvest for pea leafminer, tomato fruit borer, and potato spindle tuber viroid. If any of these pests, or other quarantine pests, are found to be generally infesting the greenhouse, exports from that production site will be halted until the exporting country's NPPO and APHIS determine that the pest risk has been mitigated.

(iv) The exporting country's NPPO must maintain records of trap placement, checking of traps, and any Medfly captures in addition to production site and packinghouse inspection records. The exporting country's NPPO must maintain an APHIS-approved quality control program to monitor or audit the trapping program. The trapping records must be maintained for APHIS's review.

(v) The tomatoes must be packed within 24 hours of harvest in a pest-exclusionary packinghouse. The tomatoes must be safeguarded by an insect-proof mesh screen or plastic tarpaulin while in transit to the packinghouse and while awaiting packing. The tomatoes must be packed in insect-proof cartons or containers, or covered with insect-proof mesh or plastic tarpaulin, for transit into the United States. These safeguards must remain intact until arrival in the United States or the consignment will be denied entry into the United States.

(vi) During the time the packinghouse is in use for exporting tomatoes to the United States, the packinghouse may only accept tomatoes from registered approved production sites.

(vii) The exporting country's NPPO is responsible for export certification, inspection, and issuance of phytosanitary certificates. Each shipment of tomatoes must be accompanied by a phytosanitary certificate issued by the NPPO and bearing the declaration, "These tomatoes were grown in an approved production site and the shipment has been inspected and found free of the pests listed in the requirements." The shipping box must be labeled with the identity of the production site.

Done in Washington, DC, this 31st day of January 2006.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E6–1553 Filed 2–3–06; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Federal Crop Insurance Corporation

7 CFR Part 457

RIN 0563–AC03

Common Crop Insurance Regulations; Mint Crop Insurance Provisions

AGENCY: Federal Crop Insurance Corporation, USDA.

ACTION: Proposed rule with request for comments.

SUMMARY: The Federal Crop Insurance Corporation (FCIC) proposes to add to 7 CFR part 457 a new § 457.169 that provides insurance for mint. The provisions will be used in conjunction with the Common Crop Insurance Policy Basic Provisions, which contain standard terms and conditions common to most crops. The intended effect of this action is to convert the mint pilot crop insurance program to a permanent

insurance program for the 2007 and succeeding crop years.

DATES: Written comments and opinions on this proposed rule will be accepted until close of business April 7, 2006, and will be considered when the rule is to be made final. Comments on information collection under the Paperwork Reduction of 1995 must be received on or before April 7, 2006.

ADDRESSES: Interested persons are invited to submit written comments to the Director, Product Development Division, Risk Management Agency, United States Department of Agriculture, 6501 Beacon Drive, Stop 0812, Room 421, Kansas City, MO 64133–4676. Comments titled "Mint Crop Insurance Provisions" may be sent via the Internet to *DirectorPDD@rma.fcic.usda.gov,* or the Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the online instructions for submitting comments. A copy of each response will be available for public inspection and copying from 7 a.m. to 4:30 p.m., c.s.t., Monday through Friday, except holidays, at the above address.

FOR FURTHER INFORMATION CONTACT: Linda Williams, Risk Management Specialist, Research and Development, Product Development Division, Risk Management Agency, at the Kansas City, MO address listed above, telephone (816) 926–7730.

SUPPLEMENTARY INFORMATION:

Executive Order 12866

The Office of Management and Budget (OMB) has determined that this rule is not significant for the purpose of Executive Order 12866 and, therefore, it has not been reviewed by OMB.

Paperwork Reduction Act of 1995

Pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the collections of information in this rule have been approved by the OMB under control number 0563–0057 through June 30, 2006.

Government Paperwork Elimination Act (GPEA) Compliance

FCIC is committed to compliance with the GPEA, which requires Government agencies, in general, to provide the public with the option of submitting information or transacting business electronically to the maximum extent possible. FCIC requires that all reinsured companies be in compliance with the Freedom to E-File Act and section 508 of the Rehabilitation Act.

Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. This rule contains no Federal mandates (under the regulatory provisions of title II of the UMRA) for State, local, and tribal governments or the private sector. Therefore, this rule is not subject to the requirements of sections 202 and 205 of the UMRA.

Executive Order 13132

It has been determined under section 1(a) of Executive Order 13132, Federalism, that this rule does not have sufficient implications to warrant consultation with the States. The provisions contained in this rule will not have a substantial direct effect on States, or on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

Regulatory Flexibility Act

FCIC certifies that this regulation will not have a significant economic impact on a substantial number of small entities. Program requirements for the Federal crop insurance program are the same for all producers regardless of the size of their farming operation. For instance, all producers are required to submit an application and acreage report to establish their insurance guarantees, and compute premium amounts, and all producers are required to submit a notice of loss and production information to determine the amount of an indemnity payment in the event of an insured cause of crop loss. Whether a producer has 10 acres or 1000 acres, there is no difference in the kind of information collected. To ensure crop insurance is available to small entities, the Federal Crop Insurance Act authorizes FCIC to waive collection of administrative fees from limited resource farmers. FCIC believes this waiver helps to ensure small entities are given the same opportunities to manage their risks through the use of crop insurance. A Regulatory Flexibility Analysis has not been prepared since this regulation does not have an impact on small entities, and, therefore, this regulation is exempt from the provisions of the Regulatory Flexibility Act (5 U.S.C. 605).

Federal Assistance Program

This program is listed in the Catalog of Federal Domestic Assistance under No. 10.450.

Executive Order 12372

This program is not subject to the provisions of Executive Order 12372, which require intergovernmental consultation with State and local officials. *See* the notice related to 7 CFR part 3015, subpart V, published at 48 FR 29115, June 24, 1983.

Executive Order 12988

This proposed rule has been reviewed in accordance with Executive Order 12988 on civil justice reform. The provisions of this rule will not have a retroactive effect. The provisions of this rule will preempt State and local laws to the extent such State and local laws are inconsistent herewith. With respect to any direct action taken by FCIC or to require the insurance provider to take specific action under the terms of the crop insurance policy, the administrative appeal provisions published at 7 CFR part 11 and 7 CFR part 400, subpart J, for the informal administrative review process of good farming practices, as applicable, must be exhausted before any action against FCIC for judicial review may be brought.

Environmental Evaluation

This action is not expected to have a significant impact on the quality of the human environment, health, and safety. Therefore, neither an Environmental Assessment nor an Environmental Impact Statement is needed.

Background

FCIC offered a pilot crop insurance program for mint beginning with the 2000 crop year in the states of Indiana, Montana, Washington, and Wisconsin. Mint crop insurance is an actual production history (APH) crop that protects against a loss in yield. However, coverage is provided for the oil that is extracted from the mint plant. If the amount of mint oil produced in the crop year is less than the production guarantee, the producer will receive an indemnity if all other policy provisions have been complied with.

The production guarantee is determined the same as all other APH crops in that the producer certifies to the number of pounds of mint oil produced per acre for at least the previous four crops years building to a base of ten crop years. The covered causes of loss are the same as for other APH crops and include such causes as adverse weather, fire, wildlife, failure of the irrigation water supply, etc.

Prevented planting coverage was not provided under the policy and, as with all pilot programs, written agreements were not available.

In the 2004 crop year, 81 producers with approximately 13,143 acres were insured under the pilot mint program. FCIC contracted with an independent firm to conduct an evaluation of the mint pilot program. The evaluation found the mint crop insurance program to be valuable risk management tool for mint producers. In fact, financial institutions were more willing to approve operating loans for those producers who purchased crop insurance. While the evaluation identified the availability of a mint crop insurance program did not have an adverse effect on the mint market, two changes in the Crop Provisions were recommended. The contractor's report identified that a benefit for mint producers in the Midwest would be to offer coverage for two separate spearmint types (native and scotch spearmint) as is available in Washington State. In addition, the evaluation identified the potential of moral hazard in allowing producers to self-certify the adequacy of their mint crop stand without having insurance providers inspect the mint acreage to verify the crop met all insurability requirements after an indemnity had been paid the previous crop year. FCIC's Board of Directors concurred with the evaluation results and approved the conversion of the pilot status to that of a permanent crop insurance program.

FCIC has revised certain provisions to be consistent with other Crop Provisions. In section 1, FCIC has also added a definition of "stolon" because the term was previously used but not defined. In section 2, FCIC has revised the language to clarify that the basic units will be divided into additional basic units by mint type. In section 6(a), provisions have been added that clarify the inspection and acceptance requirements in the crop year following an indemnified loss. FCIC has revised section 6(b) to clarify that the Winter Coverage Option must be executed before the sales closing date designated in the Special Provisions because now that the program can be expanded to additional states and counties, the sales closing dates may be different.

Section 8 has been revised to specify that the date coverage begins and ends for states other than Indiana, Montana, Washington, or Wisconsin will be provided in the Special Provisions because this is a new expanding program and until the states and counties are added, FCIC does not know what the appropriate date coverage should be. Provisions have also been added clarifying when inspection will occur for the year of application and that coverage will not attach if the insurability requirements have not been met. The provision also requires the producer to provide any information required for the crop or to determine the condition of the crop.

FCIC has also removed the prohibition against written agreements because the program is no longer considered a pilot program. Written agreements are prohibited for pilot programs because of the need to test the concept without the possibility of additional changes that could skew the results. Now written agreements will be authorized as specified in the Basic Provisions and the Mint Crop Provisions.

With respect to the Winter Coverage Option, FCIC has revised certain language for readability. Further, FCIC has added a provision that specifies that acreage on which a Winter Coverage Option payment has been made will receive zero production for the purposes of determining the subsequent year's approved yield.

FCIC intends to convert the mint pilot crop insurance program to a permanent crop insurance program beginning with the 2007 crop year. Mint insurance would then be available in any state in county in which mint was included in the actuarial documents. To effectuate this, FCIC proposes to amend the Common Crop Insurance regulations (7 CFR part 457) by adding a new section § 457.169, Mint Crop Insurance Provisions. These provisions will replace and supersede the current unpublished provisions that insure mint under a pilot program status.

List of Subjects in 7 CFR Part 457

Crop insurance, Mint, Reporting and recordkeeping requirements.

Proposed Rule

Accordingly, as set forth in the preamble, the Federal Crop Insurance Corporation proposes to amend 7 CFR part 457, Common Crop Insurance Regulations, for the 2007 and succeeding crop years as follows:

PART 457—COMMON CROP INSURANCE REGULATIONS

1. The authority citation for 7 CFR part 457 continues to read as follows:

Authority: 7 U.S.C. 1506(l), 1506(p).

2. Section 457.169 is added to read as follows:

§ 457.169 Mint crop insurance provisions.

The Mint Crop Insurance Provisions for the 2007 and succeeding crop years are as follows:

FCIC policies:

United States Department of Agriculture

Federal Crop Insurance Corporation

Reinsured policies:

(Appropriate Title for Insurance Provider)

Both FCIC and reinsured policies:

Mint Crop Insurance Provisions

1. Definitions.

Adequate Stand. A population of live mint plants that equals or exceeds the minimum required number of plants or percentage of ground cover, as specified in the Special Provisions.

Appraisal. A method of determining potential production by harvesting and distilling a representative sample of the mint crop.

Cover crop. A small grain crop seeded into mint acreage to reduce soil erosion and wind damage.

Cutting. Severance of the upper part of the mint plant from its stalk and roots.

Distillation. A process of extracting mint oil from harvested mint plants by heating and condensing.

Existing mint. Mint planted for harvest during a previous crop year.

Ground cover. Mint plants, including mint foliage and stolons, grown on insured acreage.

Harvest. Removal of mint from the windrow.

Mint. A perennial spearmint or peppermint plant of the family Labiatae and the genus *Mentha* grown for distillation of mint oil.

Mint oil. Oil produced by the distillation of harvested mint plants.

New mint. Mint planted for harvest for the first time.

Planted acreage. In addition to the definition in the Basic Provisions, land in which mint stolons have been placed in a manner appropriate for the planting method and at the correct depth into a seedbed that has been properly prepared.

Pound. 16 ounces avoirdupois.

Stolon. A stem at or just below the surface of the ground that produces new mint plants at its tips or nodes.

Windrow. Mint that is cut and placed in a row.

2. Unit Division.

A basic unit, as defined in section 1 of the Basic Provisions, will be divided into additional basic units by each mint type designated in the Special Provisions.

3. Insurance Guarantees, Coverage Levels, and Prices for Determining Indemnities.

(a) In addition to the requirements of section 3 of the Basic Provisions, you may only select one price election for all the mint in the county insured under this policy unless the actuarial documents provide different price elections by type, in which case you may only select one price election for each type designated in the actuarial documents. The price elections you choose for each type must have the same percentage relationship to the maximum price election offered by us for each type. For example, if you choose 100 percent of the maximum price election for one specific type, you must also choose 100 percent of the maximum price election for other types.

(b) In addition to the provisions in section 3 of the Basic Provisions, you must report:

(1) The total amount of mint oil produced from insurable acreage for all cuttings for each unit;

(2) Any damage to or removal of mint plants or stolons; the stand age; any change in practices; or any other circumstance that may reduce the expected yield below the yield upon which the insurance guarantee is based, and the number of affected acres;

(3) The date existing mint acreage was planted;

(4) The date new mint acreage was initially planted; and

(5) The type of mint.

(c) If you fail to notify us of any circumstance that may reduce your yields or insurable acres from previous levels, we will reduce your production guarantee and insurable acres at any time we become aware of the circumstance based on our estimate of the effect of damage to or removal of mint plants or stolons; stand age; change in practices; and any other circumstance that may affect the yield potential or insurable acres of the insured crop.

4. Contract Changes.

In accordance with section 4 of the Basic Provisions, the contract change date is June 30 preceding the cancellation date.

5. Cancellation and Termination Dates.

In accordance with section 2 of the Basic Provisions, the cancellation date is September 30 and the termination date is November 30. If your policy is terminated after insurance has attached for the subsequent crop year, coverage will be deemed to not have attached to the acreage for the subsequent crop year.

6. Insured Crop.

(a) In accordance with the provisions of section 8 of the Basic Provisions, the crop insured will be all mint types in the county for which a premium rate is provided by the actuarial documents:

(1) In which you have a share;

(2) That are planted for harvest and distillation for mint oil;

(3) That have an adequate stand by the date coverage begins; and

(4) That have been:

(i) Inspected and accepted by us for the first crop year you are insured, and for the subsequent crop year following an indemnified loss; or

(ii) Certified by you as having an adequate stand on the date coverage begins after the first crop year you are insured, and in the subsequent crop years, unless an indemnity was paid the previous crop year.

(b) In lieu of the provisions of section 8 of the Basic Provisions that prohibit insurance of a second crop harvested following the same crop in the same crop year, multiple harvests of mint on the same acreage will be considered as one mint crop.

(c) In addition to the coverages provided in these Crop Provisions, you may also elect the Winter Coverage Option, which provides coverage for mint that is damaged after the date coverage ends in the fall and before the date coverage begins in the spring. Coverage under the option is effective only if you execute the option by the sales closing date designated in the Special Provisions for the Winter Coverage Option.

7. Insurable Acreage.

(a) Mint interplanted with a cover crop will not be considered interplanted for the purposes of section 9 of the Basic Provisions if the cover crop is destroyed prior to its maturity and is not harvested as grain.

(b) In addition to the provisions of section 9 of the Basic Provisions, we will not insure any acreage that:

(1) Does not meet rotation requirements contained in the actuarial documents; or

(2) Exceeds existing mint age limitations contained in the actuarial documents.

8. Insurance Period.

In lieu of the provisions of section 11 of the Basic Provisions:

(a) Coverage begins on each unit or part of a unit for acreage with an adequate stand on the following calendar dates:

(1) June 16 in Indiana, Montana, and Wisconsin;

(2) May 16 in Washington; and

(3) For all other states, the date as provided in the Special Provisions.

(b) For the year of application, we will inspect all mint acreage within the two-week period before coverage begins. Insurance will attach on the date coverage begins after your properly completed application is received in our local office, unless we inspect the acreage during the two-week period and determine it does not meet insurability requirements as specified in section 2 of the Basic Provisions, the application, or these Crop Provisions. You must provide any information we require for the crop or to determine the condition of the crop.

(c) Coverage ends for each unit or part of a unit at the earliest of:

(1) Total destruction of the insured crop;

(2) Final adjustment of a loss;

(3) Harvest for each cutting;

(4) Abandonment of the crop; or

(5) The following calendar date:

(i) September 30 in Indiana and Wisconsin;

(ii) October 15 in Montana;

(iii) October 31 in Washington; and

(iv) For all other states, the date as provided in the Special Provisions.

9. Causes of Loss.

(a) In accordance with the provisions of section 12 of the Basic Provisions, insurance is provided only against the following causes of loss that occur during the insurance period:

(1) Adverse weather conditions;

(2) Fire;

(3) Insects or plant disease (except Verticillium Wilt disease), but not damage due to insufficient or improper application of control measures;

(4) Wildlife;

(5) Earthquake;

(6) Volcanic eruption; or

(7) Failure of the irrigation water supply, if caused by an insured cause of loss listed in sections 9(a)(1) through (6) that occurs during the insurance period.

(b) In addition to the causes of loss excluded in section 12 of the Basic Provisions, we will not insure against any loss of production that:

(1) Occurs after harvest;

(2) Is due to your failure to distill the crop, unless such failure is due to actual physical damage to the crop caused by an insured cause of loss that occurs during the insurance period; or

(3) Is due to Verticillium Wilt disease.

10. Duties In The Event of Damage or Loss.

In addition to your duties contained in section 14 of the Basic Provisions, if you discover that any insured mint is damaged, or if you intend to claim an indemnity on any unit:

(a) You must give us notice of probable loss at least 15 days before the beginning of any cutting or immediately if probable loss is discovered after cutting has begun or when cutting should have begun; and

(b) You must timely harvest and completely distill a sample of the crop on any acreage you do not intend to harvest, as designated by us, to determine if an indemnity is due.

11. Settlement of Claim.

(a) We will determine your loss on a unit basis. In the event you are unable to provide separate, acceptable production records:

(1) For any optional units, we will combine all optional units for which such production records were not provided; or

(2) For any basic units, we will allocate any commingled production to such units in proportion to our liability on the harvested acreage for the units.

(b) We may defer appraisals until the crop reaches maturity or the date mint harvest is general in the area.

(c) In the event of loss or damage covered by this policy, we will settle your claim by:

(1) Multiplying the insured acreage by its respective production guarantee;

(2) Multiplying the result of section 11(c)(1) by the price election;

(3) Multiplying the total production to be counted (see section 11(d)) by the price election;

(4) Subtracting the total in section 11(c)(3) from the total in section 11(c)(2); and

(5) Multiplying the result in section 11(c)(4) by your share.

For example:

Assume that you have a 100 percent share in 100 acres of mint in the unit, with a guarantee of 50 pounds of oil per acre and a price election of $12 per pound. Because an insured cause of loss has reduced production, you only harvest and distill 2,500 pounds of oil. Your indemnity would be calculated as follows:

(1) 100 acres × 50 pounds = 5,000 pound guarantee;

(2) 5,000 pound guarantee × $12 price election = $60,000 value of guarantee;

(3) 2,500 pounds production to count × $12 price election = $30,000 value of production to count;

(4) $60,000 − $30,000 = $30,000 loss; and

(5) $30,000 × 100 percent share = $30,000 indemnity payment.

(d) The total production to count (in pounds of oil) from all insurable acreage on the unit will include:

(1) All appraised production as follows:

(i) Not less than the production guarantee per acre for acreage:

(A) That is abandoned;

(B) That is put to another use without our consent;

(C) For which you fail to meet the requirements contained in section 10 of these Crop Provisions;

(D) That is damaged solely by uninsured causes; or

(E) For which you fail to provide production records that are acceptable to us;

(ii) All production lost due to uninsured causes;

(iii) All unharvested production;

(iv) All potential production on insured acreage that you intend to put to another use or abandon with our consent:

(A) If you do not elect to continue to care for the crop, we may give you our consent to put the acreage to another use if you agree to leave intact and provide sufficient care for representative samples of the crop in locations acceptable to us (The amount of production to count for such acreage will be based on the harvested production or appraisals from the samples at the time harvest should have occurred. If you do not leave the required samples intact, or fail to provide sufficient care for the samples, the amount of production to count will be not less than the production guarantee per acre); or

(B) If you elect to continue to care for the crop, the amount of production to count for the acreage will be the harvested production, or the appraised production at the time the crop reaches maturity.

(2) All harvested production from the insurable acreage.

(e) Harvested production must be distilled to determine production to count.

(f) Any oil distilled from plants growing in the mint will be counted as mint oil on a weight basis.

(g) You are responsible for the cost of distilling samples for loss adjustment purposes.

12. Late and Prevented Planting.

The late and prevented planting provisions of the Basic Provisions are not applicable.

13. Winter Coverage Option.

(a) The provisions of this option are continuous and will be attached to and made part of your insurance policy, if:

(1) You elect the Winter Coverage Option on your application, or on a form approved by us, on or before the fall sales closing date for the crop year in which you wish to insure mint under this option, and pay the additional premium indicated in the actuarial documents for this optional coverage; and

(2) You have not elected coverage under the Catastrophic Risk Protection Endorsement.

(b) This option provides a guarantee equal to 60 percent of the guarantee determined under section 3 of these Crop Provisions.

(c) If you elect this option, all of the insurable acreage in the county will be insured by this option.

(d) In addition to the requirements of section 6 of the Basic Provisions, any acreage of new mint planted after the applicable acreage reporting date must be reported to us not later than two weeks after planting.

(e) In lieu of section 6(a) of these Crop Provisions, the crop insured will be all mint types in the county for which a premium rate is provided by the actuarial documents:

(1) In which you have a share;

(2) That are planted for harvest and distillation as mint oil;

(3) That have an adequate stand on the date coverage begins, if an existing stand of mint;

(4) For new mint acreage, that is planted during the Winter Coverage Option insurance period; and

(5) That has been:

(i) Inspected and accepted by us for the first crop year you are insured (We will inspect all mint acreage and will notify you of the acceptance or rejection of your application not later than November 15. If we fail to notify you by that date, your application will be accepted unless other grounds exist to reject the application, as specified in the Basic Provisions, the application, or these Crop Provisions);

(ii) Inspected and accepted by us for the subsequent crop year following an indemnified loss;

(iii) Certified by you as having an adequate stand on the date coverage begins after the first crop year you are insured, and in the subsequent crop years, unless an indemnity was paid the previous crop year; or

(iv) Certified by you within two weeks of planting new mint acreage that was planted during the Winter Coverage Option insurance period.

(f) Coverage under this option begins:

(1) On existing mint acreage with an adequate stand at 12:01 a.m. on the calendar date listed below:

(i) October 1 in Indiana and Wisconsin;

(ii) October 16 in Montana;

(iii) November 1 in Washington; and

(iv) For all other states, the date as provided in the Special Provisions.

(2) On new mint acreage, on the later of the date the crop is planted (provided the acreage is planted during the Winter Coverage Option insurance period) or the date we accept your application.

(g) Coverage under this option ends on the unit or part of the unit at 11:59 p.m. on the calendar date listed below:

(1) June 15 in Indiana, Montana, and Wisconsin;

(2) May 15 in Washington; and

(3) For all other states, the date as provided in the Special Provisions.

(h) In lieu of section 10(a) of these Crop Provisions, you must give notice of probable loss within 72 hours after you discover any insured mint is damaged and does not have an adequate stand, but no later than the date coverage ends for this option.

(i) In addition to the requirements of section 10 of these Crop Provisions, you must give us notice if you want our consent to put any mint acreage to another use before a determination can be made if there is an adequate stand on the acreage. We will inspect the acreage and you must agree in writing no payment or indemnity will be made for the acreage put to another use. The total production to count for acreage put to another use with our consent according to this section will be the production guarantee.

(j) In addition to section 11(a) of these Crop Provisions we will make a Winter Coverage Option payment only on acreage that had an adequate stand on the date that insurance attached if the adequate stand was lost due to an insured cause of loss occurring within the Winter Coverage Option insurance period and the acreage consists of at least 20 acres or 20 percent of the insurable planted acres in the unit.

(k) In lieu of section 11(b) of these Crop Provisions, we may defer appraisals until the date coverage ends under this option.

(l) In lieu of section 11(c) of these Crop Provisions, in the event of loss or damage covered by this policy, we will settle your claim by:

(1) Multiplying 60 percent by your production guarantee per acre;

(2) Multiplying the result in section 13(l)(1) by the number of acres that do not have an adequate stand;

(3) Multiplying the result in section 13(l)(2) by the price election; and

(4) Multiplying the result in section 13(l)(3) by your share.

For example:

Assume that you have a 100 percent share in 100 acres of mint with a guarantee of 50 pounds of oil per acre and a price election of $12 per pound. Also assume that you do not have an adequate stand on 50 acres by the date coverage ends for this option because an insured cause has damaged the stand. Your Winter Coverage Option payment would be calculated as follows:

(1) 60 percent × 50 pound guarantee = 30 pound guarantee per acre;

(2) 30 pound guarantee per acre × 50 acres without an adequate stand = 1,500 pounds;

(3) 1,500 pounds × $12 price election = $18,000; and

(4) $18,000 × 100 percent share = $18,000 Winter Coverage Option payment.

(m) In lieu of section 11(d) of these Crop Provisions, the population of live mint plants to be counted from insurable acreage on the unit will be not less than the population of live mint plants in an adequate stand for acreage:

(1) That is abandoned;

(2) That is put to another use without our consent;

(3) For which you fail to meet the requirements contained in section 13(h); or

(4) That is damaged solely by uninsured causes.

(n) Acreage for which a Winter Coverage Option payment has been made is no longer insurable under the Crop Provisions for the current crop year. Any mint production subsequently harvested from uninsured acreage for the crop year and not kept separate from production from insured acreage will be considered production to count.

(o) Acreage for which a Winter Coverage Option payment has been made will receive an amount of production of zero when computing subsequent year's approved yield.

(p) Sections 11(e), (f), and (g) of these Crop Provisions do not apply to this option.

Signed in Washington, DC, on January 30, 2006.

Eldon Gould,

Manager, Federal Crop Insurance Corporation.

[FR Doc. E6–1529 Filed 2–3–06; 8:45 am]

BILLING CODE 3410–08–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 1250

[Docket No. PY–05–005]

Egg Research and Promotion Program; Section 610 Review

AGENCY: Agricultural Marketing Service.

ACTION: Notice of regulatory review and request for comments.

SUMMARY: This document announces the Agricultural Marketing Service's (AMS) review of the Egg Research and Promotion Program (conducted under the Egg Research and Promotion Order), under the criteria contained in Section 610 of the Regulatory Flexibility Act (RFA).

DATES: Written comments must be received by April 7, 2006.

ADDRESSES: Interested persons are invited to submit written comments concerning this notice to Angela C. Snyder, Chief, Research and Promotion, Office of the Deputy Administrator, Poultry Programs, Agricultural Marketing Service, U.S. Department of Agriculture, 1400 Independence Avenue, SW.; STOP 0256, Room 3932-South; Washington, DC 20250–0256; or by fax to (202) 720–5631. Alternatively, comments may be submitted electronically to: *angie.snyder@usda.gov* or *http://www.regulations.gov*. All comments should reference the docket number and the date and page number of this issue of the **Federal Register**. All comments received will be made available for public inspection at the above address during regular business hours. A copy of this notice may be found at: *http://www.ams.usda.gov/poultry/pyrp.htm/*.

FOR FURTHER INFORMATION CONTACT: Angela C. Snyder, Office of the Deputy Administrator, Poultry Programs, Agricultural Marketing Service, U.S. Department of Agriculture, 1400 Independence Avenue, SW.; STOP 0256, Room 3932-South; Washington, DC 20250–0256 telephone (760) 386–0424; fax (202) 720–5631, or e-mail at *angie.snyder@usda.gov*.

SUPPLEMENTARY INFORMATION: The Egg Research and Consumer Information Act of 1974, as amended (7 U.S.C. 1201 *et seq.*), authorized the Egg Research and Promotion Order (7 CFR part 1250), which is industry-operated and funded with oversight by USDA. The Egg Research and Promotion Order's objective is to establish, finance, and carry out promotion, research, and education programs to improve, maintain, and develop markets for eggs, egg products, spent fowl, and products of spent fowl.

The program became effective on August 1, 1976, when the Egg Research and Promotion Order (7 CFR part 1250) was implemented. In accordance with the legislation, the American Egg Board was established, and assessments at 5 cents per 30-dozen case of eggs soon began to be levied. Since that time, assessments have fluctuated from 2½ cents per 30-dozen case of eggs to the current 10 cents per 30-dozen case approved by producer referendum in 1994.

Assessments collected under this program are used to carry out promotion, research, and education programs to improve, maintain, and develop markets for eggs, egg products, spent fowl, and products of spent fowl.

The program is administered by the American Egg Board, which is composed of egg producers and egg producer representatives. Each of the 18

members and their specific alternates are appointed by the Secretary of Agriculture from nominations submitted by certified producer organizations. The Secretary annually appoints half of the Board, nine members and nine alternates, for 2-year terms.

AMS published in the **Federal Register** (64 FR 8014; February 18, 1999) its plan to review certain regulations, including the Egg Research and Promotion Program (conducted under the Egg Research and Promotion Order), under criteria contained in section 610 of the Regulatory Flexibility Act (RFA; 5 U.S.C. 601–612). The plan was updated in the **Federal Register** on August 14, 2003 (68 FR 48574). Because many AMS regulations impact small entities, AMS decided, as a matter of policy, to review certain regulations which, although they may not meet the threshold requirement under section 610 of the RFA, warrant review. Accordingly, this notice and request for comments is made for the Egg Research and Promotion Order.

The purpose of the review is to determine whether the Order should be continued without change, amended, or rescinded (consistent with the objectives of the Egg Research and Consumer Information Act of 1974) to minimize the impacts on small entities. AMS will consider the continued need for the Order; the nature of complaints or comments received from the public concerning the Order; the complexity of the Order; the extent to which the Order overlaps, duplicates, or conflicts with other Federal rules, and, to the extent feasible, with State and local regulations; and the length of time since the Order has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the Order.

Written comments, views, opinions, and other information regarding the Order's impact on small businesses are invited.

Dated: January 31, 2006.

Lloyd C. Day,

Administrator, Agricultural Marketing Service.

[FR Doc. E6–1563 Filed 2–3–06; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF ENERGY

Office of Energy Efficiency and Renewable Energy

10 CFR Part 430

[Docket No. EE–RM–PET–100]

Energy Efficiency Program for Consumer Products: California Energy Commission Petition for Exemption From Federal Preemption of California's Water Conservation Standards for Residential Clothes Washers

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Petition for Exemption.

SUMMARY: The Department of Energy (hereafter "the Department") announces the filing of the California Energy Commission's Petition for Exemption from Federal Preemption of California's Water Conservation Standards for Residential Clothes Washers (hereafter "California Petition"). To help the Department evaluate the California Petition's request, the Department invites interested members of the public to submit comments they may have on the California Petition and information related to the evaluation factors outlined in the Energy Policy and Conservation Act.

DATES: The Department will accept written comments, data, and information regarding the California Petition until, but no later than April 7, 2006.

ADDRESSES: A document entitled "California Preemption Exemption Petition" is available for review on the Internet at *http://www.eere.energy.gov/buildings/ appliance_standards/ state_petitions.html* or from Ms. Brenda Edwards-Jones, U.S. Department of Energy, Building Technologies Program, EE–2J, Room 1J–018, 1000 Independence Ave., SW., Washington, DC 20585–0121, or by telephone (202) 586–2945.

Please submit comments, identified by docket number EE–RM–PET–100 by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *E-mail: California.Petition@ee.doe.gov.* Include either the docket number EE–RM–PET–100, and/or "California Preemption Exemption Petition" in the subject line of the message.
- *Mail:* Ms. Brenda Edwards-Jones, U.S. Department of Energy, Building Technologies Program, Mailstop EE–2J, Room 1J–018, 1000 Independence Avenue, SW., Washington, DC 20585–0121. Please submit one signed original paper copy.
- *Hand Delivery/Courier:* Ms. Brenda Edwards-Jones, U.S. Department of Energy, Building Technologies Program, Room 1J–018, 1000 Independence Avenue, SW., Washington, DC 20585–0121.

Instructions: All submissions received must include the agency name and docket number for this proceeding. For detailed instructions on submitting comments and additional information on the proceeding, see section II. C of this document (Submission of Comments).

Docket: For access to the docket to read the background documents relevant to this matter, go to the U.S. Department of Energy, Forrestal Building, Room 1J–018 (Resource Room of the Building Technologies Program), 1000 Independence Avenue, SW., Washington, DC, (202) 586–2945, between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays. Available documents include the following items: The California Petition; California's 2005 water plan, *California Water Plan Update 2005: Public Review Draft;* prior Department rulemakings regarding clothes washers or comments received. Please call Ms. Brenda Edwards-Jones at the above telephone number for additional information regarding visiting the Resource Room.

Please note: The Department's Freedom of Information Reading Room (formerly Room 1E–190 at the Forrestal Building) is no longer housing rulemaking materials.

Electronic copies of the California Petition are available online at either the Department of Energy's Web site at the following URL address: *http://www.eere.energy.gov/buildings/ appliance_standards/ state_petitions.html* or the California Energy Commission's Web site at the following URL address: *http://www.energy.ca.gov/appliances/2005–09–13_ PETITION_CLOTHES_ WASHERS.PDF.* An electronic copy of California's water plan update and related material is available online at the California Department of Water Resources Web site at the following URL address: *http://www.waterplan.water.ca.gov/.* Electronic copies of prior Department rulemakings regarding clothes washers and of the Final Rule Technical Support Document for clothes washers are available from the Department's Building Technologies Program's Web site at the following URL address:

http://www.eere.energy.gov/buildings/appliance_standards/residential/clothes_washers.html.

This notice also refers to California standards for residential clothes washers adopted by the California Energy Commission (CEC) in 2004. Material related to this State regulation is available at the following URL address under Docket # 03–AAER–1(RCW): *http://www.energy.ca.gov/appliances/2003rulemaking/clothes_washers/index.html.*

FOR FURTHER INFORMATION CONTACT: Bryan Berringer, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Program, EE–2J, 1000 Independence Avenue, SW., Washington, DC 20585–0121, (202) 586–0371, or e-mail: *Bryan.Berringer@ee.doe.gov.*

Thomas DePriest, Esq., U.S. Department of Energy, Office of General Counsel, GC–72, 1000 Independence Avenue, SW., Washington, DC 20585; (202) 586–9507, e-mail: *Thomas.DePriest@hq.doe.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

A. Authority

Part B of Title III of the Energy Policy and Conservation Act, as amended (hereafter "Act"or EPCA) established the Energy Conservation Program for Consumer Products Other Than Automobiles. (42 U.S.C. 6291–6309) Products covered under the program, including residential clothes washers, and the authority to regulate them, are listed in section 322. (42 U.S.C. 6292) Section 325(g) (42 U.S.C. 6295(g)) establishes standards for certain types of residential clothes washers and requires the Department to issue two rulemakings to consider further amendments.

Federal energy efficiency requirements for residential products generally preempt State laws or regulations concerning energy conservation testing, labeling, and standards. (42 U.S.C. 6297(a)–(c)) However, the Department can grant waivers of Federal preemption (hereafter "waiver" or "exemption") for particular State laws or regulations, in accordance with the procedures and other provisions of section 327(d) of the Act. (42 U.S.C. 6297(d)) In particular, section 327(d)(1)(A) of EPCA provides that any State or river basin commission with a State regulation regarding energy use, energy efficiency, or water use requirements for products regulated by the Energy Conservation Program, may petition for an exemption from Federal preemption and seek to apply its own State regulation. (42 U.S.C. 6297(d)(1)(A))

B. Background

1. Department Rulemakings Regarding Clothes Washers

On January 12, 2001, the Department issued a final rule for energy efficiency and design standards for five product classes of clothes washers (hereafter referred to as the January 2001 final rule): Top-loading compact; Top-loading, standard; Front-loading; Top-loading, semi-automatic; and Top-loading, suds-saving. (66 FR 3314–3333) The January 2001 final rule set minimum energy efficiency standards that would become effective on January 1, 2004, and January 1, 2007. DOE standards for residential products are energy efficiency standards only; DOE has not set a water use requirement for residential clothes washers. (10 CFR 430.32(g))

TABLE I.1.—FEDERAL RESIDENTIAL CLOTHES WASHER STANDARD LEVELS

Product class	Capacity ($ft.^3$)	Modified energy factor ($ft.^3$/kWh/cycle)	
		Effective date 1/1/2004	Effective date 1/1/2007
Top-Loading, compact	<1.6	0.65	0.65
Top-Loading, standard	≥1.6	1.04	1.26
Front-Loading	.....	1.04	1.26
Top-Loading, Semi-automatic	.....	Unheated rinse water option	Unheated rinse water option.
Suds-saving	.....	Unheated rinse water option	Unheated rinse water option.

The January 2001 final rule constituted the second residential clothes washer rulemaking required by EPCA. The initial standards prescribed in EPCA, as amended by the National Appliance Energy Conservation Act of 1987, required an unheated water option, and permitted a water rinse option for clothes washers manufactured on or after January 1, 1988. (42 U.S.C. 6295(g)) Subsequent standard amendments made by the Department established the five product classes in Table I.1 and set minimum energy efficiency standards.

The Energy Policy Act of 2005 amended the Act to adopt new energy efficiency and water conservation standards for commercial clothes washers. The commercial clothes washer standards require products manufactured on or after January 1, 2007, to have a modified energy factor of at least 1.26 and a water factor of not more than 9.5. (42 U.S.C. 6313(e))

2. California Petition for Waiver of Federal Preemption and Summary of State Regulation

On September 16, 2005, the Department received a petition for an exemption from the California Energy Commission (CEC) (hereafter referred to as the California Petition), dated September 13, 2005, pursuant to the requirements of section 327(d) of the Act (42 U.S.C. 6297(d)) and Title 10 Code of Federal Regulations (CFR) Part 430, Subpart D, and Sections 430.41(a)(1) and 430.42 of the CFR. However, by letter dated November 18, 2005, the Department notified the CEC that its petition had failed to comply with certain requirements set out in 10 CFR 430.42(c). The CEC responded on December 5, 2005, and provided the required information. By letter dated December 23, 2005, the Department notified the CEC that it had accepted the California petition as supplemented.

California Assembly Bill 1561, passed by the California legislature and signed into law in 2002, required the CEC to adopt water efficiency standards for residential clothes washers by January 2004, and to file a petition with the Department for a waiver by April 2004. The law also required that the new standards be at least as efficient as commercial clothes washers. (California Public Resources Code section 25402 (e)) California currently requires that commercial clothes washers meet a maximum water factor of 9.5 by January 1, 2007, the same standard as prescribed by Section 342 of EPCA, as amended by the Energy Policy Act of 2005 in August of 2005. (20 C.C.R. 1605.3(p) and 42 U.S.C. 6313(e)) (CEC, No. 1 at 2) [1]

In 2004, the CEC adopted water efficiency standards for Top- and Front-Loading residential clothes washers, setting a two-tier standard of 8.5 maximum water factor effective January 1, 2007, and of 6.0 maximum water factor, effective January 1, 2010. (20 C.C.R 1605.2(p)) (CEC, No. 1 at 3)

3. Factors to Consider in Granting or Declining an Exemption

Section 327(d) of the Act sets forth factors that the Secretary of Energy (hereafter "Secretary") is to consider in evaluating whether to grant an exemption. (42 U.S.C. 6297(d)) Section 327 (d)(1)(B) requires the Secretary to grant an exemption if the Secretary determines that the proffered State regulation "is needed to meet unusual and compelling State or local water interests." (42 U.S.C. 6297(d)(1)(B)) According to section 327(d)(1)(C) of the Act, "unusual and compelling" interests are defined as interests which "(i) are substantially different in nature or magnitude than those prevailing in the United States generally; and (ii) are such that the costs, benefits, burdens, and reliability of energy or water savings resulting from the State regulation make such regulation preferable or necessary when measured against the costs, benefits, burdens, and reliability of alternative approaches to energy or water savings or production, including reliance on reasonably predictable market-induced improvements in efficiency of all products subject to the State regulation." (42 U.S.C. 6297(d)(1)(C))

According to sections 327(d)(3)–(4), the Secretary may not grant an exemption if the Secretary finds the State regulation would "significantly burden manufacturing, marketing, distribution, sale, or servicing of the covered product on a national basis," or "result in the unavailability" in the State of any covered product's "performance characteristics (including reliability), features, sizes, capacities, and volumes that are substantially the same as those generally available in the State at the time of the Secretary's finding, except that the failure of some classes (or types) to meet this criterion shall not affect the Secretary's determination of whether to prescribe a rule for other classes (or types)." (41 U.S.C. 6297(d)(3) and (4)) To evaluate whether the State regulation will create a significant burden, the Secretary is to consider "all relevant factors," including the following:

"(A) The extent to which the State regulation will increase manufacturing or distribution costs of manufacturers, distributors, and others;

(B) The extent to which the State regulation will disadvantage smaller manufacturers, distributors, or dealers or lessen competition in the sale of the covered product in the State;

(C) The extent to which the State regulation would cause a burden to manufacturers to redesign and produce the covered product type (or class), taking into consideration the extent to which the regulation would result in a reduction—

(i) In the current models, or in the projected availability of models, that could be shipped on the effective date of the regulation to the State and within the United States; or

(ii) In the current or projected sales volume of the covered product type (or class) in the State and the United States; and

(D) The extent to which the State regulation is likely to contribute significantly to a proliferation of State appliance efficiency requirements and the cumulative impact such requirements would have." (U.S.C. 6297(d)(3)(A) through (D))

II. Discussion

A. Summary of Reasons for Petition

The California Petition seeks waivers of Federal preemption for all classes of residential clothes washers that are covered products under the Act, "including but not necessarily limited to—Compact and Standard; Top-Loading and Front-Loading; Automatic and Semi-Automatic; and Suds-Saving and Non-Suds-Saving." (CEC, No. 1 at p. 4)

According to the California Petition, the CEC states that California currently uses, and will continue to need, cost-effective water conservation strategies. The CEC states that every water supply source for the State is "over-appropriated" and water demand is projected to grow rapidly. (CEC, No. 1 at p. 1) Furthermore, the CEC claims that clothes washer standards are distinctly preferable to alternative approaches to water savings and production. (CEC, No. 1 at p. 26) The CEC additionally argues that California's local and state water interests are unusual and compelling, and that "California's water interests (and associated energy interest) are different in both nature and magnitude than those prevailing in the United States generally. * * *" (CEC, No. 1 at p. 5)

The California Petition also provides information relating to the California standard's burden on manufacturing, marketing, distribution, sale, or servicing of the residential clothes washers on a national basis, and states that California's water efficiency standards will achieve benefits without significantly impacting the residential clothes washer industry or the consumer-usefulness of appliances. (CEC, No. 1 at pp. 37 through 41)

B. Issues on Which the Department Seeks Comment

The Department is interested in receiving comments on all aspects of the California Petition and this notice. The Department is especially interested in public comment on information related to the evaluation of factors outlined in section 327 of the Act, including the following: whether the California Petition has established that California has unusual and compelling State or local water interests to warrant a waiver from Federal preemption; whether the State regulation will be burdensome; and whether the State regulation will affect the availability of covered products with features generally available in California. In that regard, the Department is particularly interested in receiving comment on the following questions:

- Are California's water interests "unusual and compelling," and how do they compare to those of the Nation and of other States? (42 U.S.C. 6297(d)(1)(B))
- Are there other factors and information in addition to the California Petition the Department should consider in determining whether California's water interests are "unusual and compelling"? (42 U.S.C. 6297(d)(1)(C))

[1] A notation in the form "CEC, No. 1 at p. 2" identifies a written comment the Department has received and has included in the docket of this rulemaking. This particular notation refers to a comment (1) By the California Energy Commission (CEC), (2) in document number 1 in the docket of this proceeding (maintained in the Resource Room of the Building Technologies Program), and (3) appearing on page 2 of document number 1.

• Are the water use issues "substantially different in nature or magnitude than those prevailing in the United States generally?" Should the phrase, "in the United States generally" be interpreted to include comparison to regions as well as national averages? Are the water use issues in California substantially different in nature or magnitude than those prevailing in other western states? (42 U.S.C. 6297(d)(1)(C)(i))

• Are there "alternative approaches to * * * [clothes washer] water savings" that could achieve the same water savings in California as would be achieved by the California clothes washer standards? (42 U.S.C. 6297(d)(1)(C)(ii))

• Are there "alternative approaches to * * * water savings or production" not considered in the California water plan that could achieve the same water savings in California as would be achieved by the California clothes washer standards? (42 U.S.C. 6297(d)(1)(C)(ii))

• Are there alternative policies or programs in California that can achieve the same water savings at the same or lower cost or burden, or with greater reliability and benefit? (42 U.S.C. 6297(d)(1)(C)(ii))

• Are there estimates of market-induced improvements in efficiency of all products subject to the California regulation? (42 U.S.C. 6297(d)(1)(C)(ii))

• Is the analysis used in the California Petition accurate? For example, are the State's savings estimates correct? How valid are the State's assumptions?

• Is California Petition's statement that water supplies are not "fungible" and that it is very difficult to transfer any water savings from one sector of the State to another accurate? Are there ways California can transfer water savings more easily?

• What impacts would the State standards have on manufacturing, marketing, distribution, sale, or servicing of covered products on a national basis? (42 U.S.C. 6297(d)(3))

• What impact will the California clothes washer standard have on manufacturing or distribution costs of manufacturers, distributors and others? (42 U.S.C. 6297(d)(3)(A))

• Will the California clothes washer standard disadvantage smaller manufacturers, distributors, or dealers or lessen competition in California? (42 U.S.C. 6297(d)(3)(B))

• To what extent would the California standard cause a burden to manufacturers to redesign their residential clothes washers? (42 U.S.C. 6297(d)(3)(C))

• Would the California standard result in a reduction in product availability? (42 U.S.C. 6297(d)(3)(C)(i))

• Would the California standard result in a reduction in sales volume of clothes washers either in California or in the United States as a whole? (42 U.S.C. 6297(d)(3)(C)(ii))

• To what extent is the California regulation likely to contribute significantly to a proliferation of State appliance efficiency requirements? What cumulative impact would such requirements have? (42 U.S.C. 6297(d)(3)(D))

• Would the California regulation impact the availability in the State of any covered product type (or class) of performance characteristics (including reliability), features, sizes, capacities, and volumes that are substantially the same as those generally available in the State? (42 U.S.C. 6297(d)(4))

• Would the California standard affect the availability of classes of clothes washers or clothes washer performance characteristics, reliability, features, sizes, capacities and volumes that are generally available in California? (42 U.S.C. 6297(d)(4))

After the period for written comments, the Department will consider the information and views submitted, and make a decision on whether to prescribe a waiver from Federal preemption for California with regard to water use standards for residential clothes washers.

C. Submission of Comments

The Department will accept comments, data, and information regarding this notice no later than the date provided at the beginning of the notice. Please submit comments, data, and information electronically. Send them to the following e-mail address: *California.Petition@ee.doe.gov*. Submit electronic comments in WordPerfect, Microsoft Word, PDF, or text (ASCII) file format and avoid the use of special characters or any form of encryption. Identify comments in electronic format by the docket number EE-RM-PET–100 and wherever possible include the electronic signature of the author. Absent an electronic signature, comments submitted electronically must be followed and authenticated by submitting the signed original paper document. DOE does not accept telefacsimiles (faxes).

In accordance with 10 CFR 1004.11, any person submitting information that he or she believes to be confidential and exempt by law from public disclosure should submit two copies: one copy of the document including all the information believed to be confidential, and one copy of the document with the information believed to be confidential deleted. The Department will make its own determination about the confidential status of the information and treat it according to its determination.

Factors of interest to the Department when evaluating requests to treat submitted information as confidential include: (1) A description of the items; (2) whether and why such items are customarily treated as confidential within the industry; (3) whether the information is generally known by or available from other sources; (4) whether the information has previously been made available to others without obligation concerning its confidentiality; (5) an explanation of the competitive injury to the submitting person which would result from public disclosure; (6) when such information might lose its confidential character due to the passage of time; and (7) why disclosure of the information would be contrary to the public interest.

Issued in Washington, DC, on January 27, 2006.

Douglas L. Faulkner,

Acting Assistant Secretary, Energy Efficiency and Renewable Energy.

[FR Doc. 06–1041 Filed 2–3–06; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2005–23319; Directorate Identifier 2005–CE–52–AD]

RIN 2120–AA64

Airworthiness Directives; Raytheon Aircraft Company 65, 90, 99, and 100 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede Airworthiness Directive (AD) 92–07–05, which applies to certain Raytheon Aircraft Company (Raytheon) 65, 90, 99, and 100 series airplanes. AD 92–07–05 currently requires you to inspect the rudder trim tab for proper moisture drainage provisions, and if the correct drainage provisions do not exist, prior to further flight, modify the rudder trim tab. Since we issued AD 92–07–05, FAA has received and evaluated new service information that requires the

actions of AD 92–07–05 for the added serial numbers LJ–1281 through LJ–1732 for the Model C90A airplanes. Consequently, this proposed AD retains all the actions of AD 92–07–05 and adds serial numbers LJ–1281 through LJ–1732 for the Model C90A airplanes in the applicability section. We are issuing this proposed AD to prevent water accumulation in the rudder trim tab, which could result in a change in the mass properties and thus result in the lower flutter speed of the airplane. Airplane flutter could result in failure and loss of control of the airplane.

DATES: We must receive comments on this proposed AD by April 10, 2006.

ADDRESSES: Use one of the following addresses to comment on this proposed AD:

- DOT Docket Web site: Go to *http://dms.dot.gov* and follow the instructions for sending your comments electronically.
- Government-wide rulemaking web site: Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- Mail: Docket Management Facility; U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, Room PL–401, Washington, DC 20590–0001.
- Fax: 1–202–493–2251.
- Hand Delivery: Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Contact Raytheon Aircraft Company, P.O. Box 85, Wichita, Kansas 67201–0085; telephone: (800) 429–5372 or (316) 676–3140 for the service information identified in this proposed AD.

You may examine the comments on this proposed AD in the AD docket on the Internet at *http://dms.dot.gov*.

FOR FURTHER INFORMATION CONTACT: Steven E. Potter, Aerospace Engineer, Wichita Aircraft Certification Office (ACO), FAA, 1801 Airport Road, Wichita, Kansas 67209; telephone: (316) 946–4124; facsimile: (316) 946–4107.

SUPPLEMENTARY INFORMATION:

Comments Invited

How do I comment on this proposed AD? We invite you to send any written relevant data, views, or arguments regarding this proposal. Send your comments to an address listed under **ADDRESSES.** Include the docket number, "FAA–2005–23319; Directorate Identifier 2005–CE–52–AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the proposed AD. We will consider all comments received by the closing date and may amend the proposed AD in light of those comments.

We will post all comments we receive, without change, to *http://dms.dot.gov*, including any personal information you provide. We will also post a report summarizing each substantive verbal contact with FAA personnel concerning this proposed rulemaking. Using the search function of the DOT docket Web site, anyone can find and read the comments received into any of our dockets, including the name of the individual who sent the comment (or signed the comment on behalf of an association, business, labor union, etc.). You may review the DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78) or you may visit *http://dms.dot.gov*.

Examining the Dockets

Where can I go to view the docket information? You may examine the docket that contains the proposal, any comments received and any final disposition on the Internet at *http://dms.dot.gov*, or in person at the DOT Docket Offices between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Office (telephone 1–800–647–5227) is located on the plaza level of the Department of Transportation NASSIF Building at the street address stated in **ADDRESSES.** Comments will be available in the AD docket shortly after the Docket Management Facility receives them.

Discussion

Has FAA taken any action to this point? We received and evaluated new service information on Beech (now Raytheon) Models 65–90, 65–A90, 65–A90–1, 65–A90–2, 65–A90–3, 65–A90–4, B90, C90, C90A, E90, H90, 99, 99A, A99A, B99, C99, 100, A100, and B100 airplanes that caused us to issue AD 92–07–05, Amendment 39–8201 (57 FR 8721, March 12, 1992). AD 92–07–05 currently requires the following on certain Raytheon Aircraft Company (Raytheon) Models 65–90, 65–A90, 65–A90–1, 65–A90–2, 65–A90–3, 65–A90–4, B90, C90, C90A, E90, H90, 99, 99A, A99A, B99, C99, 100, A100, and B100 airplanes:

- Inspect the rudder trim tab for proper moisture drainage provisions; and
- If the correct drainage provisions do not exist, prior to further flight, modify the rudder trim tab to provide the correct drainage provisions.

What has happened since AD 92–07–05 to initiate this proposed AD action? Since we issued AD 92–07–05, FAA has received and evaluated new service information that requires the actions of AD 92–07–05 for the added serial numbers LJ–1281 through LJ–1732 for the Model C90A airplanes.

What is the potential impact if FAA took no action? This condition, if not corrected, could result in water accumulation in the rudder trim tab, which could result in a change in the mass properties and thus result in the lower flutter speed of the airplane. Airplane flutter could result in failure and loss of control of the airplane.

Relevant Service Information

Is there service information that applies to this subject? We have reviewed:

- Raytheon Aircraft Company Service Bulletin No. SB 55–2365, Revision 2, Issued: January 1991, Revised: October 2005; and
- Beech Service Bulletin No. 2365, Revision 1, dated December 1991.

What are the provisions of this service information? The service information describes procedures for:

- Inspecting the rudder trim tab for proper moisture drainage provisions; and
- If the correct drainage provisions do not exist, prior to further flight, modifying the rudder trim tab to provide the correct drainage provisions.

FAA's Determination and Requirements of the Proposed AD

Why have we determined AD action is necessary and what would this proposed AD require? We are proposing this AD to address an unsafe condition that we determined is likely to exist or develop on other products of this same type design. The proposed AD would supersede AD 92–07–05 with a new AD that would incorporate the actions in the previously-referenced service bulletins. The proposed AD would require you to use the service information described previously to perform these actions.

Costs of Compliance

How many airplanes would this proposed AD impact? We estimate that this proposed AD affects 2,407 airplanes in the U.S. registry.

What would be the cost impact of this proposed AD on owners/operators of the affected airplanes? We estimate the following costs to do this proposed inspection:

Labor cost	Parts cost	Total cost per airplane	Total cost on U.S. operators
1 work hour × $65 = $65	Not Applicable	$65	2,407 × $65 = $156,455

We estimate the following costs to do any necessary modification of the rudder trim tab to provide the correct drainage provisions that would be required based on the results of this proposed inspection. We have no way of determining the number of airplanes that may need this modification:

Labor cost	Parts cost	Total cost per airplane
1 work hour × $65 = $65	$25	$90

Authority for This Rulemaking

What authority does FAA have for issuing this rulemaking action? Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in subtitle VII, part A, subpart III, Section 44701, "General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

Would this proposed AD impact various entities? We have determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that the proposed regulation:

1. Is not a "significant regulatory action" under Executive Order 12866;

2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

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

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. The FAA amends § 39.13 by removing Airworthiness Directive (AD) 92–07–05, Amendment 39–8201, and adding the following new airworthiness directive:

Raytheon Aircraft Company: Docket No. FAA–2005–23319; Directorate Identifier 2005–CE–52–AD.

When Is the Last Date I Can Submit Comments on This Proposed AD?

(a) The Federal Aviation Administration (FAA) must receive comments on this airworthiness directive (AD) action by April 10, 2006.

What Other ADs Are Affected by This Action?

(b) This AD supersedes AD 92–07–05; Amendment 39–8201.

What Airplanes Are Affected by This AD?

(c) This AD affects the following airplane models and serial numbers that are certificated in any category:

(1) Group 1 (maintains the actions from AD 92–07–05):

Model	Serial numbers
(i) 65–90, 65–A90, B90, C90, and C90A	LJ–1 through LJ–1280.
(ii) E90	LW–1 through LW–347.
(iii) 99, 99A, A99, A99A, B99, and C99	U–1 through U–136 and U–146 through U–239.
(iv) 100 and A100	B1 through B–94, B–100 through B–204, and B–206 through B247.
(v) B100	BE–1 through BE–137.
(vi) 65–A90–1 (U–21A, JU–21A, RU–21D, RU–21H, RU–21A, U–21G)	LM–1 through LM–141.
(vii) 65–A90–2 (RU–21B)	LS–1, LS–2, and LS–3.
(viii) 65–A90–3 (RU–21C)	LT–1 and LT–2
(ix) 65–A90–4 (RU–21EA, U–21H, RU–21H)	LU–1 through LU–16.
(x) H90 (T–44A)	LL–1 through LL–61
(xi) 99A (FACH)	U–137 through U–145.
(xii) A100 (U–21F)	B95 through B–99.

(2) Group 2: Model C90A, serial numbers LJ–1281 through LJ–1732.

What Is the Unsafe Condition Presented in This AD?

(d) This AD results from receiving and evaluating new service information that requires the actions of AD 92–07–05 for the added serial numbers LJ–1281 through LJ–1732 for the Model C90A airplanes. The actions specified in this AD are intended to prevent water accumulation in the rudder trim tab, which could result in a change in the mass properties and thus result in the lower flutter speed of the airplane. Airplane flutter could result in failure and loss of control of the airplane.

What Must I Do To Address This Problem?

(e) To address this problem, you must do the following:

Actions	Compliance	Procedures
(1) *For Group 1 Airplanes:* Inspect the rudder trim tab for proper moisture drainage provisions.	Within 150 hours time-in-service (TIS) after April 30, 1992 (the effective date of AD 92–07–05), unless already done.	Follow Beech Service Bulletin No. 2365, Revision 1, dated December 1991.
(2) *For Group 1 Airplanes:* If the correct drainage provisions do not exist, prior to further flight, modify the rudder trim tab.	Before further flight after the inspection required by paragraph (e)(1) of this AD.	Follow Beech Service Bulletin No. 2365, Revision 1, dated December 1991.
(3) *For Group 2 Airplanes:* Inspect the rudder trim tab for proper moisture drainage provisions.	Within 150 hours time-in-service (TIS) after the effective date of this AD, unless already done.	Follow Raytheon Aircraft Company Service Bulletin No. SB 55–2365, Revision 2, Issued: January 1991, Revised: October 2005.
(4) *For Group 2 Airplanes:* If the correct drainage provisions do not exist, prior to further flight, modify the rudder trim tab.	Before further flight after the inspection required by paragraph (e)(3) of this AD.	Follow Raytheon Aircraft Company Service Bulletin No. SB 55–2365, Revision 2, Issued: January 1991, Revised: October 2005.

May I Request an Alternative Method of Compliance?

(f) The Manager, Wichita Aircraft Certification Office (ACO), FAA, has the authority to approve alternative methods of compliance (AMOCs) for this AD, if requested using the procedures found in 14 CFR 39.19.

(i) For information on any already approved AMOCs or for information pertaining to this AD, contact Steven E. Potter, Aerospace Engineer, Wichita ACO, FAA, 1801 Airport Road, Wichita, Kansas 67209; telephone: (316) 946–4124; facsimile: (316) 946–4107.

(ii) AMOCs approved for AD 92–07–05 are not approved for this AD.

May I Get Copies of the Documents Referenced in This AD?

(g) To get copies of the documents referenced in this AD, contact Raytheon Aircraft Company, P.O. Box 85, Wichita, Kansas 67201–0085; telephone: (800) 429–5372 or (316) 676–3140. To view the AD docket, go to the Docket Management Facility; U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, Room PL–401, Washington, DC, or on the Internet at *http://dms.dot.gov*. The docket number is Docket No. FAA–2005–23319; Directorate Identifier 2005–CE–52–AD.

Issued in Kansas City, Missouri, on January 31, 2006.

John R. Colomy,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. E6–1562 Filed 2–3–06; 8:45 am]

BILLING CODE 4910–13–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2005–MD–0014; FRL–8028–3]

Approval and Promulgation of Air Quality Implementation Plans; Maryland; Amendments to the Control of VOC Emissions From Yeast Manufacturing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve a State Implementation Plan (SIP) revision submitted by Maryland. This revision pertains to the amendment of a regulation that controls volatile organic compound (VOC) emissions from yeast manufacturing facilities. This action is being taken under the Clean Air Act (CAA or the Act).

DATES: Written comments must be received on or before March 8, 2006.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA–R03–OAR–2005–MD–0014 by one of the following methods:

A. *Http://www.regulations.gov*. Follow the on-line instructions for submitting comments.

B. E-mail: *morris.makeba@epa.gov*.

C. Mail: EPA–R03–OAR–2005–MD–0014, Makeba Morris, Chief, Air Quality Planning Branch, Mailcode 3AP21, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

D. Hand Delivery: At the previously-listed EPA Region III address. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–R03–OAR–2005–MD–0014. EPA's policy is that all comments received will be included in the public docket without change, and may be made available online at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or e-mail. The *http://www.regulations.gov* Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *http://www.regulations.gov*, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the electronic docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are available at the Maryland Department of the Environment, 1800 Washington Boulevard, Suite 705, Baltimore, Maryland, 21230.

FOR FURTHER INFORMATION CONTACT: Rose Quinto, (215) 814–2182, or by e-mail at *quinto.rose@epa.gov*.

SUPPLEMENTARY INFORMATION: On October 31, 2005, the Maryland Department of the Environment (MDE) submitted a revision to the Maryland SIP. The SIP revision consists of amendments to COMAR 26.11.19.17—Control of VOC Emissions from Yeast Manufacturing.

I. Background

COMAR 26.11.19.17 contains requirements for the control of VOC emissions from sources that manufacture yeast. In 2004, the regulation was amended to clarify requirements for sources that manufacture both nutritional yeast and specialty yeast. The amendment provided more flexibility for sources that could manufacture specialty yeast and meet VOC standards that were developed for the lower emitting nutritional yeast. The amendment also included changes that made Maryland's regulation consistent with EPA's maximum achievable control technology (MACT) standards for nutritional yeast. In addition, the amendment required sources to demonstrate that the standards were met at least 98 percent of the time for each 12-month period.

II. Summary of SIP Revision

The amendments submitted on October 31, 2005 to COMAR 26.11.19.17 are: (1) To reinstate the requirements for non-nutritional and specialty yeast installations to meet certain operational requirements to minimize VOC emissions, and (2) to clarify the 98 percent compliance demonstration is a 12-month rolling average.

The amendment requires pure culture and yeasting installations (non-nutritional and specialty yeast installations) to monitor temperature, pH, and sugar content of the batch to minimize the formation and emission of VOC. The amendment also requires batch production information be collected each month and that the semi-annual reports submitted to MDE include this monthly data. The semi-annual report shall include: (1) A summary of the number of batches for each month and calculations showing the percent of batches that met the VOC standards for each month, and (2) calculations showing the percent of batches that met the VOC standards during the previous six 12-month rolling average periods. Affected sources are required to meet the VOC standards for at least 98 percent of the batches produced during each rolling 12-month period, beginning July 1, 2004.

III. Proposed Action

EPA is proposing to approve the Maryland SIP revision for the amendments to the regulation regarding the control of VOC emissions from yeast manufacturing facilities, which was submitted on October 31, 2005. Implementation of these amendments will result in the reduction of VOC emissions from yeast manufacturing facilities. EPA is soliciting public comments on the issues discussed in this document. These comments will be considered before taking final action.

IV. Statutory and Executive Order Reviews

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this proposed action is not a "significant regulatory action" and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355 (May 22, 2001)). This action merely proposes to approve state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this proposed rule 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 this rule proposes to approve pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). This proposed rule also does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it merely proposes to approve a state rule implementing a Federal requirement, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. This proposed rule also is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it is not economically significant.

In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 *note*) do not apply. As required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996), in issuing this proposed rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct. EPA has complied with Executive Order 12630 (53 FR 8859, March 15, 1988) by examining the takings implications of the rule in accordance with the "Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings" issued under the executive order.

This proposed rule pertaining to Maryland's amendments to the regulations pertaining to the control of VOC emissions from yeast

manufacturing facilities, does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: January 26, 2006.

Donald S. Welsh,

Regional Administrator, Region III.

[FR Doc. E6–1596 Filed 2–3–06; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA–HQ–OAR–2005–0155; FRL–8028–4]

RIN 2060–AK18

National Perchloroethylene Air Emission Standards for Dry Cleaning Facilities

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; extension of public comment period.

SUMMARY: EPA is announcing that the comment period on the proposed National Perchloroethylene Emission Standards for Dry Cleaning Facilities, published on December 21, 2005 (70 FR 75884), is being extended until March 23, 2006.

DATES: The comment period has been extended from February 6, 2006 to on or before March 23, 2006.

ADDRESSES: *Comments.* Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2005–0155, by one of the following methods:

- *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *E-mail: a-and-r-docket@epa.gov,* Attention Docket ID No. EPA–HQ–OAR–2005–0155.
- *Fax:* (202) 566–1741, Attention Docket ID No. EPA–HQ–OAR–2005–0155.
- *Mail:* U.S. Postal Service, send comments to: EPA Docket Center (6102T), Attention Docket ID No. EPA–HQ–OAR–2005–0155, 1200 Pennsylvania Avenue, NW., Washington, DC 20460. Please include a total of two copies.
- *Hand Delivery:* In person or by courier, deliver comments to: EPA Docket Center (6102T), Attention Docket ID No. EPA–HQ–OAR–2005–0155, 1301 Constitution Avenue, NW., Room B–108, Washington, DC 20004. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information. Please include a total of two copies.

Instructions: Direct your comments to Docket ID No. EPA–HQ–OAR–2005–0155. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be confidential business information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or e-mail. Send or deliver information identified as CBI to only the following address: Mr. Roberto Morales, OAQPS Document Control Officer, EPA (C404–02), Attention Docket ID No. EPA–HQ–OAR–2005–0155, Research Triangle Park, NC 27711. Clearly mark the part or all of the information that you claim to be CBI. The *http://www.regulations.gov* Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *http://www.regulations.gov,* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.*

Docket: All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.*, CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at the EPA Docket Center, Docket ID No. EPA–HQ–OAR–2005–0155, EPA West Building, Room B–102, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the EPA Docket Center is (202) 566–1742. A reasonable fee may be charged for copying docket materials.

FOR FURTHER INFORMATION CONTACT: Ms. Rhea Jones, EPA, Office of Air Quality Planning and Standards, Sector Policies and Programs Division, Program Design Group, Research Triangle Park, NC 27711; telephone number (919) 541–2940; facsimile number (919) 541–5689; e-mail address *jones.rhea@epa.gov.*

SUPPLEMENTARY INFORMATION: *Regulated Entities.* Categories and entities potentially regulated by the proposed rule are industrial and commercial PCE dry cleaners. The proposed rule affects the following categories of sources:

Category	NAICS [1] Code	Examples of potentially regulated entities
Coin-operated Laundries and Dry Cleaners	812310	Dry-to-dry machines. Transfer machines.
Dry Cleaning and Laundry Services (except coin-operated)	812320	Dry-to-dry machines. Transfer machines.
Industrial Launderers	812332	Dry-to-dry machines. Transfer machines.

[1] North American Industry Classification System.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by the proposed rule. To determine whether your facility is regulated by the proposed rule, you should examine the applicability criteria in 40 CFR 63.320 of subpart M (1993 Dry Cleaning NESHAP). If you have any questions regarding the applicability of the proposed rule to a particular entity, contact the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

Submitting CBI: Do not submit information which you claim to be CBI to EPA through *http://www.regulations.gov* or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information submitted on a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

Worldwide Web (WWW). In addition to being available in the docket, an electronic copy of the proposed rule is also available on the WWW. Following the Administrator's signature, a copy of the proposed rule will be posted on EPA's Technology Transfer Network (TTN) policy and guidance page for newly proposed or promulgated rules at *http://www.epa.gov/ttn/oarpg.* The TTN provides information and technology exchange in various areas of air pollution control.

Comment Period

We received a request to extend the public comment period to March 23, 2006. We agreed to this request, therefore, the public comment period will now end on March 23, 2006, rather than February 6, 2006.

How can I get copies of the proposed amendments and other related information?

EPA has established the official public docket for the proposed rulemaking under docket ID No. EPA–HQ–OAR–2005–0155. Information on how to access the docket is presented above in the **ADDRESSES** section. In addition, information may be obtained from the webpage for the proposed rulemaking at: *http://www.epa.gov/ttn/atw/dryperc/dryclpg.html,* or from the **Federal Register** (70 FR 75884, December 21, 2005).

Dated: January 27, 2006.

William L. Wehrum,

Acting Assistant Administrator for Air and Radiation.

[FR Doc.06–1070 Filed 2–3–06 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[I.D. 013006I]

RIN 0648–AT09

Fisheries of the Exclusive Economic Zone Off Alaska; Groundfish, Crab, Salmon, and Scallop Fisheries of the Bering Sea and Aleutian Islands Management Area and Gulf of Alaska

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Announcement of availability of proposed amendments to fishery management plans; request for comments.

SUMMARY: The North Pacific Fishery Management Council (Council) has submitted Amendments 78 and 65 to the Fishery Management Plan (FMP) for Groundfish of the Bering Sea and Aleutian Islands Management Area (BSAI), Amendments 73 and 65 to the FMP for Groundfish of the Gulf of Alaska (GOA), Amendments 16 and 12 to the FMP for Bering Sea/Aleutian Islands King and Tanner Crabs, Amendments 7, 9, and 11 to the FMP for the Scallop Fishery Off Alaska, and Amendments 7 and 8 to the FMP for Salmon Fisheries in the Exclusive Economic Zone Off the Coast of Alaska. These amendments, if approved, would revise the FMPs by identifying and authorizing protection measures for essential fish habitat (EFH) and habitat areas of particular concern (HAPCs) in all five FMPs and update the biological and management information in the scallop FMP. This action is necessary to revise the descriptions of EFH in the FMPs based on the best available scientific information and to protect areas that have important habitat features for the sustainability of managed fish stocks. This action also is necessary to provide an updated FMP for scallop fishery management. This action is intended to promote the goals and objectives of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), the FMPs, and other applicable laws. Comments from the public are welcome.

DATES: Comments on the amendments must be received by close of business on April 7, 2006.

ADDRESSES: Send comments to Sue Salveson, Assistant Regional Administrator, Sustainable Fisheries Division, Alaska Region, NMFS, Attn: Records Officer. Comments may be submitted by:

- Mail: P.O. Box 21668, Juneau, AK 99802.
- Hand delivery: 709 West 9th Street, Room 420A, Juneau, AK.
- Fax: 907–586–7557.
- E-mail: *EFH-HAPC-NOA–0648–AT09@noaa.gov.* Include in the subject line the following document identifier: EFH-HAPC NOA. E-mail comments, with or without attachments, are limited to 5 megabytes.
- Webform at the Federal eRulemaking Portal: *www.regulations.gov.* Follow the instructions at that site for submitting comments.

Copies of FMP amendments, maps of the EFH and HAPC areas, the Environmental Impact Statement (EIS) for EFH, and the Environmental Assessment/Regulatory Impact Review/Initial Regulatory Flexibility Analysis (EA/RIR/IRFA) for HAPCs may be obtained from the same address or from the Alaska Region NMFS website at *www.fakr.noaa.gov.*

FOR FURTHER INFORMATION CONTACT: Melanie Brown, 907–586–7228 or *melanie.brown@noaa.gov.*

SUPPLEMENTARY INFORMATION: The Magnuson-Stevens Act requires that the Council submit any FMP amendment it prepares to NMFS for review and approval, disapproval, or partial approval. The Magnuson-Stevens Act also requires that NMFS, upon receiving a FMP amendment, immediately publish a notice in the **Federal Register** that the amendment is available for public review and comment.

Section 303(a)(7) of the Magnuson-Stevens Act requires that each FMP describe and identify EFH, minimize to the extent practicable the adverse effects of fishing on EFH, and identify other measures to promote the conservation and enhancement of EFH. The Council adopted the EFH and HAPC amendments in February 2005. If approved by NMFS, these amendments would revise the FMPs by updating the description and identification of EFH, changing the identification of HAPCs, and authorizing protection measures for

EFH and HAPCs. This action would continue the Council's policy of implementing precautionary conservation measures for the Alaska fisheries, as described in the management policies and objectives added to the groundfish FMPs in 2004 (69 FR 31091, June 2, 2004).

The Council developed the EFH and HAPC FMP amendments as a result of a new and thorough EIS analysis of the measures needed to identify and conserve EFH in Alaska. The analysis stemmed from a United States District Court order resulting from litigation that challenged the approval of previous EFH amendments to the Council's FMPs (*American Oceans Campaign et al.* v. *Daley et al.*, Civil Action N. 99–982–GK).

The amendments specify EFH and HAPC provisions for each FMP. The following summarizes the amendments under each group of provisions. The EIS for EFH, the EA/RIR/IRFA for HAPC, and maps of the proposed fishery restrictions described below are available from NMFS (see **ADDRESSES**).

EFH Amendments

The Council recommended three actions for EFH. Action 1 would revise the description and identification of EFH in the FMPs using new information and improved mapping. This action would ensure the best scientific information available is used to describe and identify EFH in the FMPs, as required by 50 CFR 600.815(a)(1)(ii)(B). Action 2 would adopt an approach for identifying HAPCs. The amendments would rescind existing HAPCs and would add a procedure for identifying HAPCs based on specific sites within EFH that are necessary to address particular habitat concerns.

Action 3 would establish several types of management areas in the BSAI and the GOA to minimize the adverse effects of fishing on EFH. The Aleutian Islands Habitat Conservation Area (AIHCA) would consist of the entire Aleutian Islands subarea except for specified areas that have supported the highest groundfish catches in the past. The AIHCA would be closed to all nonpelagic trawling to protect relatively undisturbed habitats. The Council determined that the AIHCA would provide a balance between continued fishing in the Aleutian Islands subarea and protection of sensitive habitats such as cold water corals. This closure would include habitat areas that are not identified as EFH. Specifically, the AIHCA would include habitat areas that extend beyond the limits of EFH for groundfish, crabs, and scallops. The Council has identified the water column in all of these areas as EFH for marine salmon, but the bottom habitats have not been well surveyed, and therefore are not considered EFH. The Council developed the AIHCA primarily to address potential effects on EFH, but included these habitat areas outside of EFH as part of the Council's overall effort to be precautionary and preclude damage to habitats that may be important for Council managed species.

The EFH amendments also would establish six Aleutian Islands Coral Habitat Protection Areas (AICHPAs) that would be closed to all bottom contact gear (nonpelagic trawl, hook-and-line, pot, dredge, and dinglebar gears) and to anchoring by fishing vessels. These areas contain especially diverse and fragile living habitat structures that are particularly sensitive to the impacts of bottom contact gear and anchoring, and have long recovery times once damaged. The Council determined that a higher level of protection is appropriate for these uncommon habitats.

In the GOA, the EFH amendments would establish ten GOA Slope Habitat Conservation Areas (GOASHCAs) where nonpelagic trawling for groundfish would be prohibited. These areas would provide refuge for rockfish and other managed species and long term protection for corals. Pelagic trawl gear used in the directed pollock fishery would be allowed in the AIHCA, AICHPAs, and GOASHCAs only in an off-bottom mode based on the performance standard contained in 50 CFR 679.7(a)(14).

HAPC Amendments

The Council also recommended three actions to identify and manage HAPCs. Action 1 identifies 15 Alaska Seamount Habitat Protection Areas where all bottom contact gear and anchoring by fishing vessels would be prohibited. Seamounts provide unique oceanographic and living habitat features that provide important habitat for fish. Action 2 establishes the GOA Coral Habitat Protection Areas where all bottom contact gear and anchoring by fishing vessels would be prohibited. During survey work using submersible dives, NMFS identified dense thickets of *Primnoa* sp. coral in these areas. These living habitat structures grow very slowly, are sensitive to disturbance by bottom contact gear and anchoring, have long recovery times, and have been identified as potential refugia for managed species. Restricting bottom contact gear and anchoring would ensure the living structures would be protected from fishing activities that may adversely impact the habitat.

Action 3 would designate the Bowers Ridge Habitat Conservation Zone (BRHCZ) as a HAPC located in the BSAI and would prohibit mobile bottom contact fishing gear (nonpelagic trawl, dredge, and dinglebar gear) in this area. The Council recommended limiting the fishery prohibition for the BRHCZ to mobile bottom contact gear until more research can be done in this area to determine if additional restrictions would be appropriate for fixed gear fisheries. The mobile bottom contact gear prohibition would provide precautionary management for Bowers Ridge and the Ulm Plateau based on the limited information available for these sites located in the BRHCZ.

Scallop FMP Update

In April 2005, the Council unanimously voted to adopt Amendment 11, a housekeeping amendment that would update the scallop FMP to reflect the current management of the scallop fishery and recent biological information. No implementing regulations would be required for this amendment.

Public Comments

NMFS is soliciting public comments on the proposed amendments through April 7, 2006. A proposed rule that would implement the EFH and HAPC amendments will be published in the **Federal Register** for public comment at a later date, following NMFS' evaluation under the Magnuson-Stevens Act procedures. Public comments on the proposed rule must be received by the end of the comment period on the amendments in order to be considered in the approval/disapproval decision on the amendments. All comments received on the amendments by the end of the comment period, whether specifically directed to the amendments or to the proposed rule, will be considered in the approval/disapproval decision. Comments received after that date will not be considered in the approval/disapproval decision on the amendments. To be considered, comments must be received—not just postmarked or otherwise transmitted—by close of business on the last day of the comment period.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: January 31, 2006.

Alan D. Risenhoover,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 06–1083 Filed 2–3–06; 8:45 am]

BILLING CODE 3510–22–S

Notices

Federal Register
Vol. 71, No. 24
Monday, February 6, 2006

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

Commodity Credit Corporation

Notice of Request for Extension and Revision of Currently Approved Information Collections

AGENCY: Commodity Credit Corporation, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Commodity Credit Corporation's (CCC) intention to request an extension for, and revision to, a currently approved information collection process in support of the Foreign Market Development Cooperation (Cooperator) Program and the Market Access Program (MAP).

DATES: Comments on this notice must be received by April 7, 2006, to be assured of consideration.

ADDITIONAL INFORMATION OR COMMENTS: Contact Director, Marketing Operations Staff, Foreign Agricultural Service, U.S. Department of Agriculture, 1400 Independence Avenue, SW., Washington, DC 20250–1042, (202) 720–4327.

SUPPLEMENTARY INFORMATION:

Title: Foreign Market Development Cooperator Program and Market Access Program.

OMB Number: 0551–0026.

Expiration Date of Approval: June 30, 2006.

Type of Request: Extension and revision of a currently approved information collection process.

Abstract: The primary objective of the Foreign Market Development Cooperator Program and the Market Access Program is to encourage and aid in the creation, maintenance and expansion of commercial export markets for U.S. agricultural products through cost-share assistance to eligible trade organizations. The programs are a cooperative effort between CCC and the eligible trade organizations. Currently, there are about 70 organizations participating directly in the programs with activities in more than 100 countries. Prior to initiating program activities, each Cooperator or MAP participant must submit a detailed application to Foreign Agricultural Service (FAS) which includes an assessment of overseas market potential; market or country strategies, constrains, goals and benchmarks; proposed market development activities; estimated budgets; and performance measures. Prior years' plans often dictate the content of current year plans because many activities are continuations of previous activities. Each Cooperator or MAP participant is also responsible for submitting: (1) Reimbursement claims for approved costs incurred in carrying out approved activities, (2) an end-of-year contribution report, (3) travel reports, and (4) progress reports/evaluation studies. Cooperators, or MAP participants must maintain records on all information submitted to FAS. The information collected is used by FAS to manage, plan, evaluate and account for Government resources. The reports and records are required to ensure the proper and judicious use of public funds.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 21 hours per response.

Respondents: Non-profit trade organizations, state groups, cooperative, and commercial entities.

Estimated Number of Respondents: 71.

Estimated Number of Responses per Respondent: 62.

Estimated Total Annual Burden on Respondents: 91,442 hours.

Copies of this information collection can be obtained from Kimberly Chisley, the Agency Information Collection Coordinator, at (202) 720–2568.

Request for Comments: Send comments regarding the accuracy of the burden estimate, ways to minimize the burden, including through the use of automated collection techniques or other forms of information technology, or any other aspect of this collection of information, to: Director, Marketing Operations Staff, U.S. Department of Agriculture, 1400 Independence Ave., SW., STOP 1042, Washington, DC 20250–1042. Facsimile submissions may be sent to (202) 720–9361 and electronic mail submissions should be addressed to: *mosadmin@fas.usda.gov.* All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Signed at Washington, DC on January 26, 2006.

W. Kirk Miller,

Acting Administrator, Foreign Agricultural Service, and Vice President, Commodity Credit Corporation.

[FR Doc. 06–1051 Filed 2–3–06; 8:45 am]

BILLING CODE 3410–10–M

DEPARTMENT OF AGRICULTURE

Forest Service

Notice of Resource Advisory Committee, Sundance, WY

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: Pursuant to the authorities in the Federal Advisory Committee Act (Pub. L. 92–463) and under the Secure Rural Schools and Community Self-Determination Act of 2000 (Pub. L. 106–393) the Black Hills National Forests's Crook County Resource Advisory Committee will meet Monday, February 20th, 2006 in Sundance, Wyoming for a business meeting. The meeting is open to the public.

SUPPLEMENTARY INFORMATION: The business meeting on February 20th will begin at 6:30 p.m., at the USFS Bearlodge Ranger District office, 121 South 21st Street, Sundance, Wyoming. Agenda topics will include presentation of appointments to the Crook County Resource Advisory Committee, election of officers, review of previously funded projects and examination of new project proposals. A public forum will begin at 8:30 p.m. (MT).

FOR FURTHER INFORMATION CONTACT: Steve Kozel, Bearlodge District Ranger and Designated Federal Officer at (307) 283–1361.

Dated: January 26, 2006.

Steven J. Kozel,

District Ranger, Bearlodge Ranger District.

[FR Doc. 06–955 Filed 2–3–06; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

National Agricultural Statistics Service

Notice of Intent To Seek Approval To Conduct an Information Collection

AGENCY: National Agricultural Statistics Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–113) and Office of Management and Budget regulations at 5 CFR part 1320 (60 FR 44978, August 29, 1995), this notice announces the intention of the National Agricultural Statistics Service (NASS) to request approval to conduct a new information collection, the Distillers Grains Survey.

DATES: Comments on this notice must be received by April 7, 2006 to be assured of consideration.

ADDRESSES: Comments may be mailed to Ginny McBride, NASS Clearance Officer, U.S. Department of Agriculture, Room 5336 South Building, 1400 Independence Avenue SW., Washington, DC 20250 or sent electronically to *gmcbride@nass.usda.gov.*

FOR FURTHER INFORMATION CONTACT: Joseph T. Reilly, Associate Administrator, National Agricultural Statistics Service, U.S. Department of Agriculture, (202) 720–4333.

SUPPLEMENTARY INFORMATION:

Title: Distillers Grains Survey.

Type of Request: Intent to Seek Approval to Conduct a New Information Collection.

Abstract: The primary objective of the National Agricultural Statistics Service is to prepare and issue State and national estimates of crop and livestock production, prices, and disposition. The goal of this NASS project is to conduct a large-scale survey to measure livestock producers' use of distillers grains, which are nutritional by-products of ethyl alcohol (ethanol) production.

President Bush has encouraged increases in energy production so America will be less dependent on foreign oil. U.S. production of ethanol is a part of that energy strategy and recent passage of the Renewable Fuels Standard by Congress strengthens the ethanol industry's continued expansion. As more ethanol is produced, there is also more of an important by-product of the corn ethanol dry mill process: distillers grains. These distillers grains contain valuable protein, fiber, vitamins, and minerals and can be utilized as quality livestock feed. Secretary of Agriculture Johanns, then Governor of Nebraska, said in July 2002, "We must develop other markets for ethanol and its by-products. As all ethanol producers can tell you, markets for the by-products help make the plant profitable." Distillers grains are now sold mainly to livestock operations in the immediate vicinity of ethanol plants. Marketing of the increasingly large volume of distillers grains to more livestock producers at higher feed ratios would generate more sales, contributing to plant stability and profitability.

Three small-scale studies of distillers grains were conducted in 2003 by the Iowa Department of Agriculture and Land Stewardship in partnership with the USDA/Federal-State Market Improvement Program. A status and assessment survey was conducted for each segment of the industry—ethanol producers, feed companies and marketers, and livestock feeders—to obtain data such as operation profiles, types and quantities of distillers grains, product qualities, volume of sales, pricing, storage facilities, marketing channels, plant services, transportation requirements, species fed, and feed ratios. In its summary report, which was disseminated at conferences and workshops, the Iowa Department of Agriculture and Land Stewardship noted that ethanol plants "must be able to sell their distillers grains, not just dispose of them * * *. It is an excellent product and more livestock feeders must be educated about its benefits and encouraged to make it a vital and substantial part of their feeding rations." To facilitate the marketing of distillers grains locally, regionally, and globally, the Department concluded that: (1) The nation's livestock feeders must be surveyed and tracked; different surveys should be administered to target feeders in States with the largest concentrations of specific species. (2) Any barriers to usage must be addressed. (3) The customer base must be expanded and the feed usage raised. (4) Distillers grains promotions and education must be greatly expanded to match the increased levels of distillers grains being produced.

NASS will collaborate with Nebraska Corn Development's Utilization & Marketing Board, an agency of the State of Nebraska, to conduct a survey of livestock producers in 12 Midwestern States in early 2007. The survey will contact livestock operations to determine the extent of feeding of ethanol by-products, any factors preventing the use of distillers grains in feed rations, and aspects on which producers base their decisions regarding livestock feed, such as nutrient values, product consistency, product form, product testing, inclusion rates, economics, shelf life, storage, and transportation. The probability-based survey will include beef (cow/calf and feedlot), dairy, and swine species with targeted size-of-operation criteria. Due to the complex structure of the poultry industry and limited resources available for this survey, poultry will not be studied. The survey will be conducted in Illinois, Indiana, Iowa, Kansas, Michigan, Minnesota, Missouri, Nebraska, North Dakota, Ohio, South Dakota, and Wisconsin. The survey reference date will be the calendar year 2006. Approximately 9,400 operations will be contacted by mail about February 1, 2007, with a second mailing and telephone follow-up later in the month. The National Agricultural Statistics Service will publish summaries in June 2007 at the regional level, combining all States surveyed for each livestock species. Most of the figures will be proportions or percentages which will allow statistical comparisons among operations not feeding distillers grains.

These data will be collected under the authority of 7 U.S.C. 2204(a). Individually identifiable data collected under this authority are governed by Section 1770 of the Food Security Act of 1985, 7 U.S.C. 2276, which requires USDA to afford strict confidentiality to non-aggregated data provided by respondents.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 20 minutes per response.

Respondents: Farm operators.

Estimated Number of Respondents: 9,400.

Estimated Total Annual Burden on Respondents: 3,200 hours.

Copies of this information collection and related instructions can be obtained without charge from Ginny McBride, NASS Clearance Officer, at (202) 720–5778.

Comments: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) The accuracy of the agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (c) Ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated,

electronic, mechanical, or other technological collection techniques or other forms of information technology.

All responses to this notice will become a matter of public record and be summarized in the request for OMB approval.

Signed at Washington, DC, January 19, 2006.

Joseph T. Reilly,

Associate Administrator.

[FR Doc. E6–1530 Filed 2–3–06; 8:45 am]

BILLING CODE 3410–20–P

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the New Mexico Advisory Committee

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights, that a meeting of the New Mexico State Advisory Committee will convene at 1 p.m. (MST) and adjourn at 4 p.m. (MST), Thursday, February 23, 2006, at the Courtyard Marriott Airport, 1920 Yale Blvd, Albuquerque, New Mexico 87106. The purpose of the meeting is to provide a status report on the Commission and regional programs, discuss the Farmington report, *The Farmington Report: Civil Rights for Native Americans 30 Years Later,* and future planning.

Persons desiring additional information, or planning a presentation to the Committee, should contact John F. Dulles, Director of the Rocky Mountain Regional Office, (303) 866–1040 (TDD 303–866–1049). Hearing-impaired persons who will attend the meeting and require the services of a sign language interpreter should contact the Regional Office at least ten (10) working days before the scheduled date of the meeting.

The meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission.

Dated at Washington, DC February 1, 2006.

Ivy L. Davis,

Acting Chief, Regional Programs Coordination Unit.

[FR Doc. E6–1551 Filed 2–3–06; 8:45 am]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Alaska Individual Fishing Quota Cost Recovery Program Requirements.

Form Number(s): None.

OMB Approval Number: 0648–0398.

Type of Request: Regular submission.

Burden Hours: 5,452.

Number of Respondents: 2,700.

Average Hours Per Response: 2 hours to complete Individual Fishing Quota (IFQ) Permit Holder Fee Submission Form; 2 hours to complete IFQ Registered Buyer Ex-vessel Value and Volume Report; 2 hours to complete the appeal process; and 30 minutes for prepayment of fees.

Needs and Uses: The Magnuson-Stevens Fishery Conservation and Management Act requires that the Secretary of Commerce maintain a Cost Recovery Program to cover the management and enforcement costs of the Individual Fishing Quotas for Pacific Halibut and Sablefish in the Alaska Fisheries (IFQs) Program. This Cost Recovery Program requires Registered Buyers to submit information about the volume and value of IFQ species landings and for the IFQ permit holders to calculate and submit fees.

Affected Public: Business or other for-profit organizations; individuals or households.

Frequency: Annually and on occasion.

Respondent's Obligation: Mandatory.

OMB Desk Officer: David Rostker, (202) 395–3897.

Copies of the above information collection proposal can be obtained by calling or writing Diana Hynek, Departmental Paperwork Clearance Officer, (202) 482–0266, Department of Commerce, Room 6625, 14th and Constitution Avenue, NW., Washington, DC 20230 (or via the Internet at *dHynek@doc.gov*).

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to David Rostker, OMB Desk Officer, Fax number (202) 395–7285, or *David_Rostker@omb.eop.gov.*

Dated: January 31, 2006.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. E6–1528 Filed 2–3–06; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Processed Product Family of Forms.

Form Number(s): None.

OMB Approval Number: 0648–0018.

Type of Request: Regular submission.

Burden Hours: 680.

Number of Respondents: 1,320.

Average Hours Per Response: 30 minutes for the annual survey and 15 minutes for the monthly report.

Needs and Uses: This is a survey of seafood and industrial fish processing firms. The firms processing fish from certain fisheries must report on their annual volume, the wholesale value of products, and monthly employment figures. Data are used in economic analyses to estimate the capacity and extent to which processors utilize domestic harvest. These analyses are necessary to carry out the provision of the Magnuson-Stevens Fishery Conservation and Management Act.

Affected Public: Business or other for-profit organizations.

Frequency: Annually and monthly.

Respondent's Obligation: Mandatory.

OMB Desk Officer: David Rostker, (202) 395–3897.

Copies of the above information collection proposal can be obtained by calling or writing Diana Hynek, Departmental Paperwork Clearance Officer, (202) 482–0266, Department of Commerce, Room 6625, 14th and Constitution Avenue, NW., Washington, DC 20230 (or via the Internet at *dHynek@doc.gov*).

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to David Rostker, OMB Desk Officer, Fax number (202) 395–7285, or *David_Rostker@omb.eop.gov.*

Dated: January 31, 2006.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. E6–1531 Filed 2–3–06; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Alaska Seabird Avoidance Program.

Form Number(s): None.

OMB Approval Number: 0648–0474.

Type of Request: Regular submission.

Burden Hours: 16,000.

Number of Respondents: 2,000.

Average Hours per Response: 8 hours.

Needs and Uses: This collection describes an activity of the National Marine Fisheries Service, Alaska Region (NMFS) intended to reduce the incidental take of the short-tailed albatross and other seabird species. The goal of the Seabird Avoidance Plan is to potentially benefit the endangered short-tailed albatross population and populations of other seabird species and to reduce the risk of potentially serious economic impacts to the Alaska hook-and-line fisheries. If the incidental take limit of short-tailed albatross and other seabird species under the section 7 ESA consultation were exceeded, fishery closures could become a possibility under the section 7 consultation process.

Affected Public: Business or other for-profit organizations; individuals or households.

Frequency: Annually.

Respondent's Obligation: Mandatory.

OMB Desk Officer: David Rostker, (202) 395–3897.

Copies of the above information collection proposal can be obtained by calling or writing Diana Hynek, Departmental Paperwork Clearance Officer, (202) 482–0266, Department of Commerce, Room 6625, 14th and Constitution Avenue, NW., Washington, DC 20230 (or via the Internet at *dHynek@doc.gov*).

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to David Rostker, OMB Desk Officer, Fax number (202) 395–7285, or *David_Rostker@omb.eop.gov*.

Dated: January 31, 2006.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. E6–1535 Filed 2–3–06; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce (DOC) has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35)

Agency: Bureau of Industry and Security (BIS).

Title: Statement by Ultimate Consignee and Purchaser.

Agency Form Number: BIS–711.

OMB Approval Number: 0694–0021.

Type of Request: Extension of a currently approved collection of information.

Burden: 582 hours.

Average Time per Response: 16 minutes.

Number of Respondents: 1,884 respondents.

Needs and Uses: This collection is required by Section 748.11 of the Export Administration Regulations (EAR). The Form BIS–711 or letter puts the importer on notice of the special nature of the goods proposed for export and conveys a commitment against illegal disposition. In order to effectively control commodities, BIS must have sufficient information regarding the end-use and end-user of the U.S. origin commodities to be exported. The information will assist the licensing officer in making the proper decision on whether to approve or reject the application for the license.

Affected Public: Individuals, businesses or other for-profit institutions.

Respondent's Obligation: Required.

OMB Desk Officer: David Rostker.

Copies of the above information collection proposal can be obtained by calling or writing Diana Hynek, DOC Paperwork Clearance Officer, (202) 482–0266, Department of Commerce, Room 6625, 14th and Constitution Avenue, NW., Washington, DC 20230.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to David Rostker, OMB Desk Officer, e-mail address, *David_Rostker@omb.eop.gov*, or fax number, (202) 395–7285.

Dated: January 31, 2006.

Madeleine Clayton,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. E6–1546 Filed 2–3–06; 8:45 am]

BILLING CODE 3510–DT–P

DEPARTMENT OF COMMERCE

U.S. Census Bureau

2007 Census of Governments Prelist Survey of Special Districts

ACTION: Proposed collection; comment request.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments must be submitted on or before April 7, 2006.

ADDRESSES: Direct all written comments to Diana Hynek, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6625, 14th and Constitution Avenue, NW., Washington, DC 20230 (or via the Internet at *DHynek@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Stephen Owens, Chief, Government Organization and Special Programs Branch, Governments Division, U.S. Census Bureau, Washington, DC 20233–6800 (301 763–5149).

SUPPLEMENTARY INFORMATION:

I. Abstract

The U.S. Census Bureau plans to request approval of data collection Form G–24, Prelist Survey of Special Districts. This form will be used to verify the existence of special districts for the 2002 Census of Governments, to obtain current mailing addresses, and to identify new districts. The quinquennial Census of Governments enumerates five types of local governments: county governments, municipal governments, township governments, school district governments, and special district governments. Lists of county, municipal and township governments are kept up-to-date through the Boundary and Annexation Survey conducted annually by the Geography Division of the Census

Bureau. School district governments and other "local education agencies" are kept current through data sharing arrangements with state education agencies, and the National Center for Education Statistics. There is no national source of information on special district governments. We, therefore, enlist the help of county clerks, and other county officials to provide information on changes in special districts, including the creation of new districts, disincorporation of existing districts, and address changes. An updated list is necessary for subsequent phases of the Census of Governments to ensure complete coverage and to minimize the need for remailings caused by inaccurate addresses.

II. Method of Collection

Each of the approximately 1,500 counties, consolidated city-county governments, and independent cities designated for the survey will be sent a printed list of previously identified special districts within their county areas. Respondents will be requested to review and update the list to identify those districts that are no longer active, districts with address changes, and districts that are not included in the list. For new special districts, respondents will be requested to provide, in addition to the district name, mailing addresses and the names of counties included in the service area.

This data collection effort will offer fax and e-mail as electronic response options, but no electronic form on the Internet. The Census Bureau explored the possibility of an electronic form during the previous survey cycle and determined that the nature of the information—unique and specific for every respondent—rendered this too costly. The effort required to develop and deploy a comprehensive and effective electronic response instrument would far exceed both the budget and potential benefits of such a method.

In addition, in keeping with Governments Division policy, we will accept responses prepared by the respondents from their own files in either electronic, or printed form.

III. Data

OMB Number: None.
Form Number: G–24.
Type of Review: Regular.
Affected Public: County governments, consolidated city-county governments, and independent cities.
Estimated Number of Respondents: 1,500.
Estimated Time Per Response: 0.5 hours.
Estimated Total Annual Burden Hours: 750.
Estimated Total Annual Cost: $15,000.00.
Respondent's Obligation: Voluntary.
Legal Authority: Title 13 U.S.C. Section 161.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: January 31, 2006.

Madeleine Clayton,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. E6–1527 Filed 2–3–06; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Census Bureau

2007 Census of Governments Local Government Directory Survey

ACTION: Proposed collection; comment request.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments must be submitted on or before April 7, 2006.

ADDRESSES: Direct all written comments to Diana Hynek, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6625, 14th and Constitution Avenue, NW., Washington, DC 20230 (or via the Internet at DHynek@doc.gov).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Stephen Owens, Chief, Government Organization and Special Programs Branch, Governments Division, U.S. Census Bureau, Washington, DC 20233–6800 (301 763–5149).

SUPPLEMENTARY INFORMATION:

I. Abstract

The U.S. Census Bureau plans to request approval of the 2007 Census of Governments Local Government Directory Survey data collection form: Form G–30 (Special District Governments). This form will be used for the following purposes: (1) To produce the official count of local government units in the United States; (2) To obtain descriptive information on the basic characteristics of governments; (3) To identify and delete inactive units; (4) To identify file duplicates and units that were dependent on other governments; and (5) To update and verify the mailing addresses of governments.

The 2007 Census of Governments Local Government Directory Survey consists of two basic content areas: Government organization, and government employment. For government organization we will ask for authorizing legislation, method of governance, web address, services provided, and corrections to the name and address of the government. For government employment we will ask for full-time employees, part-time employees and annual payroll.

II. Method of Collection

Each of the 36,000 special district governments will be sent an appropriate form. Respondents will be asked to verify or correct the name and mailing address of the government, answer the questions on the form, and return the form. Respondents will also be given an option of responding electronically over the internet.

III. Data

OMB Number: None.
Form Number: G–30.
Type of Review: Regular.
Affected Public: Special district governments.
Estimated Number of Respondents: 36,000.
Estimated Time Per Response: 0.25 hours.
Estimated Total Annual Burden Hours: 9,000.

Estimated Total Annual Cost: $180,000.00.

Respondent's Obligation: Voluntary.

Legal Authority: Title 13 United States Code, Section 161.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) The accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) Ways to enhance the quality, utility, and clarity of the information to be collected: and (d) Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: January 31, 2006.

Madeleine Clayton,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. E6–1533 Filed 2–3–06; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

International Trade Administration

North American Free-Trade Agreement, Article 1904; NAFTA Panel Reviews; Request for Panel Review

AGENCY: NAFTA Secretariat, United States Section, International Trade Administration, Department of Commerce.

ACTION: Notice of First Request for Panel Review.

SUMMARY: On January 30, 2006, Mittal Canada Inc. (formerly Ispat Sidbec Inc.) filed a First Request for Panel Review with the United States Section of the NAFTA Secretariat pursuant to Article 1904 of the North American Free Trade Agreement. Panel review was requested of the final results of the antidumping duty administrative review made by the United States Department of Commerce, International Trade Administration, respecting Carbon and Certain Alloy Steel Wire Rod from Canada. This determination was published in the **Federal Register**, (71 FR 3822) on January 24, 2006. The NAFTA Secretariat has assigned Case Number USA–CDA–2006–1904–04 to this request.

FOR FURTHER INFORMATION CONTACT: Caratina L. Alston, United States Secretary, NAFTA Secretariat, Suite 2061, 14th and Constitution Avenue, Washington, DC 20230, (202) 482–5438.

SUPPLEMENTARY INFORMATION: Chapter 19 of the North American Free-Trade Agreement ("Agreement") establishes a mechanism to replace domestic judicial review of final determinations in antidumping and countervailing duty cases involving imports from a NAFTA country with review by independent binational panels. When a Request for Panel Review is filed, a panel is established to act in place of national courts to reiew expeditiously the final determination to determine whether it conforms with the antidumping or countervailing duty law of the country that made the determination.

Under Article 1904 of the Agreement, which came into force on January 1, 1994, the Government of the United States, the Government of Canada and the Government of Mexico established *Rules of Procedure for Article 1904 Binational Panel Reviews* ("Rules"). These Rules were published in the **Federal Register** on February 23, 1994 (59 FR 8686).

A first Request for Panel Review was filed with the United States Section of the NAFTA Secretariat, pursuant to Article 1904 of the Agreement, on January 30, 2006, requesting panel review of the final determination described above.

The Rules provide that:

(a) A Party of interested person may challenge the final determination in whole or in part by filing a Complaint in accordance with Rule 39 within 30 days after the filing of the first Request for Panel Review (the deadline for filing a Complaint is March 1, 2006);

(b) A Party, investigating authority, or interested person that does not file a Complaint but that intends to appear in support of any reviewable portion of the final determination may participate in the panel review by filing a Notice of Appearance in accordance with Rule 40 within 45 days after the filing of the first Request for Panel Review (the deadline for filing a Notice of Appearance is March 16, 2006); and

(c) The panel review shall be limited to the allegations of error of fact or law, including the jurisdiction of the investigating authority, that are set out in the Complaints filed in the panel review and the procedural and substantive defenses raised in the panel review.

Dated: January 31, 2006.

Caratina L. Alston,

United States Secretary, NAFTA Secretariat.

[FR Doc. 06–1042 Filed 2–3–06; 8:45am]

BILLING CODE 3510–GT–M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; Estuary Restoration Act Database Projects

AGENCY: National Oceanic and Atmospheric Administration (NOAA).

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted on or before April 7, 2006.

ADDRESSES: Direct all written comments to Diana Hynek, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6625, 14th and Constitution Avenue, NW., Washington, DC 20230 (or via the Internet at *dHynek@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Perry Gayaldo, NMFS Restoration Center, 1315 East-West Highway, Silver Spring, MD 20910 or *Perry.Gayaldo@noaa.gov*.

SUPPLEMENTARY INFORMATION:

I. Abstract

Estuary habitat restoration project information (e.g., location, habitat type, goals, status, monitoring information) is collected in order to populate a restoration project database mandated by the Estuary Restoration Act (ERA) of 2000. The Estuary Restoration Act Database (ERAD) contains information for estuary habitat restoration projects funded through the ERA as well as non-ERA project data that meet quality control requirements and data standards established under the Act. The database provides information to improve restoration methods, provides the basis for required reports to Congress, and tracks estuary habitat acreage restored. It is accessible to the public via the Internet for data queries and project reports. Recipients of ERA funds are

required to submit specific information on habitat restoration projects into the ERAD database through an interactive Web site available over the Internet. The projects that are not funded through the ERA can be voluntarily entered into the database by project managers. Other federal agency and private grant programs may also require recipients to enter project information in the ERAD database.

II. Method of Collection

Project managers will electronically submit estuary restoration project information via NOAA's Estuary Restoration Act Database Web site (*https://neri.noaa.gov/*). The Web site contains a user-friendly data entry interface for project managers to enter and submit project information to the ERAD database. The data entry interface consists of a series of screens, containing several pull-down menus and text boxes, where users can enter specific project information (e.g. location, acreage restored, contacts, monitoring information). To facilitate the collection of information through the data entry interface, NOAA Fisheries provides worksheets containing database fields that can be downloaded and printed from the Web site. These worksheets can be used by project managers to guide information collection, and can then serve as a reference as project managers enter project information through the Web site. The reporting forms are also available in paper format to be sent to project managers as necessary.

III. Data

OMB Number: 0648–0479.
Form Number: None.
Type of Review: Regular submission.
Affected Public: Not-for-profit institutions; state, local, and tribal governments; and businesses or other for-profit (limited to organizations in the above categories engaging in estuary habitat restoration).
Estimated Number of Respondents: 255.
Estimated Time Per Response: Four hours for new projects submitted; and two hours for updates to current projects.
Estimated Total Annual Burden Hours: 810.
Estimated Total Annual Cost to Public: None.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: January 31, 2006.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. E6–1532 Filed 2–3–06; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Submission for OMB Review; Comment Request; Correction

AGENCY: National Oceanic and Atmospheric Administration (NOAA).

SUMMARY: This corrects the title of the information collection (*OMB Control No. 0648–471*) submitted to the Office of Management and Budget for review.

The notice was published on January 17, 2006 (Vol. 71, No. 10, page 2514).

Correction

The title of the information collection was listed as "Deep Seabed Mining Exploration Licenses." The correct title is "Highly Migratory Species Scientific Research Permits, Exempted Fishing Permits, and Letters of Authorization".

Dated: January 31, 2006.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. E6–1534 Filed 2–3–06; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 013006A]

New England Fishery Management Council; Atlantic Sea Scallop; Scoping Process

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of intent to prepare a supplemental environmental impact statement (SEIS) and notice of re-initiation of scoping process; request for comments.

SUMMARY: The New England Fishery Management Council (Council) announces its intent to prepare an amendment to the Atlantic Sea Scallop Fishery Management Plan (FMP) (*Placopecten magellanicus* (*Gmelin*)) and to prepare an SEIS to analyze the impacts of any proposed management measures. The Council is also formally re-initiating a public process to determine the scope of alternatives to be addressed in the amendment and SEIS. The purpose of this notification is to alert the interested public of the re-commencement of the scoping process and to provide for public participation in compliance with environmental documentation requirements.

DATES: The Council will discuss and take scoping comments at public meetings in February 2006. For specific dates and times of the scoping meetings, see **SUPPLEMENTARY INFORMATION.** Written scoping comments must be received on or before 5 p.m., local time, March 6, 2006.

ADDRESSES: The Council will take scoping comments at public meetings in New Hampshire, Massachusetts, and New Jersey. For specific locations, see **SUPPLEMENTARY INFORMATION.**

Written comments should be submitted by any of the following methods:

- Mail: Paul J. Howard, Executive Director, New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950. Mark the outside of the envelope, "Scoping Comments on Amendment 11 to the Scallop FMP."
- E-mail: *Scallopscoping@noaa.gov*
- Fax: (978) 465–3116.

Requests for copies of the scoping document and other information should be directed to Paul J. Howard, Executive Director, New England Fishery Management Council, 50 Water Street,

Mill 2, Newburyport, MA 01950, telephone (978) 465–0492. The scoping document is accessible electronically via the Internet at *http://www.nefmc.org.*

FOR FURTHER INFORMATION CONTACT: Paul J. Howard, Executive Director, New England Fishery Management Council (978) 465–0492.

SUPPLEMENTARY INFORMATION:

Background

The U.S. Atlantic sea scallop fishery is managed as one stock complex along the east coast from Maine to Cape Hatteras, North Carolina. The Atlantic Sea Scallop FMP became effective on May 15, 1982. The FMP has been amended a number of times since then. In 1994, Amendment 4 began a limited access program for the directed scallop fleet with day-at-sea (DAS) limits and other measures to manage the scallop resource more effectively. Limited access vessels were assigned to different DAS permit categories (full-time, part-time or occasional) according to their 1985–1990 fishing activity. A "general category" permit was created for vessels that did not qualify for limited access. These vessels could apply for a general category permit and land up to 400 lb (181.4 kg) of scallops a day. At the time, this possession limit was deemed suitable and sufficient to accommodate scallop bycatch on long trips and sporadic small-scale scallop fishing near shore by non-qualifying vessels. Until now, the Council has recommended that the general category permit remain open access, meaning any vessel can qualify for a permit. Since 1999, there has been considerable growth in fishing effort and landings by vessels with general category permits, primarily as a result of resource recovery and higher scallop prices. This additional effort has been a contributing factor to why the FMP has been exceeding the fishing mortality targets. Additional measures for the Atlantic Sea Scallop FMP are being considered for two reasons: To effectively manage the general category fishery to address capacity, and to change the scallop fishing year to allow better and more timely integration of updated science into the management process.

Measures Under Consideration

The Council may consider a host of management measures to improve the effectiveness of general category management including, but not limited to, the following: Limited entry for the general category fleet; allocation of scallop resource to the general category fleet; restricting limited access scallop vessels from fishing under general category rules; use of output controls such as a hard total allowable catch (hard TAC) for the general category fleet; use of sectors and harvesting cooperatives (dedicated access privileges) for the general category fleet; and limits on the landings of incidental scallop catch. As for a change in the scallop fishing year, the amendment will consider a range of dates in addition to the status quo date of March 1.

It is possible that during the scoping process other issues will be raised related to the purpose of this amendment, and if appropriate, those issues will be considered by the Council as well.

Scoping Process

All persons affected by or otherwise interested in scallop management are invited to participate in determining the scope and significance of issues to be analyzed by submitting written comments (see ADDRESSES) and/or by attending one of the scoping meetings. Scope consists of the range of actions, alternatives, and impacts to be considered. Alternatives include the following: not amending the management plan (taking no action), developing an amendment that contains management measures such as those discussed in this notice, or other reasonable courses of action. Impacts may be direct, indirect, or cumulative.

This scoping process will also identify and eliminate from detailed analysis issues that are not relevant or feasible. When, after the scoping process is completed, the Council proceeds with the development of an amendment to the Scallop FMP, the Council will prepare an SEIS to analyze the impacts of the range of alternatives under consideration. The Council will hold public hearings to receive comments on the draft amendment and on the analysis of its impacts presented in the SEIS.

Scoping Hearing Schedule

The Council will discuss and take scoping comments at the following public meetings:

1. Tuesday, February 21, 7 p.m., Rutgers Cooperative Research & Extension, 4 Moore Road, Cape May, NJ 08210; telephone (609) 465–5115.

2. Wednesday, February 22, 7 p.m., Urban Forestry Center, 45 Elwyn Road, Portsmouth, NH 03801; telephone (603) 431–6774.

3. Thursday, February 23, 7 p.m., Hyannis Airport (Gourley Conference Room) , 480 Barnstable Road, Hyannis, MA 02601; telephone (508) 775–2020.

Special Accommodations

These meetings are accessible to people with physical disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Paul J. Howard (see **ADDRESSES**) at least 5 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: January 31, 2006.

Alan D. Risenhoover,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. E6–1585 Filed 2–3–06; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 011806G]

Marine Mammals; File No. 918–1820

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; issuance of permit.

SUMMARY: Notice is hereby given that Squalus, Inc., P.O. Box 301, Myakka City, FL 34251 [Marco Peters, Responsible Party] has been issued a permit to import four South American (Patagonian) sea lions (*Otaria flavescens*) for public display.

ADDRESSES: The permit and related documents are available for review upon written request or by appointment in the following office(s):

Permits, Conservation and Education Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 713–2289; fax (301) 427–2521; and

Southeast Region, NMFS, 263 13th Avenue South, Saint Petersburg, FL 33701; phone (727) 824–5312; fax (727) 824–5309.

FOR FURTHER INFORMATION CONTA CT: Kate Swails or Jennifer Skidmore, (301) 713–2289.

SUPPLEMENTARY INFORMATION: On November 23, 2005, notice was published in the **Federal Register** (70 FR 70788) that a request for a public display permit to import one male and three female, captive-born, juvenile sea lions from Park Atlantis, Mexico City, Mexico to Squalus' facilities in Myakka City, Florida had been submitted by the above-named organization. The requested permit has been issued under the authority of the Marine Mammal Protection Act of 1972, as amended (16

U.S.C. 1361 *et seq.*), the Regulations Governing the Taking and Importing of Marine Mammals (50 CFR part 216).

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), a determination was made that the permitted activity is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Dated: January 30, 2006.

Stephen L. Leathery,

Chief, Permits, Conservation and Education Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. E6–1591 Filed 2–6–06; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 080905A]

Small Takes of Marine Mammals Incidental to Specified Activities; Low-Energy Seismic Survey on the Louisville Ridge, Southwest Pacific Ocean

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of issuance of an incidental harassment authorization.

SUMMARY: In accordance with provisions of the Marine Mammal Protection Act (MMPA) as amended, notification is hereby given that an Incidental Harassment Authorization (IHA) to take small numbers of marine mammals, by harassment, incidental to conducting an oceanographic survey in the southwestern Pacific Ocean (SWPO) has been issued to the Scripps Institution of Oceanography (Scripps).

DATES: Effective from January 20, 2006, through January 19, 2007.

ADDRESSES: The authorization and application containing a list of the references used in this document may be obtained by writing to this address or by telephoning the contact listed here. The application is also available at: *http://www.nmfs.noaa.gov/pr/permits/incidental.htm.*

FOR FURTHER INFORMATION CONTACT: Kenneth Hollingshead, Office of Protected Resources, NMFS, (301) 713–2289, ext 128.

SUPPLEMENTARY INFORMATION:

Background

Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce to allow, upon request, the incidental, but not intentional, taking of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review.

An authorization may be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s) and will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses and that the permissible methods of taking and requirements pertaining to the monitoring and reporting of such takings are set forth. NMFS has defined "negligible impact" in 50 CFR 216.103 as " * * * an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival."

Section 101(a)(5)(D) of the MMPA established an expedited process by which citizens of the United States can apply for an authorization to incidentally take small numbers of marine mammals by harassment. Except with respect to certain activities not pertinent here, the MMPA defines "harassment" as:

> any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild [Level A harassment]; or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering [Level B harassment].

Section 101(a)(5)(D) establishes a 45-day time limit for NMFS review of an application followed by a 30-day public notice and comment period on any proposed authorizations for the incidental harassment of marine mammals. Within 45 days of the close of the comment period, NMFS must either issue or deny issuance of the authorization.

Summary of Request

On June 29, 2005, NMFS received an application from Scripps for the taking, by harassment, of several species of marine mammals incidental to conducting a low-energy marine seismic survey program during early 2006 in the SWPO. Scripps plans to conduct a seismic survey of several seamounts on the Louisville Ridge in the SWPO as part of the Integrated Ocean Drilling Program (IODP). As presently scheduled, the seismic survey will occur from about January 21 to February 26, 2006.

The purpose of the research program is to conduct a planned scientific rock-dredging, magnetic, and seismic survey program of six seamounts of the Louisville seamount chain. The results will be used to: (1) Test hypotheses about the eruptive history of the submarine volcanoes, the subsequent formation (by subaerial erosion and submergence) of its many guyots, and motion of the hotspot plume; and (2) design an effective IODP cruise (not currently scheduled) to drill on carefully-selected seamounts. Included in the research planned for 2006 is scientific rock dredging, extensive total-field and three-component magnetic surveys, the use of multi-beam and Chirp techniques to map the seafloor, and high-resolution seismic methods to image the subsea floor. Following the cruise, chemical and geochronologic analyses will be conducted on rocks from 25 sites.

Description of the Activity

The seismic surveys will involve one vessel. The source vessel, the *R/V Roger Revelle*, will deploy a pair of low-energy Generator-Injector (GI) airguns as an energy source (each with a discharge volume of 45 in^3), plus a 450-m (1476-ft) long, 48-channel, towed hydrophone streamer. As the airguns are towed along the survey lines, the receiving system will receive the returning acoustic signals.

The program will consist of approximately 1840 km (994 nm) of surveys, including turns. Water depths within the seismic survey areas are 800–2300 m (2625–7456 ft). The GI guns will be operated on a small grid (see inset in Figure 1 in Scripps (2006)) for about 28 hours at each of 6 seamounts between approximately January 28 to February 19, 2006. There will be additional seismic operations associated with equipment testing, start-up, and repeat coverage of any areas where initial data quality is sub-standard.

The *Revelle* is scheduled to depart from Papeete, French Polynesia, on or about January 21, 2006, and to arrive at Wellington, New Zealand, on or about February 26, 2006. The GI guns will be used for about 28 hours on each of 6 seamounts between about January 28th to February 19th. The exact dates of the activities may vary by a few days

because of weather conditions, repositioning, streamer operations and adjustments, airgun deployment, or the need to repeat some lines if data quality is substandard. The overall area within which the seismic surveys will occur is located between approximately 25° and 45° S., and between 155° and 175° W. The surveys will be conducted entirely in International Waters.

In addition to the operations of the GI guns, a 3.5-kHz sub-bottom profiler and passive geophysical sensors to conduct total-field and three-component magnetic surveys will be operated during seismic surveys. A Kongsberg-Simrad EM–120 multi-beam sonar will be used continuously throughout the cruise.

The energy to the airguns is compressed air supplied by compressors on board the source vessel. Seismic pulses will be emitted at intervals of 6–10 seconds. At a speed of 7 knots (13 km/h), the 6–10 sec spacing corresponds to a shot interval of approximately 21.5–36 m (71–118 ft).

The generator chamber of each GI gun, the one responsible for introducing the sound pulse into the ocean, is 45 in^3. The larger (105 in^3) injector chamber injects air into the previously-generated bubble to maintain its shape, and does not introduce more sound into the water. The two 45/105 in^3 GI guns will be towed 8 m (26.2 ft) apart side by side, 21 m (68.9 ft) behind the *Revelle*, at a depth of 2 m (6.6 ft).

General-Injector Airguns

Two GI-airguns will be used from the *Revelle* during the proposed program. These 2 GI-airguns have a zero to peak (peak) source output of 230.7 dB re 1 microPascal-m (3.4 bar-m) and a peak-to-peak (pk-pk) level of 235.9B (6.2 bar-m). However, these downward-directed source levels do not represent actual sound levels that can be measured at any location in the water. Rather, they represent the level that would be found 1 m (3.3 ft) from a hypothetical point source emitting the same total amount of sound as is emitted by the combined airguns in the airgun array. The actual received level at any location in the water near the airguns will not exceed the source level of the strongest individual source and actual levels experienced by any organism more than 1 m (3.3 ft) from any GI gun will be significantly lower.

Further, the root mean square (rms) received levels that are used as impact criteria for marine mammals (see Richardson *et al.*, 1995) are not directly comparable to these peak or pk-pk values that are normally used to characterize source levels of airgun arrays. The measurement units used to describe airgun sources, peak or pk-pk decibels, are always higher than the rms decibels referred to in biological literature. For example, a measured received level of 160 dB rms in the far field would typically correspond to a peak measurement of about 170 to 172 dB, and to a pk-pk measurement of about 176 to 178 decibels, as measured for the same pulse received at the same location (Greene, 1997; McCauley *et al.*, 1998, 2000). The precise difference between rms and peak or pk-pk values depends on the frequency content and duration of the pulse, among other factors. However, the rms level is always lower than the peak or pk-pk level for an airgun-type source.

The depth at which the sources are towed has a major impact on the maximum near-field output, because the energy output is constrained by ambient pressure. The normal tow depth of the sources to be used in this project is 2.0 m (6.6 ft), where the ambient pressure is approximately 3 decibars. This also limits output, as the 3 decibars of confining pressure cannot fully constrain the source output, with the result that there is loss of energy at the sea surface. Additional discussion of the characteristics of airgun pulses is provided in Scripps application and in previous **Federal Register** documents (see 69 FR 31792 (June 7, 2004) or 69 FR 34996 (June 23, 2004)).

Received sound levels have been modeled by Lamont-Doherty Earth Observatory (L-DEO) for a number of airgun configurations, including two 45-in^3 Nucleus G-guns (G guns), in relation to distance and direction from the airguns. The L-DEO model does not allow for bottom interactions, and is therefore most directly applicable to deep water. Based on the modeling, estimates of the maximum distances from the GI guns where sound levels of 190, 180, 170, and 160 dB microPascal-m (rms) are predicted to be received are shown in Table 1. Because the model results are for the G guns, which have more energy than GI guns of the same size, those distances are overestimates of the distances for the 45 in^3 GI guns.

TABLE 1.—DISTANCES TO WHICH SOUND LEVELS ≥190, 180, 170, AND 160 DB RE 1 μPA (RMS) MIGHT BE RECEIVED FROM TWO 45-IN^3 G GUNS, SIMILAR TO THE TWO 45-IN^3 GI GUNS THAT WILL BE USED DURING THE SEISMIC SURVEY IN THE SW PACIFIC OCEAN DURING JANUARY–FEBRUARY 2006. DISTANCES ARE BASED ON MODEL RESULTS PROVIDED BY L–DEO.

Water depth	Estimated distances at received levels (m)			
	190 dB	180 dB	170 dB	160 dB
100–1000 m	15	60	188	525
>1000 m	10	40	125	350

Some empirical data concerning the 180- and 160-dB distances have been acquired based on measurements during an acoustic verification study conducted by L–DEO in the northern Gulf of Mexico between May 27 and June 3, 2003 (Tolstoy *et al.*, 2004). Although the results are limited, the data showed that water depth affected the radii around the airguns where the received level would be 180 dB re 1 microPa (rms), NMFS' current injury threshold safety criterion applicable to cetaceans (NMFS, 2000). Similar depth-related variation is likely in the 190–dB distances applicable to pinnipeds. Correction factors were developed for water depths 100–1000 m (328–3281 ft) and less than 100 m (328 ft). The proposed survey will occur in depths 800–2300 m (2625–7456 ft), so only the correction factor for intermediate water depths is relevant here.

The empirical data indicate that for deep water (>1000 m (3281 ft)), the L–DEO model tends to overestimate the received sound levels at a given distance (Tolstoy *et al.*, 2004). However, to be precautionary pending acquisition of additional empirical data, it is proposed that safety radii during airgun operations in deep water will be the values predicted by L–DEO's model (Table 1). Therefore, the assumed 180- and 190-dB radii are 40 m (131 ft) and 10 m (33 ft), respectively.

Bathymetric Sonar and Sub-bottom Profiler

The Kongsberg-Simrad EM120 multi-beam sonar operates at 11.25–12.6 kHz, and is mounted in the hull of the *Revelle*. It operates in several modes, depending on water depth. In the proposed survey, it will be used in deep (>800-m) water, and will operate in "deep" mode. The beamwidth is 1° or 2° fore-aft and a total of 150° athwartship. Estimated maximum source levels are 239 and 233 dB at 1° and 2° beam widths, respectively. Each "ping" consists of nine successive fan-shaped transmissions, each ensonifying a sector that extends 1° or 2° fore-aft. In the "deep" mode, the total duration of the transmission into each sector is 15 ms. The nine successive transmissions span an overall cross-track angular extent of about 150°, with 16-ms gaps between the pulses for successive sectors. A receiver in the overlap area between two sectors would receive two 15-ms pulses separated by a 16-ms gap. The "ping" interval varies with water depth, from approximately 5 sec at 1000 m (3281 ft) to 20 sec at 4000 m (13123 ft/2.2 nm).

Sub-bottom Profiler—The sub-bottom profiler is normally operated to provide information about the sedimentary features and the bottom topography that is simultaneously being mapped by the multi-beam sonar. The energy from the sub-bottom profiler is directed downward by a 3.5-kHz transducer mounted in the hull of the *Revelle*. The output varies with water depth from 50 watts in shallow water to 800 watts in deep water. Pulse interval is 1 second (sec) but a common mode of operation is to broadcast five pulses at 1-s intervals followed by a 5-sec pause. The beamwidth is approximately 30° and is directed downward. Maximum source output is 204 dB re 1 microPa (800 watts) while normal source output is 200 dB re 1 microPa (500 watts). Pulse duration will be 4, 2, or 1 ms, and the bandwith of pulses will be 1.0 kHz, 0.5 kHz, or 0.25 kHz, respectively.

Although the sound levels have not been measured directly for the sub-bottom profiler used by the *Revelle*, Burgess and Lawson (2000) measured sounds propagating more or less horizontally from a sub-bottom profiler similar to the Scripps unit with similar source output (i.e., 205 dB re 1 microPa m). For that profiler, the 160- and 180-dB re 1 microPa (rms) radii in the horizontal direction were estimated to be, respectively, near 20 m (66 ft) and 8 m (26 ft) from the source, as measured in 13 m (43 ft) water depth. The corresponding distances for an animal in the beam below the transducer would be greater, on the order of 180 m (591 ft) and 18 m (59 ft) respectively, assuming spherical spreading. Thus the received level for the Scripps sub-bottom profiler would be expected to decrease to 160 and 180 dB about 160 m (525 ft) and 16 m (52 ft) below the transducer, respectively, assuming spherical spreading. Corresponding distances in the horizontal plane would be lower, given the directionality of this source (30° beamwidth) and the measurements of Burgess and Lawson (2000).

Characteristics of Airgun Pulses

Discussion of the characteristics of airgun pulses was provided in several previous **Federal Register** documents (see 69 FR 31792 (June 7, 2004) or 69 FR 34996 (June 23, 2004)) and is not repeated here. Reviewers are encouraged to read these earlier documents for additional information.

Comments and Responses

A notice of receipt and request for 30-day public comment on the application and proposed authorization was published on October 17, 2005 (70 FR 60287). During the 30-day public comment period, NMFS received comments only from the Marine Mammal Commission (Commission). It is the Commission's view that

(1) Considerable uncertainty exists regarding the effects of sound on marine mammals;

(2) Better understanding of those effects will require carefully designed studies, the results of which may not be available for years;

(3) Important activities should not be postponed or delayed until such results become available; and

(4) Until the results of needed studies become available and uncertainties are resolved or clarified, it is essential that agencies take a precautionary approach (as defined in the previous statements and publications) in authorizing and conducting activities.

Comment 1: The Commission believes that NMFS' preliminary determinations are reasonable provided NMFS is satisfied that the proposed mitigation and monitoring activities are adequate to detect marine mammals in the vicinity of the proposed operations and to ensure that marine mammals are not being taken in unanticipated ways or numbers.

Response: For this activity, the radius of the zone of potential impact ranges from 10 to 60 m (33 to 216.5 ft) depending upon water depth and whether the sighted mammal is a pinniped, a small cetacean, or a large cetacean (see Table 1). Considering the very small size of the conservative shutdown zones, the speed of the vessel when towing the airgun (7 kts), the length of daylight at this time of the year, and the marine mammal avoidance measures that are implemented by the vessel for animals on the vessel's track, it is very unlikely that any marine mammals would enter the safety zone undetected. If a marine mammal enters the small safety zone, operational shutdown will be implemented until the animal leaves the safety zone.

Comment 2: The Commission notes that its April 2004 Beaked Whale Conference explored issues related to the vulnerability of beaked whales to anthropogenic sound. Discussions at the workshop appear to lend support to the hypothesis that beaked whales have unique characteristics that make them particularly vulnerable to certain anthropogenic sound sources (e.g., sonars). Preliminary research findings presented at the workshop suggest that at least some beaked whales exhibit a unique dive behavior that raises the possibility that they may live in a physiologic condition of chronic supersaturation that would increase their susceptibility to received sound levels less than 180 dB. Workshop participants theorized that the animals' behavioral response to anthropogenic sound, coupled with their susceptibility to gas bubble formation may lead to strandings (which in many cases are lethal). The Commission recognizes that the evidence with respect to this scenario is preliminary and that other explanations and scenarios exist. However, the uncertainties concerning the effects of sound on these species underscore the need for caution.

Response: NMFS notes that the MMC's workshop summary report is available for reading or downloading at: *http://www.mmc.gov/sound/beakedwhalewrkshp/pdf/bwhale_wrkshpsummary.pdf.*

Comment 3: The Commission notes that although the proposed study is not expected to result in injuries or deaths to beaked whales or other species of marine mammals, observers will conduct monitoring for injured or dead animals along some recently run transect lines as the source vessel returns along parallel and perpendicular transect tracks. In this regard, the Commission would be interested in learning from NMFS and/or Scripps what the probability is that an injured or dead beaked whale, other small cetacean, or elephant seal would be sighted from a ship running transects through an area or retracing recently run transect lines.

Response: NMFS is unaware of any scientific studies to demonstrate efficacy of conducting marine mammal sightings from a moving vessel for incapacitated or dead marine mammals. However, Scripps notes that the *Revelle* will spend approximately 28 hours at each of the 6 seamounts. As the inset to Figure 1 in the Scripp's application shows, parallel seismic lines are approximately 2.5 km (1.35 nm) apart, and the "perpendicular" lines about twice that distance. Using big-eye binoculars, injured or dead mammals that are floating should be readily visible during daytime hours.

Comment 4: The Commission notes that to obtain the best possible observations prior to initiating full-scale operations, NMFS should require Scripps not initiate ramp-up after dark and/or to maintain a low-level output from the airguns if full-scale operations may take place after dark.

Response: The IHA to Scripps, similar to other seismic IHAs, requires that ramp-up not commence if the complete safety radii are not visible for at least 30 minutes prior to ramp-up in either daylight (rain/fog) or nighttime.

Comment 5: The Commission notes that NMFS' discussion of Scripps' proposed shut-down procedures in the proposed IHA **Federal Register** notice states: "The mammal has cleared the safety radius if it is visually observed to have left the safety radius, or if it has not been seen within the zone for 15 min. (small odontocetes and pinnipeds) or 30 min. (mysticetes and large odontocetes)* * * ." The Commission notes that elephant seals can dive for much longer than 15 minutes and, thus, could be directly below the sound source when it is reactivated.

Response: For elephant seals and other pinnipeds, the safety radius around the 2–GI airgun seismic source (not the vessel itself) is 10–15 m (33–49 ft) depending upon water depth. When towing seismic airguns, the *Revelle*'s speed is about 7 knots (nm/hr or 13 km/hr). As a result, the likelihood of an elephant seal (or any other marine mammal) making a deep dive and returning to the immediate area of the vessel and its safety zone, which after 15 minutes of travel will be about 1.75 nm (3.2 km) away from the elephant seal sighting location, is considered remote.

Comment 6: The Commission believes NMFS should require that operations be suspended immediately if a dead or seriously injured marine mammal is found in the vicinity of the operations, pending authorization to proceed or issuance of regulations authorizing such takes under section 101(a)(5)(A) of the MMPA.

Response: A standard condition in all seismic IHAs is for an emergency shut-down. The IHA states that "If observations are made or credible reports are received that one or more marine mammals or sea turtles are within the area of this activity in an injured or mortal state, or are indicating acute distress, the seismic airguns will be immediately shut down and the Chief of the Permits, Conservation and Education Division, Office of Protected Resources or a staff member contacted. The airgun array will not be restarted until review and approval has been given by the Director, Office of Protected Resources or his designee." However, this requirement pertains only to recently deceased marine mammals, not long-dead "floaters."

Description of Habitat and Marine Mammals Affected by the Activity

Forty species of cetacean, including 31 odontocete (dolphin and small- and large-toothed whale) species and nine mysticete (baleen whales) species, are believed by scientists to occur in the southwest Pacific in the proposed seismic survey area. More detailed information on these species is contained in the Scripps application and the National Science Foundation (NSF) EA which are available at: *http://www.nmfs.noaa.gov/pr/permits/incidental.htm*. Table 2 in both the Scripps application and NSF EA summarizes the habitat, occurrence, and regional population estimate for these species. The following species may be affected by this low-intensity seismic survey: Sperm whale, pygmy and dwarf sperm whales, southern bottlenose whale, Arnoux's beaked whale, Cuvier's beaked whale, Shepherd's beaked whale, mesoplodont beaked whales (Andrew's beaked whale, Blainville's beaked whale, gingko-toothed whale, Gray's beaked whale, Hector's beaked whale, spade-toothed whale, strap-toothed whale), melon-headed whale, pygmy killer whale, false killer whale, killer whale, long-finned pilot whale, short-finned pilot whale, rough-toothed dolphin, bottlenose dolphin, pantropical spotted dolphin, spinner dolphin, striped dolphin, short-beaked common dolphin, hourglass dolphin, Fraser's dolphin , Risso's dolphin, southern right whale dolphin, spectacled porpoise, humpback whale, southern right whale, pygmy right whale, common minke whale, Antarctic minke whale, Bryde's whale, sei whale, fin whale and blue whale. Because the proposed survey area spans a wide range of latitudes (25–45° S), tropical, temperate, and possibly polar species are all likely to be found there. The survey area is all in deep-water habitat but is close to oceanic island (Kermadec Islands) habitats, so both coastal and oceanic species might be encountered. However, abundance and density estimates of cetaceans found there are provided for reference only, and are not necessarily the same as those that likely occur in the survey area.

Five species of pinnipeds could potentially occur in the proposed seismic survey area: Southern elephant seal, leopard seal, crabeater seal, Antarctic fur seal, and the sub-Antarctic fur seal. All are likely to be rare, if they occur at all, as their normal distributions are south of the Scripps survey area. Outside the breeding season, however, they disperse widely in the open ocean (Boyd, 2002; King, 1982; Rogers, 2002). Only three species of pinniped are known to wander regularly into the area (Reeves *et al.*, 1999): the Antarctic fur seal, the sub-Antarctic fur seal, and the leopard seal. Leopard seals are seen as far north as the Cook Islands (Rogers, 2002).

Potential Effects on Marine Mammals

As outlined in several previous NMFS documents, the effects of noise on marine mammals are highly variable, and can be categorized as follows (based on Richardson *et al.*, 1995):

(1) The noise may be too weak to be heard at the location of the animal (i.e., lower than the prevailing ambient noise level, the hearing threshold of the animal at relevant frequencies, or both);

(2) The noise may be audible but not strong enough to elicit any overt behavioral response;

(3) The noise may elicit reactions of variable conspicuousness and variable relevance to the well being of the marine mammal; these can range from temporary alert responses to active avoidance reactions such as vacating an area at least until the noise event ceases;

(4) Upon repeated exposure, a marine mammal may exhibit diminishing responsiveness (habituation), or disturbance effects may persist; the latter is most likely with sounds that are highly variable in characteristics, infrequent and unpredictable in occurrence, and associated with situations that a marine mammal perceives as a threat;

(5) Any anthropogenic noise that is strong enough to be heard has the potential to reduce (mask) the ability of a marine mammal to hear natural sounds at similar frequencies, including calls from conspecifics, and underwater environmental sounds such as surf noise;

(6) If mammals remain in an area because it is important for feeding, breeding or some other biologically important purpose even though there is chronic exposure to noise, it is possible that there could be noise-induced physiological stress; this might in turn have negative effects on the well-being or reproduction of the animals involved; and

(7) Very strong sounds have the potential to cause temporary or permanent reduction in hearing sensitivity. In terrestrial mammals, and presumably marine mammals, received sound levels must far exceed the animal's hearing threshold for there to be any temporary threshold shift (TTS) in its hearing ability. For transient sounds, the sound level necessary to cause TTS is inversely related to the duration of the sound. Received sound levels must be even higher for there to be risk of permanent hearing impairment. In addition, intense acoustic or explosive events may cause trauma to tissues associated with organs vital for hearing, sound production, respiration and other functions. This trauma may include minor to severe hemorrhage.

Effects of Seismic Surveys on Marine Mammals

The Scripps' application provides the following information on what is known about the effects on marine mammals of the types of seismic operations planned by Scripps. The types of effects considered here are (1) tolerance, (2) masking of natural sounds, (2) behavioral disturbance, and (3) potential hearing impairment and other non-auditory physical effects (Richardson *et al.*, 1995). Given the relatively small size of the airguns planned for the present project, its effects are anticipated to be considerably less than would be the case with a large array of airguns. Scripps and NMFS believe it is very unlikely that there would be any cases of temporary or especially permanent hearing impairment, or non-auditory physical effects. Also, behavioral disturbance is expected to be limited to distances less than 525 m (1722 ft) from the source, the zone calculated for 160 dB or the onset of Level B harassment. Additional discussion on species-specific effects can be found in the Scripps application.

Tolerance

Numerous studies (referenced in Scripps, 2005) have shown that pulsed sounds from airguns are often readily detectable in the water at distances of many kilometers, but that marine mammals at distances more than a few kilometers from operating seismic vessels often show no apparent response. That is often true even in cases when the pulsed sounds must be readily audible to the animals based on measured received levels and the hearing sensitivity of that mammal group. However, most measurements of airgun sounds that have been reported concerned sounds from larger arrays of airguns, whose sounds would be detectable farther away than that planned for use in the proposed survey. Although various baleen whales, toothed whales, and pinnipeds have been shown to react behaviorally to airgun pulses under some conditions, at other times mammals of all three types have shown no overt reactions. In general, pinnipeds and small odontocetes seem to be more tolerant of exposure to airgun pulses than are baleen whales. Given the relatively small, low-energy airgun source planned for use in this project, mammals are expected to tolerate being closer to this source than would be the case for a larger airgun source typical of most seismic surveys.

Masking

Masking effects of pulsed sounds (even from large arrays of airguns) on marine mammal calls and other natural sounds are expected to be limited (due in part to the small size of the GI airguns), although there are very few specific data on this. Given the small acoustic source planned for use in the SWPO, there is even less potential for masking of baleen or sperm whale calls during the present research than in most seismic surveys (Scripps, 2005). GI-airgun seismic sounds are short pulses generally occurring for less than 1 sec every 6–10 seconds or so. The 6–10 sec spacing corresponds to a shot interval of approximately 21.5–36 m (71–118 ft). Sounds from the multi-beam sonar are very short pulses, occurring for 15 msec once every 5 to 20 sec, depending on water depth.

Some whales are known to continue calling in the presence of seismic pulses. Their calls can be heard between the seismic pulses (Richardson *et al.*, 1986; McDonald *et al.*, 1995, Greene *et al.*, 1999). Although there has been one report that sperm whales cease calling when exposed to pulses from a very distant seismic ship (Bowles *et al.*, 1994), a recent study reports that sperm whales continued calling in the presence of seismic pulses (Madsen *et al.*, 2002). Given the relatively small source planned for use during this survey, there is even less potential for masking of sperm whale calls during the present study than in most seismic surveys. Masking effects of seismic pulses are expected to be negligible in the case of the smaller odontocete cetaceans, given the intermittent nature of seismic pulses and the relatively low source level of the airguns to be used in the SWPO. Also, the sounds important to small odontocetes are predominantly at much higher frequencies than are airgun sounds.

Most of the energy in the sound pulses emitted by airgun arrays is at low frequencies, with strongest spectrum levels below 200 Hz and considerably lower spectrum levels above 1000 Hz. Among marine mammals, these low frequencies are mainly used by mysticetes, but generally not by odontocetes or pinnipeds. An industrial sound source will reduce the effective communication or echolocation distance only if its frequency is close to that of the marine mammal signal. If little or no overlap occurs between the industrial noise and the frequencies used, as in the case of many marine mammals relative to airgun sounds, communication and echolocation are not expected to be disrupted. Furthermore, the discontinuous nature of seismic pulses makes significant masking effects unlikely even for mysticetes.

A few cetaceans are known to increase the source levels of their calls in the presence of elevated sound levels, or possibly to shift their peak frequencies in response to strong sound signals (Dahlheim, 1987; Au, 1993; Lesage *et al.*, 1999; Terhune, 1999; as reviewed in Richardson *et al.*, 1995). These studies involved exposure to other types of anthropogenic sounds, not seismic pulses, and it is not known whether these types of responses ever occur upon exposure to seismic sounds. If so, these adaptations, along with directional hearing, pre-adaptation to tolerate some masking by natural sounds (Richardson *et al.*, 1995), and the relatively low-power acoustic sources being used in this survey, would all reduce the importance of masking marine mammal vocalizations.

Disturbance by Seismic Surveys

Disturbance includes a variety of effects, including subtle changes in behavior, more conspicuous dramatic changes in behavioral activities, and displacement. However, there are difficulties in defining which marine mammals should be counted as "taken by harassment". For many species and situations, scientists do not have detailed information about their reactions to noise, including reactions to seismic (and sonar) pulses. Behavioral reactions of marine mammals to sound

are difficult to predict. Reactions to sound, if any, depend on species, state of maturity, experience, current activity, reproductive state, time of day, and many other factors. If a marine mammal does react to an underwater sound by changing its behavior or moving a small distance, the impacts of the change may not rise to the level of a disruption of a behavioral pattern. However, if a sound source would displace marine mammals from an important feeding or breeding area, such a disturbance would likely constitute Level B harassment under the MMPA. Given the many uncertainties in predicting the quantity and types of impacts of noise on marine mammals, scientists often resort to estimating how many mammals may be present within a particular distance of industrial activities or exposed to a particular level of industrial sound. With the possible exception of beaked whales, NMFS believes that this is a conservative approach and likely overestimates the numbers of marine mammals that are affected in some biologically important manner.

The sound exposure criteria used to estimate how many marine mammals might be harassed behaviorally by the seismic survey are based on behavioral observations during studies of several species. However, information is lacking for many species. Detailed information on potential disturbance effects on baleen whales, toothed whales, and pinnipeds can be found on pages 33–37 and Appendix A in Scripps's SWPO application.

Hearing Impairment and Other Physical Effects

Temporary or permanent hearing-impairment is a possibility when marine mammals are exposed to very strong sounds, but there has been no specific documentation of these effects for marine mammals exposed to airgun pulses. Current NMFS policy precautionarily sets impulsive sounds equal to or greater than 180 and 190 dB re 1 microPa (rms) as the exposure thresholds for onset of Level A harassment for cetaceans and pinnipeds, respectively (NMFS, 2000). Those criteria have been used in defining the safety (shut-down) radii for seismic surveys. However, those criteria were established before there were any data on the minimum received levels of sounds necessary to cause auditory impairment in marine mammals. As discussed in the Scripps application and summarized here,

1. The 180-dB criterion for cetaceans is probably quite precautionary, i.e., lower than necessary to avoid TTS let alone permanent auditory injury, at least for delphinids.

2. The minimum sound level necessary to cause permanent hearing impairment is higher, by a variable and generally unknown amount, than the level that induces barely-detectable TTS.

3. The level associated with the onset of TTS is often considered to be a level below which there is no danger of permanent damage.

Given the small size of the two 45 in^3 GI-airguns, along with the proposed monitoring and mitigation measures, there is little likelihood that any marine mammals will be exposed to sounds sufficiently strong to cause even the mildest (and reversible) form of hearing impairment. Several aspects of the planned monitoring and mitigation measures for this project are designed to detect marine mammals occurring near the 2 GI-airguns (and bathymetric sonar), and to avoid exposing them to sound pulses that might (at least in theory) cause hearing impairment. In addition, research and monitoring studies on gray whales, bowhead whales and other cetacean species indicate that many cetaceans are likely to show some avoidance of the area with ongoing seismic operations. In these cases, the avoidance responses of the animals themselves will reduce or avoid the possibility of hearing impairment.

Non-auditory physical effects may also occur in marine mammals exposed to strong underwater pulsed sound. Possible types of non-auditory physiological effects or injuries that theoretically might occur in mammals close to a strong sound source include stress, neurological effects, bubble formation, resonance effects, and other types of organ or tissue damage. It is possible that some marine mammal species (i.e., beaked whales) may be especially susceptible to injury and/or stranding when exposed to strong pulsed sounds. However, Scripps and NMFS believe that it is especially unlikely that any of these non-auditory effects would occur during the survey given the small size of the acoustic sources, the brief duration of exposure of any given mammal, and the mitigation and monitoring measures. The following paragraphs discuss the possibility of TTS, permanent threshold shift (PTS), and non-auditory physical effects.

TTS

TTS is the mildest form of hearing impairment that can occur during exposure to a strong sound (Kryter, 1985). When an animal experiences TTS, its hearing threshold rises and a sound must be stronger in order to be heard. TTS can last from minutes or hours to (in cases of strong TTS) days. Richardson *et al.* (1995) note that the magnitude of TTS depends on the level and duration of noise exposure, among other considerations. For sound exposures at or somewhat above the TTS threshold, hearing sensitivity recovers rapidly after exposure to the noise ends. Little data on sound levels and durations necessary to elicit mild TTS have been obtained for marine mammals.

For toothed whales exposed to single short pulses, the TTS threshold appears to be, to a first approximation, a function of the energy content of the pulse (Finneran *et al.*, 2002). Given the available data, the received level of a single seismic pulse might need to be on the order of 210 dB re 1 microPa rms (approx. 221–226 dB pk-pk) in order to produce brief, mild TTS. Exposure to several seismic pulses at received levels near 200–205 dB (rms) might result in slight TTS in a small odontocete, assuming the TTS threshold is (to a first approximation) a function of the total received pulse energy (Finneran *et al.*, 2002). Seismic pulses with received levels of 200–205 dB or more are usually restricted to a zone of no more than 100 m (328 ft) around a seismic vessel operating a large array of airguns. Because of the small airgun source planned for use during this project, such sound levels would be limited to distances within a few meters directly astern of the *Revelle*.

There are no data, direct or indirect, on levels or properties of sound that are required to induce TTS in any baleen whale. However, TTS is not expected to occur during this survey given the small size of the source limiting these sound pressure levels to the immediate proximity of the vessel, and the strong likelihood that baleen whales would avoid the approaching airguns (or vessel) before being exposed to levels high enough for there to be any possibility of TTS.

TTS thresholds for pinnipeds exposed to brief pulses (single or multiple) have not been measured, although exposures up to 183 dB re 1 microPa (rms) have been shown to be insufficient to induce TTS in California sea lions (Finneran *et al.*, 2003). However, prolonged exposures show that some pinnipeds may incur TTS at somewhat lower received levels than do small odontocetes exposed for similar durations (Kastak *et al.*, 1999; Ketten *et al.*, 2001; Au *et al.*, 2000). For this research cruise therefore, TTS is unlikely for pinnipeds.

A marine mammal within a zone with a radius of ≤100 m (≤328 ft) around a typical large array of operating airguns might be exposed to a few seismic pulses with levels of ≥205 dB, and possibly more pulses if the mammal moved with the seismic vessel. Also, around smaller arrays, such as the 2 GI-airgun array proposed for use during this survey, a marine mammal would need to be even closer to the source to be exposed to levels greater than or equal to 205 dB. However, as noted previously, most cetacean species tend to avoid operating airguns, although not all individuals do so. In addition, ramping up airgun arrays, which is now standard operational protocol for many U.S. and some foreign seismic operations, should allow cetaceans to move away from the seismic source and avoid being exposed to the full acoustic output of the airgun array. Even with a large airgun array, it is unlikely that these cetaceans would be exposed to airgun pulses at a sufficiently high level for a sufficiently long period to cause more than mild TTS, given the relative movement of the vessel and the marine mammal. However, with a large airgun array, TTS would be possible in odontocetes that bow-ride or otherwise linger near the airguns. Bow-riding odontocetes mostly would be at or above the surface, and thus not exposed to strong sound pulses given the pressure-release effect at the surface. However, bow-riding animals generally dive below the surface intermittently. If they did so while bow-riding near airguns, they would be exposed to strong sound pulses, possibly repeatedly. During this project, the anticipated 180-dB radius is less than 60 m (197 ft), the array is towed about 21 m (69 ft) behind the *Revelle*, the bow of the *Revelle* will be about 104 m (341 ft) ahead of the airguns, and the 205-dB radius would be less than 50 m (165 ft). Thus, TTS would not be expected in the case of odontocetes bow riding during airgun operations, and if some cetaceans did incur TTS through exposure to airgun sounds, it would very likely be a temporary and reversible phenomenon.

NMFS believes that, to avoid Level A harassment, cetaceans should not be exposed to pulsed underwater noise at received levels exceeding 180 dB re 1 microPa (rms). The corresponding limit for pinnipeds has been set at 190 dB. The predicted 180- and 190-dB distances for the airgun arrays operated by Scripps during this activity are summarized in Table 1 in this document. These sound levels are not considered to be the levels at or above which TTS might occur. Rather, they are the received levels above which, in the view of a panel of bioacoustics specialists convened by NMFS (at a time before TTS measurements for marine mammals started to become available), one could not be certain that there would be no injurious effects, auditory or otherwise, to marine mammals. As noted here, TTS data that are now available imply that, at least for dolphins, TTS is unlikely to occur unless the dolphins are exposed to airgun pulses substantially stronger than 180 dB re 1 microPa (rms).

It has also been shown that most whales tend to avoid ships and associated seismic operations. Thus, whales will likely not be exposed to such high levels of airgun sounds. Because of the relatively slow ship speed, any whales close to the trackline could move away before the sounds become sufficiently strong for there to be any potential for hearing impairment. Therefore, there is little potential for whales being close enough to an array to experience TTS. In addition, ramping up the airgun array should allow cetaceans to move away from the seismic source and avoid being exposed to the full acoustic output of the GI airguns.

Permanent Threshold Shift (PTS)

When PTS occurs there is physical damage to the sound receptors in the ear. In some cases there can be total or partial deafness, while in other cases the animal has an impaired ability to hear sounds in specific frequency ranges. Although there is no specific evidence that exposure to pulses of airgun sounds can cause PTS in any marine mammals, even with the largest airgun arrays, physical damage to a mammal's hearing apparatus can potentially occur if it is exposed to sound impulses that have very high peak pressures, especially if they have very short rise times (time required for sound pulse to reach peak pressure from the baseline pressure). Such damage can result in a permanent decrease in functional sensitivity of the hearing system at some or all frequencies.

Single or occasional occurrences of mild TTS are not indicative of permanent auditory damage in terrestrial mammals. However, very prolonged exposure to sound strong enough to elicit TTS, or shorter-term exposure to sound levels well above the TTS threshold, can cause PTS, at least in terrestrial mammals (Kryter, 1985). Relationships between TTS and PTS thresholds have not been studied in marine mammals but are assumed to be similar to those in humans and other terrestrial mammals. The low-to-moderate levels of TTS that have been induced in captive odontocetes and pinnipeds during recent controlled studies of TTS have been confirmed to be temporary, with no measurable residual PTS (Kastak *et al.*, 1999; Schlundt *et al.*, 2000; Finneran *et al.*, 2002; Nachtigall *et al.*, 2003). In terrestrial mammals, the received sound level from a single non-impulsive sound exposure must be far above the TTS threshold for any risk of permanent hearing damage (Kryter, 1994; Richardson *et al.*, 1995). For impulse sounds with very rapid rise times (e.g., those associated with explosions or gunfire), a received level not greatly in excess of the TTS threshold may start to elicit PTS. Rise times for airgun pulses are rapid, but less rapid than for explosions.

Some factors that contribute to onset of PTS are as follows: (1) Exposure to single very intense noises, (2) repetitive exposure to intense sounds that individually cause TTS but not PTS, and (3) recurrent ear infections or (in captive animals) exposure to certain drugs.

Cavanagh (2000) reviewed the thresholds used to define TTS and PTS. Based on his review and SACLANT (1998), it is reasonable to assume that PTS might occur at a received sound level 20 dB or more above that which induces mild TTS. However, for PTS to occur at a received level only 20 dB above the TTS threshold, it is probable that the animal would have to be exposed to the strong sound for an extended period.

Sound impulse duration, peak amplitude, rise time, and number of pulses are the main factors thought to determine the onset and extent of PTS. Ketten (1994) noted that the criteria for differentiating the sound pressure levels that result in PTS (or TTS) are location and species-specific. PTS effects may also be influenced strongly by the health of the receiver's ear.

Given that marine mammals are unlikely to be exposed to received levels of seismic pulses that could cause TTS, it is highly unlikely that they would sustain permanent hearing impairment. If we assume that the TTS threshold for odontocetes for exposure to a series of seismic pulses may be on the order of 220 dB re 1 microPa (pk-pk) (approximately 204 dB re 1 microPa rms), then the PTS threshold might be about 240 dB re 1 microPa (pk-pk). In the units used by geophysicists, this is 10 bar-m. Such levels are found only in the immediate vicinity of the largest airguns (Richardson *et al.*, 1995; Caldwell and Dragoset, 2000). However,

sea Gentryit is very unlikely that an odontocete would remain within a few meters of a large airgun for sufficiently long to incur PTS. The TTS (and thus PTS) thresholds of baleen whales and pinnipeds may be lower, and thus may extend to a somewhat greater distance from the source. However, baleen whales generally avoid the immediate area around operating seismic vessels, so it is unlikely that a baleen whale could incur PTS from exposure to airgun pulses. Some pinnipeds do not show strong avoidance of operating airguns. In summary, it is highly unlikely that marine mammals could receive sounds strong enough (and over a sufficient period of time) to cause permanent hearing impairment during this project. In this project marine mammals are unlikely to be exposed to received levels of seismic pulses strong enough to cause TTS, and because of the higher level of sound necessary to cause PTS, it is even less likely that PTS could occur. This is due to the fact that even levels immediately adjacent to the 2 GI-airguns may not be sufficient to induce PTS because the mammal would not be exposed to more than one strong pulse unless it swam alongside an airgun for a period of time.

Strandings and Mortality

Marine mammals close to underwater detonations of high explosives can be killed or severely injured, and the auditory organs are especially susceptible to injury (Ketten *et al.*, 1993; Ketten, 1995). Airgun pulses are less energetic and have slower rise times. While there is no documented evidence that airgun arrays can cause serious injury, death, or stranding, the association of mass strandings of beaked whales with naval exercises and an L-DEO seismic survey in 2002 have raised the possibility that beaked whales may be especially susceptible to injury and/or stranding when exposed to strong pulsed sounds. Information on recent beaked whale strandings may be found in Appendix A of the Scripps application and in several previous **Federal Register** documents (see 69 FR 31792 (June 7, 2004) or 69 FR 34996 (June 23, 2004)). Reviewers are encouraged to read these documents for additional information.

It is important to note that seismic pulses and mid-frequency sonar pulses are quite different. Sounds produced by the types of airgun arrays used to profile sub-sea geological structures are broadband with most of the energy below 1 kHz. Typical military mid-frequency sonars operate at frequencies of 2 to 10 kHz, generally with a relatively narrow bandwidth at any one time (though the center frequency may change over time). Because seismic and sonar sounds have considerably different characteristics and duty cycles, it is not appropriate to assume that there is a direct connection between the effects of military sonar and seismic surveys on marine mammals. However, evidence that sonar pulses can, in special circumstances, lead to physical damage and, indirectly, mortality suggests that caution is warranted when dealing with exposure of marine mammals to any high-intensity pulsed sound.

In addition to the sonar-related strandings, there was a September 2002 stranding of two Cuvier's beaked whales in the Gulf of California (Mexico) when a seismic survey by the *R/V Maurice Ewing* was underway in the general area (Malakoff, 2002). The airgun array in use during that project was the Ewing's 20-gun 8490-in^3 array. This might be a first indication that seismic surveys can have effects, at least on beaked whales, similar to the suspected effects of naval sonars. However, the evidence linking the Gulf of California strandings to the seismic surveys is inconclusive, and to date, is not based on any physical evidence (Hogarth, 2002; Yoder, 2002). The ship was also operating its multi-beam bathymetric sonar at the same time but this sonar had much less potential than these naval sonars to affect beaked whales. Although the link between the Gulf of California strandings and the seismic (plus multi-beam sonar) survey is inconclusive, this event plus the various incidents involving beaked whale strandings associated with naval exercises suggests a need for caution in conducting seismic surveys in areas occupied by beaked whales. However, the present project will involve a much smaller sound source than used in typical seismic surveys. That, along with the monitoring and mitigation measures planned for this cruise are expected to eliminate any possibility for strandings and mortality.

Non-Auditory Physiological Effects

Possible types of non-auditory physiological effects or injuries that might theoretically occur in marine mammals exposed to strong underwater sound might include stress, neurological effects, bubble formation, resonance effects, and other types of organ or tissue damage. There is no evidence that any of these effects occur in marine mammals exposed to sound from airgun arrays (even large ones). However, there have been no direct studies of the potential for airgun pulses to elicit any of these effects. If any such effects do occur, they would probably be limited to unusual situations when animals might be exposed at close range for unusually long periods.

It is doubtful that any single marine mammal would be exposed to strong seismic sounds for sufficiently long that significant physiological stress would develop. That is especially so in the case of the present project where the airguns are small, the ship's speed is relatively fast (6 knots or approximately 11 km/h), and, except while on a seismic station, the survey lines are widely spaced with little or no overlap.

Gas-filled structures in marine animals have an inherent fundamental resonance frequency. If stimulated at that frequency, the ensuing resonance could cause damage to the animal. There may also be a possibility that high sound levels could cause bubble formation in the blood of diving mammals that in turn could cause an air embolism, tissue separation, and high, localized pressure in nervous tissue (Gisner (ed), 1999; Houser *et al.*, 2001).

In April 2002, a workshop (Gentry [ed.] 2002) was held to discuss whether the stranding of beaked whales in the Bahamas in 2000 (Balcomb and Claridge, 2001; NOAA and USN, 2001) might have been related to air cavity resonance or bubble formation in tissues caused by exposure to noise from naval sonar. A panel of experts concluded that resonance in air-filled structures was not likely to have caused this stranding. Among other reasons, the air spaces in marine mammals are too large to be susceptible to resonant frequencies emitted by mid-or low-frequency sonar; lung tissue damage has not been observed in any mass, multi-species stranding of beaked whales; and the duration of sonar pings is likely too short to induce vibrations that could damage tissues (Gentry [ed.], 2002). Opinions were less conclusive about the possible role of gas (nitrogen) bubble formation/growth in the Bahamas stranding of beaked whales.

Until recently, it was assumed that diving marine mammals are not subject to decompression injury (the bends) or air embolism. However, a short paper concerning beaked whales stranded in the Canary Islands in 2002 suggests that cetaceans might be subject to decompression injury in some situations (Jepson *et al.*, 2003). If so, that might occur if they ascend unusually quickly when exposed to aversive sounds. However, the interpretation that strandings are related to decompression injury is unproven (Piantadosi and Thalmann, 2004; Fernández *et al.*, 2004). Even if that effect can occur during exposure to mid-frequency

sonar, there is no evidence that this type of effect occurs in response to low-frequency airgun sounds. It is especially unlikely in the case of this project involving only two small, low-intensity GI-airguns.

In summary, little is known about the potential for seismic survey sounds to cause either auditory impairment or other non-auditory physical effects in marine mammals. Available data suggest that such effects, if they occur at all, would be limited to short distances from the sound source. However, the available data do not allow for meaningful quantitative predictions of the numbers (if any) of marine mammals that might be affected in these ways. Marine mammals that show behavioral avoidance of seismic vessels, including most baleen whales, some odontocetes, and some pinnipeds, are unlikely to incur auditory impairment or other physical effects. Also, the planned mitigation and monitoring measures are expected to minimize any possibility of serious injury, mortality or strandings.

Possible Effects of Mid-frequency Sonar Signals

A multi-beam bathymetric sonar (Simrad EM120, 11.25–12.6 kHz) and a sub-bottom profiler will be operated from the source vessel essentially continuously during much of the planned survey. Details about these sonars were provided previously in this document.

Navy sonars that have been linked to avoidance reactions and stranding of cetaceans generally: (1) Are more powerful than the Simrad EM120 sonar; (2) have a longer pulse duration; and (3) are directed close to horizontally (vs. downward for the Simrad EM120). The area of possible influence of the Simrad EM120 is much smaller—a narrow band oriented in the cross-track direction below the source vessel. Marine mammals that encounter the Simrad EM120 at close range are unlikely to be subjected to repeated pulses because of the narrow fore-aft width of the beam, and will receive only limited amounts of pulse energy because of the short pulses and vessel speed. Therefore, as harassment or injury from pulsed sound is a function of total energy received, the actual harassment or injury threshold for the bathymetric sonar signals would be at a much higher dB level than that for longer duration pulses such as seismic signals As a result, NMFS believes that marine mammals are unlikely to be harassed or injured from the multibeam sonar.

Masking by Mid-Frequency Sonar Signals

Marine mammal communications will not be masked appreciably by the multibeam sonar signals or the sub-bottom profiler given the low duty cycle and directionality of the sonars and the brief period when an individual mammal is likely to be within its beam. Furthermore, in the case of baleen whales, the sonar signals from the Simrad EM120 do not overlap with the predominant frequencies of their calls, which would avoid significant masking.

For the sub-bottom profiler, marine mammal communications will not be masked appreciably because of their relatively low power output, low duty cycle, directionality (for the profiler), and the brief period when an individual mammal may be within the sonar's beam. In the case of most odonotocetes, the sonar signals from the profiler do not overlap with the predominant frequencies in their calls. In the case of mysticetes, the pulses from the pinger do not overlap with their predominant frequencies.

Behavioral Responses Resulting From Mid-Frequency Sonar Signals

Behavioral reactions of free-ranging marine mammals to military and other sonars appear to vary by species and circumstance. Observed reactions have included silencing and dispersal by sperm whales (Watkins *et al.*, 1985), increased vocalizations and no dispersal by pilot whales (Rendell and Gordon, 1999), and the previously-mentioned strandings by beaked whales. Also, Navy personnel have described observations of dolphins bow-riding adjacent to bow-mounted mid-frequency sonars during sonar transmissions. However, all of these observations are of limited relevance to the present situation. Pulse durations from these military tactical sonars were much longer than those of the Scripps multibeam sonar, and a given mammal would have received many pulses from the naval sonars. During Scripps' operations, the individual pulses will be very short, and a given mammal would not receive many of the downward-directed pulses as the vessel passes by.

Captive bottlenose dolphins and a white whale exhibited changes in behavior when exposed to 1-sec pulsed sounds at frequencies similar to those that will be emitted by the multi-beam sonar used by Scripps and to shorter broadband pulsed signals. Behavioral changes typically involved what appeared to be deliberate attempts to avoid the sound exposure (Schlundt *et al.*, 2000; Finneran *et al.*, 2002). The relevance of these data to free-ranging odontocetes is uncertain and in any case the test sounds were quite different in either duration or bandwidth as compared to those from a bathymetric sonar.

Scripps and NMFS are not aware of any data on the reactions of pinnipeds to sonar sounds at frequencies similar to those of the 12.0 kHz frequency of the *Revelle*'s multibeam sonar. Based on observed pinniped responses to other types of pulsed sounds, and the likely short duration of exposure to the bathymetric sonar sounds, pinniped reactions are expected to be limited to startle or otherwise brief responses of no lasting consequences to the individual animals. The pulsed signals from the sub-bottom profiler are much weaker than those from the multibeam sonar and somewhat weaker than those from the 2 GI-airgun array. Therefore, significant behavioral responses are not expected.

Hearing Impairment and Other Physical Effects

Given stranding events that have been associated with the operation of naval sonar, there is much concern that sonar noise can cause serious impacts to marine mammals (for discussion see Effects of Seismic Surveys on Marine Mammals). However, the multi-beam sonars proposed for use by Scripps are quite different than tactical sonars used for navy operations. Pulse duration of the bathymetric sonars is very short relative to the naval sonars. Also, at any given location, an individual marine mammal would be in the beam of the multi-beam sonar for much less time given the generally downward orientation of the beam and its narrow fore-aft beam-width. (Navy sonars often use near-horizontally directed sound.) These factors would all reduce the sound energy received from the multi-beam sonar rather drastically relative to that from the sonars used by the Navy. Therefore, hearing impairment by multi-beam bathymetric sonar is unlikely.

Source levels of the sub-bottom profiler are much lower than those of the airguns and the multi-beam sonar. Sound levels from a sub-bottom profiler similar to the one on the *Revelle* were estimated to decrease to 180 dB re 1 microPa (rms) at 8 m (26 ft) horizontally from the source (Burgess and Lawson, 2000), and at approximately 18 m (59 ft) downward from the source. Furthermore, received levels of pulsed sounds that are necessary to cause temporary or especially permanent hearing impairment in marine mammals appear to be higher than 180 dB (see earlier discussion). Thus, it is unlikely

that the sub-bottom profiler produces pulse levels strong enough to cause hearing impairment or other physical injuries even in an animal that is (briefly) in a position near the source.

The sub-bottom profiler is usually operated simultaneously with other higher-power acoustic sources. Many marine mammals will move away in response to the approaching higher-power sources or the vessel itself before the mammals would be close enough for there to be any possibility of effects from the less intense sounds from the sub-bottom profiler. In the case of mammals that do not avoid the approaching vessel and its various sound sources, mitigation measures that would be applied to minimize effects of the higher-power sources would further reduce or eliminate any minor effects of the sub-bottom profiler.

Estimates of Take by Harassment for the SWPO Seismic Survey

Although information contained in this document indicates that injury to marine mammals from seismic sounds potentially occurs at sound pressure levels significantly higher than 180 and 190 dB, NMFS' current criteria for where onset of Level A harassment of cetaceans and pinnipeds from impulse sound might occur are, respectively, 180 and 190 re 1 microPa rms. The rms level of a seismic pulse is typically about 10 dB less than its peak level and about 16 dB less than its pk-pk level (Greene, 1997; McCauley *et al.*, 1998; 2000a). The criterion for where onset of Level B behavioral harassment occurs is 160 dB.

Given the mitigation (see Mitigation later in this document), all anticipated effects involve a temporary change in behavior that may constitute Level B harassment. The mitigation measures will minimize or eliminate the possibility of Level A harassment or mortality. Scripps has calculated the "best estimates" for the numbers of animals that could be taken by level B harassment during the proposed SWPO seismic survey using data on marine mammal density (numbers per unit area) and estimates of the size of the affected area, as shown in the predicted RMS radii table (see Table 1).

These estimates are based on a consideration of the number of marine mammals that might be exposed to sound levels greater than 160 dB by operations with the 2 GI-gun array planned to be used for this project. The anticipated zones of influence of the multi-beam sonar and sub-bottom profiler are less than that for the airguns, so it is assumed that during simultaneous operations of these instruments that any marine mammals close enough to be affected by the multi-beam and sub-bottom profiler sonars would already be affected by the airguns. Therefore, no additional incidental takings are included for animals that might be affected by the multi-beam sonar. Given their characteristics (described previously), Level B harassment takings are considered unlikely when the multibeam and sub-bottom profiler are operating but the airguns are silent.

Table 2 provides the best estimate of the numbers of each species that would be exposed to seismic sounds greater than 160 dB and the number of marine mammals requested to be taken by Level B harassment. A detailed description on the methodology used by Scripps to arrive at the estimates of Level B harassment takes that are provided in Table 2 can be found in Scripps's IHA application for the SWPO survey.

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TABLE 2. Estimates of the possible numbers of marine mammal exposures to the different sound levels, and the numbers of different individuals that might be exposed, during the proposed SIO seismic surveys the Louisville Ridge in the SW Pacific Ocean during January-February 2006. (Specific Geographic Regions--SPSG = South Pacific Subtropical Gyre; SSTC = South Subtropical Convergence Province (Longhurst (1998)).

Species	Number of Exposures to Sound Levels ≥160 dB (rms)						Number of Individuals Exposed to Sound Levels ≥160 dB (rms)						
	Best Estimate			Maximum Estimate			Best Estimate			Pop'	Maximum		
	SPSG	SSTC	Total	SPSG	SSTC	Total	SPSG	SSTC	Total	n %	SPSG	SSTC	Total
Delphinidae													
Rough-toothed dolphin	19	30	49	36	47	83	18	29	47	0.02	35	45	80
Bottlenose dolphin	38	149	186	72	233	305	36	144	180	0.04	70	225	295
Pantropical spotted dolphin	19	30	49	36	47	83	18	29	47	0.00	35	45	80
Spinner dolphin	4	15	19	7	23	31	4	14	18	0.00	7	22	29
Striped dolphin	4	15	19	7	23	31	4	14	18	0.00	7	22	29
Common dolphin	38	149	186	72	233	305	36	144	180	0.01	70	225	295
Hourglass dolphin	4	15	19	7	23	31	4	14	18	0.01	7	22	29
Fraser's dolphin	11	15	26	22	23	45	11	14	25	0.01	21	22	43
S'n right-whale dolphin	4	45	48	7	70	77	4	43	47	NA	7	67	74
Risso's dolphin	19	74	93	36	117	153	18	72	90	0.05	35	112	147
Melon-headed whale	0	0	0	1	0	1	0	0	0	0.00	1	0	1
Pygmy killer whale	0	0	0	1	0	2	0	0	0	0.00	1	0	1
False killer whale	0	0	1	2	1	3	0	0	1	0.00	2	1	3
Killer whale	1	0	1	3	1	4	1	0	1	0.00	3	1	4
Short-finned pilot whale	1	0	1	5	0	6	1	0	1	0.00	5	0	6
Long-finned pilot whale	0	1	1	1	2	2	0	1	1	0.00	1	2	2
Odontocetes													
Physeteridae													
Sperm whale	0	1	1	1	2	3	0	1	1	0.00	1	2	3
Pygmy sperm whale	2	1	4	12	4	16	2	1	4	NA	11	4	15
Dwarf sperm whale	0	0	0	0	0	0	0	0	0	0	0	0	0
												0	
Ziphiidae												0	
Southern bottlenose whale	0	1	1	0	2	2	0	1	1	0.00	0	2	2
Arnoux's beaked whale	0	0	0	0	1	1	0	0	0	0	0	1	1
Cuvier's beaked whale	0	0	1	1	1	2	0	0	1	0.00	1	1	2
Shepard's beaked whale	0	0	0	0	0	1	0	0	0	0	0	0	1
Andrew's beaked whale	0	0	0	0	0	1	0	0	0	0	0	0	1
Blainville's beaked whale	0	0	1	1	1	2	0	0	1	NA	1	1	2

Ginkgo-t'ed beaked whale	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Gray's beaked whale	0	0	1	1	1	2	0	0	1	NA	1	1	2	0	0	1	NA	1	1	2	0	0	0	0
Hector's beaked whale	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Spade-t'hed beaked whale	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Strap-t'hed beaked whale	0	0	1	1	1	2	0	0	1	NA	1	1	2	0	0	1	NA	1	1	2	0	0	0	0
Phocoenidae																								
Spectacled porpoise	0	13	13	0	136	136	0	13	13	NA	0	132	132	0	13	13	NA	0	132	132	0	0	0	0
Mysticetes																								
Southern right whale	0	1	1	0	1	1	0	1	1	NA	0	1	1	0	1	1	NA	0	1	1	0	0	0	0
Pygmy right whale	0	1	1	0	1	1	0	1	1	NA	0	1	1	0	1	1	NA	0	1	1	0	0	0	0
Humpback whale	0	0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0
Minke whale	0	0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0
Dwarf minke whale	0	0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0
Bryde's whale	0	1	1	0	2	2	0	0	1	0.00	0	0	0	0	0	1	0.00	0	2	2	0	0	0	0
Sei whale	0	1	1	0	2	2	0	1	1	0.01	0	2	2	0	1	1	0.01	0	2	2	0	0	0	0
Fin whale	0	1	1	0	1	1	0	1	1	0.00	0	1	1	0	1	1	0.00	0	1	1	0	0	0	0
Blue whale	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Pinnipeds																								
Southern elephant seal	0	3	3	NA	NA	NA	0	3	3	0.00	0	0	0	0	3	3	0.00	0	0	0	0	0	0	0
Leopard seal	0	5	6	NA	NA	NA	0	5	5	0.00	0	0	0	0	5	5	0.00	0	0	0	0	0	0	0
Crabeater seal	0	3	3	NA	NA	NA	0	3	3	0.00	0	0	0	0	3	3	0.00	0	0	0	0	0	0	0
Antarctic fur seal	0	5	6	NA	NA	NA	0	5	5	0.00	0	0	0	0	5	5	0.00	0	0	0	0	0	0	0
Sub-antarctic fur seal	0	5	6	NA	NA	NA	0	5	5	NA	0	0	0	0	5	5	NA	0	0	0	0	0	0	0

Conclusions

Effects on Cetaceans

Strong avoidance reactions by several species of mysticetes to seismic vessels have been observed at ranges up to 6–8 km (3.2–4.3 nm) and occasionally as far as 20–30 km (10.8–16.2 nm) from the source vessel. However, reactions at the longer distances appear to be atypical of most species and situations, particularly when feeding whales are involved. Few mysticetes are expected to be encountered during the proposed survey in the SWPO (Table 2) and disturbance effects would be confined to shorter distances given the low-energy acoustic source to be used during this project. In addition, the estimated numbers presented in Table 2 are considered overestimates of actual numbers that may be harassed.

Odontocete reactions to seismic pulses, or at least the reactions of dolphins, are expected to extend to lesser distances than are those of mysticetes. Odontocete low-frequency hearing is less sensitive than that of mysticetes, and dolphins are often seen from seismic vessels. In fact, there are

documented instances of dolphins approaching active seismic vessels. However, dolphins as well as some other types of odontocetes sometimes show avoidance responses and/or other changes in behavior when near operating seismic vessels.

Taking into account the small size and the relatively low sound output of the 2 GI-gun array to be used, and the mitigation measures that are planned, effects on cetaceans are generally expected to be limited to avoidance of a small area around the seismic operation and short-term changes in behavior. Furthermore, the estimated numbers of animals potentially exposed to sound levels sufficient to cause appreciable disturbance are very low percentages of the affected populations.

Based on the 160-dB criterion, the best estimates of the numbers of individual cetaceans that may be exposed to sounds ≥ 160 dB re 1 microPa (rms) represent from 0 to approximately 0.04 percent of the regional SWPO species populations (Table 2). In the case of endangered balaenopterids, it is most likely that no more than 1 humpback, sei, or fin whale will be exposed to seismic sounds ≥ 160 dB re 1 microPa (rms), based on estimated densities of those species in the survey region. Therefore, Scripps has requested an authorization to expose up to 1 individual of each of those species to seismic sounds of ≥ 160 dB during the proposed survey. Best estimates of blue whales are that no individuals would be potentially exposed to seismic pulses with received levels ≥ 160 dB re 1 microPa (rms) (Table 2).

Higher numbers of delphinids may be affected by the proposed seismic surveys, but the population sizes of species likely to occur in the survey area are large, and the numbers potentially affected are small relative to population sizes (Table 2).

Mitigation measures such as controlled speed, course alteration, observers, ramp ups, and shut downs when marine mammals are seen within defined ranges should further reduce short-term reactions, and minimize any effects on hearing. In all cases, the effects are expected to be short-term, with no lasting biological consequence. In light of the type of effects expected and the small percentages of affected stocks of cetaceans, the action is expected to have no more than a negligible impact on the affected species or stocks of cetaceans.

Effects on Pinnipeds

Five pinniped species may be encountered at the survey sites, but their distribution and numbers have not been documented in the proposed survey area. In all likelihood, these species will be in southern feeding areas during the period for this survey. However, to ensure that the Scripps project remains in compliance with the MMPA in the event that a few pinnipeds are encountered, Scripps has requested an authorization to expose up to 3–5 individuals of each of the five pinniped species to seismic sounds with rms levels ≥ 160 dB re 1 µPa. Therefore, the survey would have, at most, a short-term effect on their behavior and no long-term impacts on individual pinnipeds or their populations. Responses of pinnipeds to acoustic disturbance are variable, but usually quite limited. Effects are expected to be limited to short-term and localized behavioral changes falling within the MMPA definition of Level B harassment. As is the case for cetaceans, the short-term exposures to sounds from the two GI-guns are not expected to result in any long-term consequences for the individuals or their populations and the activity is expected to have no more than a negligible impact on the affected species or stocks of pinnipeds.

Potential Effects on Habitat

The proposed seismic survey will not result in any permanent impact on habitats used by marine mammals, or to the food sources they utilize. The main impact issue associated with the proposed activity will be temporarily elevated noise levels and the associated direct effects on marine mammals.

One of the reasons for the adoption of airguns as the standard energy source for marine seismic surveys was that they (unlike the explosives used in the distant past) do not result in any appreciable fish kill. Various experimental studies showed that airgun discharges cause little or no fish kill, and that any injurious effects were generally limited to the water within a meter or so of an airgun. However, it has recently been found that injurious effects on captive fish, especially on fish hearing, may occur at somewhat greater distances than previously thought (McCauley *et al.*, 2000a,b; 2002; 2003). Even so, any injurious effects on fish would be limited to short distances from the source. Also, many of the fish that might otherwise be within the injury-zone are likely to be displaced from this region prior to the approach of the airguns through avoidance reactions to the approaching seismic vessel or to the airgun sounds as received at distances beyond the injury radius.

Fish often react to sounds, especially strong and/or intermittent sounds of low frequency. Sound pulses at received levels of 160 dB re 1 µPa (peak) may cause subtle changes in behavior. Pulses at levels of 180 dB (peak) may cause noticeable changes in behavior (Chapman and Hawkins, 1969; Pearson *et al.*, 1992; Skalski *et al.*, 1992). It also appears that fish often habituate to repeated strong sounds rather rapidly, on time scales of minutes to an hour. However, the habituation does not endure, and resumption of the disturbing activity may again elicit disturbance responses from the same fish.

Fish near the airguns are likely to dive or exhibit some other kind of behavioral response. This might have short-term impacts on the ability of cetaceans to feed near the survey area. However, only a small fraction of the available habitat would be ensonified at any given time, and fish species would return to their pre-disturbance behavior once the seismic activity ceased. Thus, the surveys would have little impact on the abilities of marine mammals to feed in the area where seismic work is planned. Fish that do not avoid the approaching airguns (probably a small number) may be subject to auditory or other injuries.

Zooplankton that are very close to the source may react to the airgun's shock wave. These animals have an exoskeleton and no air sacs; therefore, little or no mortality is expected. Many crustaceans can make sounds and some crustacea and other invertebrates have some type of sound receptor. However, the reactions of zooplankton to sound are not known. Some mysticetes feed on concentrations of zooplankton. A reaction by zooplankton to a seismic impulse would only be relevant to whales if it caused a concentration of zooplankton to scatter. Pressure changes of sufficient magnitude to cause this type of reaction would probably occur only very close to the source, so few zooplankton concentrations would be affected. Impacts on zooplankton behavior are predicted to be negligible, and this would translate into negligible impacts on feeding mysticetes.

Potential Effects on Subsistence Use of Marine Mammals

There is no known legal subsistence hunting for marine mammals in the SWPO, so the proposed Scripps activities will not have any impact on the availability of these species or stocks for subsistence users.

Mitigation

For the proposed seismic survey in the SWPO, Scripps will deploy 2 GI-airguns as an energy source, each with a discharge volume of 45 in^3. The

energy from the airguns is directed mostly downward. The directional nature of the airguns to be used in this project is an important mitigating factor. This directionality will result in reduced sound levels at any given horizontal distance as compared with the levels expected at that distance if the source were omnidirectional with the stated nominal source level. Also, the small size of these airguns is an inherent and important mitigation measure that will reduce the potential for effects relative to those that might occur with large airgun arrays. This measure is in conformance with NMFS policy of encouraging seismic operators to use the lowest intensity airguns practical to accomplish research objectives.

The following mitigation measures, as well as marine mammal visual monitoring (discussed later in this document), will be implemented for the subject seismic surveys: (1) Speed and course alteration (provided that they do not compromise operational safety requirements); (2) shut-down procedures; and (3) ramp-up procedures.

Speed and Course Alteration

If a marine mammal is detected outside its respective safety zone (180 dB for cetaceans, 190 dB for pinnipeds) and, based on its position and the relative motion, is likely to enter the safety zone, the vessel's speed and/or direct course may, when practical and safe, be changed to avoid the mammal in a manner that also minimizes the effect to the planned science objectives. The marine mammal activities and movements relative to the seismic vessel will be closely monitored to ensure that the marine mammal does not approach within the safety zone. If the mammal appears likely to enter the safety zone, further mitigative actions will be taken (*i.e.*, either further course alterations or shut down of the airguns).

Shut-down Procedures

Although power-down procedures are often standard operating practice for seismic surveys, power-down will not be used for this activity because powering down from two guns to one gun would make only a small difference in the 180- or 190-dB radius—probably not enough to allow continued one-gun operations if a mammal came within the safety radius for two guns.

If a marine mammal is detected outside the safety radius but is likely to enter the safety radius, and if the vessel's speed and/or course cannot be changed to avoid having the mammal enter the safety radius, the GI-guns will be shut down before the mammal is within the safety radius. Likewise, if a mammal is already within the safety zone when first detected, the airguns will be shut down immediately.

Following a shut-down, airgun activity will not resume until the marine mammal has cleared the safety zone. The animal will be considered to have cleared the safety zone if it: (1) Is visually observed to have left the safety zone, or (2) has not been seen within the zone for 15 min in the case of small odontocetes and pinnipeds, or (3) has not been seen within the zone for 30 minutes in the case of mysticetes and large odontocetes, including sperm, pygmy sperm, dwarf sperm, beaked and bottlenose whales.

During airgun operations following a shut-down whose duration has exceeded these specified limits, the airgun array will be ramped-up gradually. Ramp-up is described later in this document.

Ramp-up Procedure

A ramp-up procedure will be followed when the airguns begin operating after a period without airgun operations. The two GI guns will be added in sequence 5 minutes apart. During ramp-up procedures, the safety radius for the two GI guns will be maintained.

During the day, ramp-up cannot begin from a shut-down unless the entire 180-dB safety radius has been visible for at least 30 minutes prior to the ramp up (i.e., no ramp-up can begin in heavy fog or high sea states).

During nighttime operations, if the entire safety radius is visible using vessel lights and night-vision devices (NVDs) (as may be the case in deep and intermediate waters), then start up of the airguns from a shut down may occur, after completion of the 30-minute observation period.

Comments on past IHAs raised the issue of prohibiting nighttime operations as a practical mitigation measure. However, this is not practicable due to cost considerations and ship time schedules. If the *Revelle* was prohibited from operating during nighttime, each trip could require an additional several days to complete.

If a seismic survey vessel is limited to daylight seismic operations, efficiency would also be much reduced. Without commenting specifically on how that limitation would affect the present project, for seismic operators in general, a daylight-only requirement would be expected to result in one or more of the following outcomes: cancellation of potentially valuable seismic surveys; reduction in the total number of seismic cruises annually due to longer cruise durations; a need for additional vessels to conduct the seismic operations; or work conducted by non-U.S. operators or non-U.S. vessels when in waters not subject to U.S. law.

Marine Mammal Monitoring

Scripps must have at least three visual observers on board the *Revelle*, and at least two must be experienced marine mammal observers that NMFS has approved in advance of the start of the SWPO cruise. These observers will be on duty in shifts of no longer than 4 hours.

The visual observers will monitor marine mammals and sea turtles near the seismic source vessel during all daytime airgun operations, during any nighttime start-ups of the airguns, and at night whenever daytime monitoring resulted in one or more shut-down situations due to marine mammal presence. During daylight, vessel-based observers will watch for marine mammals and sea turtles near the seismic vessel during periods with shooting (including ramp-ups), and for 30 minutes prior to the planned start of airgun operations after a shut-down.

Use of multiple observers will increase the likelihood that marine mammals near the source vessel are detected. *Revelle* bridge personnel will also assist in detecting marine mammals and implementing mitigation requirements whenever possible (they will be given instruction on how to do so), especially during ongoing operations at night when the designated observers are on stand-by and not required to be on watch at all times.

The observer(s) will watch for marine mammals from the highest practical vantage point on the vessel, which is either the bridge or the flying bridge. The observer(s) will systematically scan the area around the vessel with Big Eye binoculars, reticle binoculars (e.g., 7 x 50 Fujinon) and with the naked eye during the daytime. Laser range-finding binoculars (Leica L.F. 1200 laser rangefinder or equivalent) will be available to assist with distance estimation. The observers will be used to determine when a marine mammal or sea turtle is in or near the safety radii so that the required mitigation measures, such as course alteration and power-down or shut-down, can be implemented. If the GI-airguns are shut down, observers will maintain watch to determine when the animal is outside the safety radius.

Observers may not be on duty during ongoing seismic operations at night; bridge personnel will watch for marine mammals during this time and will call

for the airguns to be powered-down or shut-down if marine mammals are observed in or about to enter the safety radii. However, a biological observer must be on standby at night and available to assist the bridge watch if marine mammals are detected at any distance from the *Revelle*. If the 2 GI-airgun is ramped-up at night (see previous section), two marine mammal observers will monitor for marine mammals for 30 minutes prior to ramp-up and during the ramp-up using either deck lighting or NVDs that will be available (ITT F500 Series Generation 3 binocular image intensifier or equivalent).

Post-Survey Monitoring

In addition, the biological observers will be able to conduct monitoring of most recently-run transect lines as the *Revelle* returns along parallel and perpendicular transect tracks (see inset of Figure 1 in the Scripps application). This will provide the biological observers with opportunities to look for injured or dead marine mammals (although no injuries or mortalities are expected during this research cruise).

Passive Acoustic Monitoring (PAM)

Because of the very small zone for potential Level A harassment, Scripps has not proposed to use the PAM system during this cruise.

Summary

Taking into consideration the additional costs of prohibiting nighttime operations and the likely impact of the activity (including all mitigation and monitoring), NMFS has determined that the mitigation and monitoring measures ensure that the activity will have the least practicable impact on the affected species or stocks. Marine mammals will have sufficient notice of a vessel approaching with operating seismic airguns, thereby giving them an opportunity to avoid the approaching array; if ramp-up is required, two marine mammal observers will be required to monitor the safety radii, in daylight or night-time, using shipboard lighting or NVDs for at least 30 minutes before ramp-up begins and verify that no marine mammals are in or approaching the safety radii; ramp-up may not begin unless the entire safety radii are visible.

Reporting

Scripps will submit a report to NMFS within 90 days after the end of the cruise, which is currently predicted to occur during January and February, 2006. The report will describe the operations that were conducted and the marine mammals that were detected. The report must provide full documentation of methods, results, and interpretation pertaining to all monitoring tasks. The report will summarize the dates and locations of seismic operations, marine mammal sightings (dates, times, locations, activities, associated seismic survey activities), and estimates of the numbers of affected marine mammals and a description of their reactions.

Endangered Species Act (ESA)

NMFS has issued a biological opinion regarding the effects of this action on ESA-listed species and critical habitat under the jurisdiction of NMFS. That biological opinion concluded that this action is not likely to jeopardize the continued existence of listed species or result in the destruction or adverse modification of critical habitat. A copy of the Biological Opinion is available upon request (see **ADDRESSES**).

National Environmental Policy Act (NEPA)

The NSF made a FONSI determination on November 3, 2005 (70 FR 68102, November 9, 2005), based on information contained within its EA (see 70 FR 39346, July 7, 2005 for public availability), that implementation of the subject action is not a major Federal action having significant effects on the environment within the meaning of NEPA. The NSF determined, therefore, that an environmental impact statement would not be prepared.

NMFS noted that the NSF had prepared an EA for the SWPO surveys and made this EA available upon request (October 17, 2005, 70 FR 60287). In accordance with NOAA Administrative Order 216–6 (Environmental Review Procedures for Implementing the National Environmental Policy Act, May 20, 1999), NMFS has reviewed the information contained in NSF's EA and determined that the NSF EA accurately and completely describes the proposed action alternative, and the potential impacts on marine mammals, endangered species, and other marine life that could be impacted by the preferred alternative and the other alternatives. Accordingly, NMFS adopted the NSF EA under 40 CFR 1506.3 and made its own FONSI. The NMFS FONSI also takes into consideration additional mitigation measures required by the IHA that are not in NSF's EA. Therefore, it is not necessary to issue a new EA, supplemental EA or an environmental impact statement for the issuance of an IHA to L-DEO for this activity. A copy of the EA and the NMFS FONSI for this activity is available upon request.

Determinations

NMFS has determined that the impact of conducting the seismic survey on the Louisville Ridge in the SWPO may result, at worst, in a temporary modification in behavior by certain species of marine mammals. This activity is expected to result in no more than a negligible impact on the affected species or stocks.

For reasons stated previously in this document, this determination is supported by: (1) The likelihood that, given advance notice through relatively slow ship speed and ramp-up, marine mammals are expected to move away from a noise source that is annoying before it becomes potentially injurious; (2) recent research that indicates that TTS is unlikely (at least in delphinids) until levels closer to 200–205 dB re 1 microPa are reached rather than 180 dB re 1 microPa; (3) the fact that 200–205 dB isopleths would be well within 100 m (328 ft) of the vessel even in shallow water; and (4) the likelihood that marine mammal detection in the safety zone by trained observers is close to 100 percent during daytime and remains high at night to the short distance from the seismic vessel. As a result, no take by injury or death is anticipated, and the potential for temporary or permanent hearing impairment is very low and would be avoided through the incorporation of the mitigation measures described in this document.

While the number of potential incidental harassment takes will depend on the distribution and abundance of marine mammals in the vicinity of the survey activity, the number of potential harassment takings is estimated to be small. In addition, the proposed seismic program will not interfere with any known legal subsistence hunts, since seismic operations will not take place in subsistence whaling and sealing areas and will not affect marine mammals used for subsistence purposes.

Authorization

On January 20, 2006, NMFS has issued an IHA to Scripps to take marine mammals, by harassment, incidental to conducting seismic surveys in the SWPO for a 1-year period, provided the mitigation, monitoring, and reporting requirements are undertaken.

Dated: January 31, 2006.

James H. Lecky,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 06–1074 Filed 2–3–06; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

Madrid Protocol

ACTION: Proposed collection; comment request.

SUMMARY: The United States Patent and Trademark Office (USPTO), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on the revision of a continuing information collection, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments must be submitted on or before April 7, 2006.

ADDRESSES: You may submit comments by any of the following methods:

- E-mail: *Susan.Brown@uspto.gov*. Include "0651–0051 comment" in the subject line of the message.
- Fax: 571–273–0112, marked to the attention of Susan Brown.
- Mail: Susan K. Brown, Records Officer, Office of the Chief Information Officer, Architecture, Engineering and Technical Services, Data Architecture and Services Division, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.
- Federal e-Rulemaking Portal: *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Sharon Marsh, Deputy Commissioner for Trademark Examination Policy, Office of the Commissioner for Trademarks, U.S. Patent and Trademark Office, P.O. Box 1451, Alexandria, VA 22313–1451; by telephone at 571–272–7140; or by e-mail at *Sharon.Marsh@uspto.gov*.

SUPPLEMENTARY INFORMATION:

I. Abstract

This collection of information is required by the Trademark Act of 1946, 15 U.S.C. 1051 *et seq.*, which provides for the Federal registration of trademarks, service marks, collective trademarks and service marks, collective membership marks, and certification marks. Individuals and businesses that use or intend to use such marks in commerce may file an application to register the marks with the United States Patent and Trademark Office (USPTO).

The Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks ("Madrid Protocol") is an international treaty that allows a trademark owner to seek registration in any of the participating countries by filing a single international application. The International Bureau ("IB") of the World Intellectual Property Organization ("WIPO") in Geneva, Switzerland, administers the international registration system. The Madrid Protocol Implementation Act of 2002 amended the Trademark Act to provide that: (1) The owner of a U.S. application or registration may seek protection of its mark in any of the participating countries by submitting a single international application to the IB through the USPTO, and (2) the holder of an international registration may request an extension of protection of the international registration to the United States. The Madrid Protocol became effective in the United States on November 2, 2003, and is implemented under 37 CFR part 2 and part 7. An international application submitted through the USPTO must be based on an active U.S. application or registration and must be filed by the owner of the application or registration. The USPTO reviews the international application to certify that it corresponds to the existing U.S. application or registration before forwarding the international application to the IB. The IB then reviews the international application and sends a notice of irregularity to the USPTO and the applicant if the application does not meet the filing requirements of the Madrid Protocol. After any irregularities are corrected, the IB will then register the mark and notify each country designated in the application of the request for extension of protection. The holder of the international registration may also request an extension of protection to additional countries by filing a subsequent designation.

Under section 71 of the Trademark Act, a registered extension of protection to the United States will be cancelled unless the holder of the international registration periodically files affidavits of use in commerce or excusable nonuse. Since these affidavits cannot be filed until five years after the USPTO registers an extension of protection, the USPTO will not accept these affidavits until after November 2, 2008, and their estimated burden will not be included in this collection at this time.

This collection includes the information necessary for the USPTO to process applications for international registration and related requests under the Madrid Protocol. The USPTO provides electronic forms for filing the Application for International Registration, Subsequent Designation, and Response to a Notice of Irregularity through the Trademark Electronic Application System (TEAS), which is accessible via the USPTO Web site. An electronic form for the Request for Transformation is under development. Applicants may also submit the items in this collection on paper or by using the forms provided by the IB, which are available on the WIPO Web site. The IB requires Applications for International Registration and Subsequent Designations that are filed on paper to be submitted on the official IB forms. The USPTO is adding one petition to this collection, the Petition to Review Refusal to Certify an International Application.

II. Method of Collection

By mail, hand delivery, or electronically to the USPTO.

III. Data

OMB Number: 0651–0051.

Form Number(s): PTO–2131, PTO–2132, PTO–2133.

Type of Review: Revision of a currently approved collection.

Affected Public: Individuals or households; businesses or other for-profits; not-for-profit institutions; farms; the Federal Government; and state, local or tribal governments.

Estimated Number of Respondents: 4,312 responses per year.

Estimated Time Per Response: The USPTO estimates that it will take the public approximately two minutes to one hour (0.03 to 1.0 hours) to complete the information in this collection, including the time to gather the necessary information, prepare the documents, and submit the completed request to the USPTO.

Estimated Total Annual Respondent Burden Hours: 1,012 hours per year.

Estimated Total Annual Respondent Cost Burden: $289,432 per year. The USPTO expects that the information in this collection will be prepared by attorneys. Using the professional rate of $286 per hour for associate attorneys in private firms, the USPTO estimates that the respondent cost burden for submitting the information in this collection will be approximately $289,432 per year.

Item	Estimated time for response (minutes)	Estimated annual responses	Estimated annual burden hours
Application for International Registration (PTO–2131)	15	3,600	900
Subsequent Designation (PTO–2132)	3	135	7
Response to Notice of Irregularities Issued by the IB in Connection with International Applications (PTO–2133)	10	540	92
Request that the USPTO Replace a U.S. Registration with a Subsequently Registered Extension of Protection to the United States	2	7	1
Request to Record an Assignment or Restriction of a Holder's Right to Dispose of an International Registration	5	10	1
Request that the USPTO Transform a Cancelled Extension of Protection into an Application for Registration under section 1 or 44 of the Act	5	10	1
Petition to Review Refusal to Certify an International Application	60	10	10
Affidavit of Continued Use or Excusable Nonuse under section 71 of the Act	14	(1)	0
Total		4,312	1,012

[1] None until November 2008.

Estimated Total Annual Non-hour Respondent Cost Burden: $470,031. There are no capital start-up, maintenance, or recordkeeping costs associated with this information collection. However, this collection does have annual (non-hour) costs in the form of filing costs and postage costs.

The USPTO charges fees for processing international applications and related requests under the Madrid Protocol as set forth in 37 CFR 7.6. In addition to these USPTO fees, applicants must also pay international filing fees to the IB as indicated in 37 CFR 7.7. The USPTO estimates that the total filing costs in the form of USPTO processing fees associated with this collection will be approximately $469,950 per year as calculated in the accompanying table.

Item	Estimated annual responses	Fee amount	Estimated annual filing costs
Application for International Registration, for certifying an international application based on a single basic application or registration (per international class)	1,800	$100	$180,000
Application for International Registration, for certifying an international application based on more than one basic application or registration (per international class)	1,800	150	270,000
Subsequent Designation	135	100	13,500
Response to Notice of Irregularities Issued by the IB in Connection with International Applications	540	0	0
Request that the USPTO Replace a U.S. Registration with a Subsequently Registered Extension of Protection to the United States (per international class)	7	100	700
Request to Record an Assignment or Restriction of a Holder's Right to Dispose of an International Registration	10	100	1,000
Request that the USPTO Transform a Cancelled Extension of Protection into an Application for Registration under section 1 or 44 of the Act	10	375	3,750
Petition to Review Refusal to Certify an International Application	10	100	1,000
Affidavit of Continued Use or Excusable Nonuse under section 71 of the Act (per international class)	(1)	100	0
Total	4,312		469,950

[1] None until November 2008.

The public may submit the items in this collection to the USPTO by mail through the United States Postal Service. The USPTO estimates that approximately 208 of the 4,312 responses per year will be submitted by mail and that the average first-class postage cost for a mailed submission will be 39 cents, for a total postage cost of approximately $81 per year.

The total non-hour respondent cost burden for this collection in the form of filing costs and postage costs is estimated to be $470,031 per year.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, *e.g.*, the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: January 31, 2006.

Susan K. Brown,

Records Officer, USPTO, Office of the Chief Information Officer, Architecture, Engineering and Technical Services, Data Architecture and Services Division.

[FR Doc. E6–1560 Filed 2–3–06; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF DEFENSE

Department of the Army

Armed Forces Epidemiological Board; Meeting

AGENCY: Department of the Army, DoD.

ACTION: Notice of partially-closed meeting.

SUMMARY: In accordance with section 10(1)(2) of Public Law 92–463. The Federal Advisory Committee Act, announcement is made of the following meeting:

Name of Committee: Armed Forces Epidemiological Board (AFEB).

Dates: March 7, 2006 (Closed meeting). March 8, 2006 (Open meeting).

Times: 8 a.m.–5 p.m. (March 7, 2006). 7:30 a.m.–2 p.m. (March 8, 2006).

Location: U.S. Army Medical Research and Material Command Headquarters Building. Bldg. 810, Room B18, Fort Detrick, MD (March 7, 2006) and U.S. Army Medical Research Institute of Infectious Diseases, 1425 Porter Street, Fort Detrick, MD 21702–5011.

Agenda: The purpose of the meeting is to address pending and new board issues, provide briefings for Board members on topics related to ongoing and new Board issues, conduct subcommittee meetings, and conduct an executive working session.

FOR FURTHER INFORMATION CONTACT: Colonel Roger Gibson, Executive Secretary, Armed Forces Epidemiological Board, Skyline Six, 5109 Leesburg Pike, Room 682, Falls Church, VA 220414–3258, (703) 681–8012/3.

SUPPLEMENTARY INFORMATION: In the interest of national security, and in accordance with Title 5, United States Code (U.S.C.) Appendix 2, Section 10(d) and 5 U.S.C. 552b(c)(1), March 7, 2006 may be closed to the public. In addition, any classified portions of the meeting minutes may be withheld from public disclosure in accordance with 5 U.S.C. Appendix 2, Section 10(b) and 5 U.S.C. 552(b)(1). The session on March 8, 2006 will be open to the public in accordance with Section 552b(c) of Title 5, U.S.C., specifically subparagraph (1) thereof and Title 5, U.S.C., appendix 1, subsection 10(d). Open sessions of the meeting will be limited by space accommodations. Any interested person may attend, appear before or file statements with the committee at the time and in the manner permitted by the committee.

Brenda. S. Bowen,

Army Federal Register Liaison Officer.

[FR Doc. 06–1053 Filed 2–3–06; 8:45 am]

BILLING CODE 3710–08–M

DEPARTMENT OF DEFENSE

Department of the Army; Corps of Engineers

Intent To Prepare a Programmatic Draft Environmental Impact Statement/ Environmental Impact Report for the Los Angeles River Ecosystem Restoration Study, Los Angeles, CA

AGENCY: Department of the Army, U.S. Army Corps of Engineers, DoD.

ACTION: Notice of intent.

SUMMARY: The study area is located within the Los Angeles Basin on a broad alluvial plain flanked by the Santa Monica Mountains, to the west, and by the San Gabriel Mountains to the northeast. The Los Angeles River flows from the headwaters of Bell Creek and Calabasas Creek in the San Fernando Valley community of Canoga Park southeast through the San Fernando Valley some 35 miles to downtown Los Angeles. From there it continues in a southerly direction until it empties into the Pacific Ocean at Long Beach. The specific study area comprises the 32 miles of the River within the City of Los Angeles that extends from Owensmouth Avenue, in the upper reaches of northwest San Fernando Valley, to the border of the City of Vernon, at the southern end of Downtown Los Angeles. The study proposes to consider a range of activities to restore riparian and aquatic habitat, and related habitat functions, in and adjacent to the Los Angeles River. Compatible activities to conserve cultural resources, and to provide recreational and interpretive amenities, will also be considered.

Purpose: The purpose of this study is to identify a range of opportunities to improve the general environment of the Los Angeles River through ecosystem restoration and related measures. The study area includes several locations where potential exists for restoring a more natural riverine environment along the Los Angeles River, while maintaining and improving levels of flood protection. Creation of treatment wetlands in and around the river, to treat effluent river flows and to restore missing linkages of fragmented habitat, would also be pursued. Restored areas would provide natural riparian habitat to support indigenous wildlife and avifauna along a corridor transecting most of the San Fernando Valley, and extending into downtown Los Angeles. Other purposes include provision of public access to the river, identification of incidental recreation space, and delineation of trails. Site-specific Environmental Impact Statement-Environment Impact Reports (EIS/EIR) would be prepared in the future to evaluate and document individual projects that may result from this study.

ADDRESSES: U.S. Army Corps of Engineers, Los Angeles District, Environmental Resources Branch, CESPL–PD–RN, 915 Wilshire Boulevard, Los Angeles, CA 90017. Attention to Randy Tabije, Ecosystem Planning.

FOR FURTHER INFORMATION CONTACT: Randy Tabije, Environmental Coordinator, (213) 452–3871 or e-mail at *Roland.R.Tabije@usace.army. mil.*

SUPPLEMENTARY INFORMATION:

1. *Authorization.* The proposed feasibility study was authorized under Congressional Resolution, which reads as follows:

> Senate Resolution, approved 25 June 1969, reading in part: "Resolved by the Committee on Public Works of the United States Senate, that the Board of Engineers for Rivers and Harbors, created under section 3 of the River and Harbor Act, approved June 13, 1902, be, and is hereby requested to review the report of the Chief of Engineers on the Los Angeles and San Gabriel Rivers and Ballona Creek, California, published as House Document Numbered 838, Seventy-sixth Congress, and other pertinent reports, with a view to determining whether any modifications contained herein are advisable at the present time, in the resources in the Los Angeles County Drainage Area."

2. *Background.* The Los Angeles River is subject to serious flooding and experienced two major floods in the 1930's that caused substantial loss of life and substantial property damage. During the late 1930's, in response, the Federal Government constructed the concrete flood control channel in the Los Angeles River. The City of Los Angeles and other local agencies have expressed interest and early support for a feasibility study that would evaluate the potential for restoration of environmental resources on the Los Angeles River.

3. *Proposed Objectives.* The proposed objectives are as follows:

a. Restore a more natural riverine environment along the river.

b. Improve water quality by developing treatment wetlands to treat effluent river flows.

c. Restore and re-connect fragmented wetland habitats.

d. Within the Los Angeles Basin, maintain and improve current levels of flood protection.

e. Protect the community's cultural and historic resources along this reach of the River, while improving connectivity and public access to historical and cultural sites in this area.

f. Visually improve the River's scenic values through environmental restoration.

g. Improve linkages to existing recreational features in the vicinity of the River, and enhance open space along the River.

h. Better manage, optimize and conserve water resources.

i. Restore, protect, and augment habitat quality, quantity, and connectivity. Based on these objectives, the programmatic EIS/EIR would evaluate a range of potential alternative sites as a basis for selecting site specific improvements.

4. *Scoping Process. a.* Potential impacts associated with the proposed action will be evaluated. Resource categories that will be analyzed include: land use, physical environment, geology, biological resources, agricultural resources, air quality, ground water, recreational usage, aesthetics, cultural resources, transportation, communications, hazardous waste, socioeconomics and safety.

b. Participation of affected Federal, State and local resource agencies, native American groups and concerned interest groups/individuals is encouraged in the scoping process. Time and location of the Public Scoping meetings will be announced by means of letters, public announcements and news releases. Public participation will be especially important in defining the scope of analysis in the EIS/EIR, identifying potentially significant environmental issues, and obtaining relevant published and unpublished data, gathering personal input on relevant issues, and identifying acceptable mitigative measures for proposed actions. Those interested in providing information or data relevant to the environmental or social impacts to be included or considered in the environmental analysis can furnish this information by writing to the points of contact indicated above, or by attending a public scoping meeting. A mailing list will also be established so pertinent data may be distributed to interested parties.

Dated: January 27, 2006.

Mark R. Blackburn,

Lieutenant Colonel, U.S. Army Deputy District Engineer.

[FR Doc. 06–1052 Filed 2–3–06; 8:45 am]

BILLING CODE 3710–KF–M

DEPARTMENT OF DEFENSE

Department of the Army; Corps of Engineers

Estuary Habitat Restoration Council; Open Meeting

AGENCY: Department of the Army, U.S. Army Corps of Engineers, DoD.

ACTION: Notice of open meeting.

SUMMARY: In accordance with section 105(h) of the Estuary Restoration Act of 2000, (Title I, Pub. L. 106–457), announcement is made of the forthcoming meeting of the Estuary Habitat Restoration Council. The meeting is open to the public.

DATES: The meeting will be held February 21, 2006, from 10 a.m. to 11:30 a.m.

ADDRESSES: The meeting will be in room 3M60/70 in the GAO building located at 441 G Street, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Ms. Ellen Cummings, Headquarters, U.S. Army Corps of Engineers, Washington, DC 20314–1000, (202) 761–4750; or Ms. Cynthia Garman-Squier, Office of the Assistant Secretary of the Army (Civil Works), Washington, DC, (703) 695–6791.

SUPPLEMENTARY INFORMATION: The Estuary Habitat Restoration Council consists of representatives of five agencies. These are the National Oceanic and Atmospheric Administration, Environmental Protection Agency, U.S. Fish and Wildlife Service, Department of Agriculture, and Army. The duties of the Council include soliciting, reviewing, and evaluating project proposals, and submitting to the Secretary of the Army a prioritized list of projects recommended for construction.

Agenda topics will include decisions on recommending additional proposals to the Secretary of the Army for funding, a brief update on projects previously recommended, a discussion of minor changes to be incorporated in the next solicitation for proposals, and a report on the habitat trends report produced by the National Oceanic and Atmospheric Administration.

Current security measures require that persons interested in attending the meeting must pre-register with use before 2 p.m. February 16, 2006. We cannot guarantee access for requests received after that time. Please contact Ellen Cummings to pre-register. When leaving a voice mail message please provide the name of the individual attending, the company or agency represented, and a telephone number, in case there are any questions. The public should enter on the "G" Street side of the GAO building. All attendees are required to show photo identification and must be escorted to the meeting room by Corps personnel. Attendee's bags and other possessions are subject to being searched. All attendees arriving between one-half hour before and one-half hour after 10 a.m. will be escorted to the meeting. Those who are not pre-registered and/or arriving later than the allotted time will be unable to attend the public meeting.

Brenda S. Bowen,

Army Federal Register Liaison Officer.

[FR Doc. 06–1050 Filed 2–3–06; 8:45 am]

BILLING CODE 4710–92–M

DEPARTMENT OF EDUCATION

Recognition of Accrediting Agencies, State Agencies for the Approval of Public Postsecondary Vocational Education, and State Agencies for the Approval of Nurse Education

AGENCY: National Advisory Committee on Institutional Quality and Integrity, Department of Education (The Advisory Committee).

What Is the Purpose of This Notice?

The purpose of this notice is to invite written comments on accrediting agencies and State approval agencies whose applications to the Secretary for renewed recognition, requests for an expansion of the scope of recognition, or reports will be reviewed at the Advisory Committee meeting to be held on June 5–7, 2006, at the Hilton Arlington Hotel, 950 North Stafford Street, Arlington, Virginia.

Where Should I Submit My Comments?

Please submit your written comments by mail, fax, or e-mail no later than March 8, 2006 to Ms. Robin Greathouse, Accreditation and State Liaison. You may contact her at the U.S. Department of Education, Room 7105, MS 8509, 1990 K Street, NW., Washington, DC 20006, telephone: (202) 219–7011, fax: (202) 219–7005, or e-mail: *Robin.Greathouse@ed.gov*. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service at 1–800–877–8339.

What Is the Authority for the Advisory Committee?

The National Advisory Committee on Institutional Quality and Integrity is established under Section 114 of the Higher Education Act (HEA), as amended, 20 U.S.C. 011c. One of the purposes of the Advisory Committee is to advise the Secretary of Education on the recognition of accrediting agencies and State approval agencies.

Will This Be My Only Opportunity To Submit Written Comments?

Yes, this notice announces the only opportunity you will have to submit written comments. However, a subsequent **Federal Register** notice will announce the meeting and invite individuals and/or groups to submit requests to make oral presentations before the Advisory Committee on the agencies that the Committee will review. That notice, however, does not offer a second opportunity to submit written comments.

What Happens to the Comments That I Submit?

We will review your comments, in response to this notice, as part of our evaluation of the agencies' compliance with Section 496 of the Higher Education Act of 1965, as amended, and the Secretary's Criteria for Recognition of Accrediting Agencies and State Approval Agencies. The Criteria are regulations found in 34 CFR part 602 (for accrediting agencies) and in 34 CFR part 603 (for State approval agencies) and are found at the following site: *http://www.ed.gov/admins/finaid/accred/index.html.* We will also include your comments with the staff analyses we present to the Advisory Committee at its June 2006 meeting. Therefore, in order for us to give full consideration to your comments, it is important that we receive them by March 8, 2006.

In all instances, your comments about agencies seeking continued recognition and/or an expansion of an agency's scope of recognition must relate to the Criteria for Recognition. In addition, your comments for any agency whose interim report or progress report is scheduled for review must relate to the issues raised and the Criteria for Recognition cited in the Secretary's letter that requested the interim report.

What Happens to Comments Received After the Deadline?

We will review any comments received after the deadline. If such comments, upon investigation, reveal that the accrediting agency or State approval agency is not acting in accordance with the Criteria for Recognition, we will take action either before or after the meeting, as appropriate.

What Agencies Will the Advisory Committee Review at the Meeting?

The Secretary of Education recognizes accrediting agencies and State approval agencies for public postsecondary vocational education and nurse education if the Secretary determines that they meet the Criteria for Recognition. Recognition means that the Secretary considers the agency to be a reliable authority as to the quality of education offered by institutions or programs it accredits that are encompassed within the scope of recognition she grants to the agency.

The following agencies will be reviewed during the June 2006 meeting of the Advisory Committee:

Nationally Recognized Accrediting Agencies

Petition for Initial Recognition

1. *National Oriental Medicine Accreditation Agency (Requested scope of recognition:* The accreditation of freestanding educational institutions of Oriental Medicine and programs that offer entry-level professional doctoral degrees in Oriental Medicine.)

Petition for Renewal of Recognition That Include an Expansion of the Scope of Recognition

1. *Accrediting Council for Independent Colleges and Schools (Current scope of recognition:* The accreditation of private postsecondary institutions offering certificates or diplomas and postsecondary institutions offering associate's, bachelor's, or master's degrees in programs that are designed to train and educate persons for careers or professions where business applications or doctrines, supervisory or management techniques, professional or paraprofessional applications, and other business-related applications support or constitute the career.) (Requested scope of recognition: The accreditation of private postsecondary institutions offering certificates or diplomas, and postsecondary institutions offering associate, bachelors, or master's degrees in programs designed to educate students for professional, technical, or occupational careers including those that offer those programs via distance education.)

2. *American College of Nurse-Midwives, Division of Accreditation (Current scope of recognition:* The accreditation and preaccreditation of basic certificate and basic graduate nurse-midwifery education programs for registered nurses, the pre-accreditation and accreditation of pre-certification nurse-midwifery education programs and the accreditation and pre-accreditation of direct-entry midwifery programs for the non-nurse.) (Requested scope of recognition: The accreditation and preaccreditation of basic certificate, basic graduate nurse-midwifery, direct-entry midwifery, and pre-certification nurse-midwifery education programs. The accreditation and pre-accreditation of freestanding institutions of midwifery education that may offer other related health care programs to include nurse practitioner programs, and including those institutions and programs that offer distance education.)

3. *Joint Review Committee on Education in Radiologic Technology (Current scope of recognition:* The accreditation of educational programs for radiographers and radiation therapists.) (Requested scope of recognition: The accreditation of educational programs in radiography, including magnetic resonance; radiation therapy; and medical dosimetry at the certificate and the associate, baccalaureate, and graduate levels, including programs using distance education methodology.)

4. *National Council for Accreditation of Teacher Education (Current scope of recognition:* The accreditation throughout the United States of professional education units providing baccalaureate and graduate degree programs for the preparation of teachers and other professional personnel for elementary and secondary schools.) (Requested scope of recognition: The accreditation throughout the United States of professional education units providing baccalaureate and graduate degree programs for the preparation of teachers and other professional personnel for elementary and secondary schools including programs offering distance education.)

Petitions for Renewal of Recognition That Include a Contraction of the Scope of Recognition

1. *Accreditation Council for Pharmacy Education (Current scope of recognition:* The accreditation and preaccreditation of professional degree programs in pharmacy leading to the degrees of Baccalaureate in Pharmacy and Doctor of Pharmacy.) (Requested scope of recognition: The accreditation and preaccreditation of professional degree programs in pharmacy leading to the Doctor of Pharmacy degree.)

Petitions for Renewal of Recognition

1. *American Bar Association, Council of the Section of Legal Education and Admissions to the Bar (Current and requested scope of recognition:* The accreditation throughout the United States of programs in legal education that lead to the first professional degree in law, as well as freestanding law schools offering such programs.)

2. *American Dental Association, Commission on Dental Accreditation (Current and requested scope of recognition:* The accreditation of predoctoral dental education programs (leading to the D.D.S or D.M.D degree); advanced dental education programs and allied dental education programs that are fully operational or have attained "accreditation eligible" status, and for its accreditation of programs offered via distance education.)

3. *Council on Chiropractic Education, Commission on Accreditation (Current and requested scope of recognition:* The accreditation of programs leading to the Doctor of Chiropractic degree and single-purpose institutions offering the Doctor of Chiropractic program.)

4. *Joint Review Committee on Educational Programs in Nuclear Medicine Technology (Current and requested scope of recognition:* The accreditation of higher education programs for the nuclear medicine technologist.)

5. *National Accrediting Commission of Cosmetology Arts and Sciences (Current and requested scope of recognition:* The accreditation throughout the United States of postsecondary schools and departments of cosmetology arts and sciences and massage therapy.)

6. *Southern Association of Colleges and Schools, Commission on Colleges (Current and requested scope of recognition:* The accreditation and preaccreditation ("Candidate for Accreditation") of degree-granting institutions of higher education in Alabama, Florida, Georgia, Kentucky, Louisiana, Mississippi, North Carolina, South Carolina, Tennessee, Texas, and Virginia, including distance education programs offered at those institutions.)

7. *Western Association of Schools and Colleges, Accrediting Commission for Senior Colleges and Universities (Current and requested scope of recognition:* The accreditation and preaccreditation ("Candidate for Accreditation") of senior colleges and universities in California, Hawaii, the United States territories of Guam and American Samoa, the Republic of Palau, the Federated States of Micronesia, the Commonwealth of the Northern Mariana Islands and the Republic of the Marshall Islands, including distance education programs offered at those institutions.)

Interim Report (An interim report is a follow-up report on an accrediting agency's compliance with specific criteria for recognition.)

1. Accrediting Bureau of Health Education Schools.

2. American Speech-Language-Hearing Association, Council on Academic Accreditation in Audiology and Speech—Language Pathology.

3. Distance Education and Training Council, Accrediting Commission.

Progress Report (A report describing the agency's progress in implementing new accreditation processes/or procedures.)

1. Montessori Accreditation Council for Teacher Education, Commission on Accreditation

State Agencies Recognized For the Approval of Public Postsecondary Vocational Education

Interim Report

1. Puerto Rico State Agency for the Approval of Public Postsecondary Vocational, Technical Institutions and Programs.

Progress Report

1. Oklahoma State Regents for Higher Education.

State Agency Recognized For the Approval of Nurse Education

Petition for Renewal of Recognition

1. New York State Board of Regents, State Education Department, Office of the Professions (Nursing Education).

Where Can I Inspect Petitions and Third-Party Comments Before and After the Meeting?

All petitions and those third-party comments received in advance of the meeting, will be available for public inspection at the U.S. Department of Education, Room 7105, MS 8509, 1990 K Street, NW., Washington, DC 20006, telephone (202) 219–7011 between the hours of 8 a.m. and 3 p.m., Monday through Friday, until May 8, 2006. They will be available again after the June 5–7, 2006 Advisory Committee meeting. An appointment must be made in advance of such inspection.

How May I Obtain Electronic Access to This Document?

You may view this document, as well as all other Department of Education documents published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at the following site: *http://www.ed.gov/legislation/FedRegister*. To use PDF you must have Adobe Acrobat Reader, which is available free at this site. If you have questions about using PDF, call the U.S. Government Printing Office (GPO), toll free, at 1–888–293–6498; or in the Washington, DC, area at (202) 512–1530.

Note: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: *http://www.gpoaccess.gov/index.html*.

Authority: 5 U.S.C. Appendix 2

Dated: January 31, 2006.

Sally L. Stroup,

Assistant Secretary for Postsecondary Education.

[FR Doc. E6–1549 Filed 2–3–06; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Office of Energy Efficiency and Renewable Energy

Biomass Research and Development Technical Advisory Committee

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces an open meeting of the Biomass Research and Development Technical Advisory Committee under the Biomass Research and Development Act of 2000. The Federal Advisory Committee Act (Pub. L. No. 92–463, 86 Stat. 770) requires that agencies publish these notices in the **Federal Register** to allow for public participation. This notice announces the meeting of the Biomass Research and Development Technical Advisory Committee.

DATES: March 2, 2006 at 8 a.m. to 5 p.m.; March 3, 2006 at 8 a.m. to 12 noon.

ADDRESSES: National Renewable Energy Laboratory, Building 17—Room 4B, 1617 Cole Boulevard, Golden, CO 80401.

FOR FURTHER INFORMATION CONTACT: Neil Rossmeissl, Designated Federal Officer for the Committee, Office of Energy Efficiency and Renewable Energy, U.S. Department of Energy, 1000 Independence Avenue, SW., Washington, DC 20585; (202) 586–8668 or Harriet Foster at (202) 586–4541; E-mail: *harriet.foster@ee.doe.gov*.

SUPPLEMENTARY INFORMATION:

Purpose of Meeting: To provide advice and guidance that promotes research and development leading to the

production of biobased fuels and biobased products.

Tentative Agenda: Agenda will include the following:

- Orientation Session for New Members.
- Review of the Updated Vision Document.
- Review of the Energy Policy Act of 2005 Impact on Biomass Research.
- Review of Organization for the 2006 Biomass Roadmap Regional Workshops.
- Discussion of Analysis and Policy Subcommittee Business.
- Discussion of Public Relations Efforts.
- Review of the 2006 Work Plan.
- Review of Biomass Efforts in the Colorado Region.

Public Participation: In keeping with procedures, members of the public are welcome to observe the business of the Biomass Research and Development Technical Advisory Committee. To attend the meeting and/or to make oral statements regarding any of the items on the agenda, you should contact Neil Rossmeissl at 202–586–8668 or the Biomass Initiative at 202–586–4541 or *harriet.foster@ee.doe.gov* (e-mail). You must make your request for an oral statement at least 5 business days before the meeting. Members of the public will be heard in the order in which they sign up at the beginning of the meeting. Reasonable provision will be made to include the scheduled oral statements on the agenda. The Chair of the Committee will make every effort to hear the views of all interested parties. If you would like to file a written statement with the Committee, you may do so either before or after the meeting. The Chair will conduct the meeting to facilitate the orderly conduct of business.

Minutes: The minutes of the meeting will be available for public review and copying at the Freedom of Information Public Reading Room; Room 1E–190; Forrestal Building; 1000 Independence Avenue, SW., Washington, DC, between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

Issued at Washington, DC on February 1, 2006.

Rachel Samuel,

Deputy Advisory Committee Management Officer.

[FR Doc. 06–1066 Filed 2–3–06; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Energy Information Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Energy Information Administration (EIA), Department of Energy (DOE).

ACTION: Agency information collection activities: Proposed collection; comment request.

SUMMARY: The Energy Information Administration (EIA) is soliciting comments on the proposed three-year extension to the Form EIA–28, "Financial Reporting System (FRS)."

DATES: Written comments must be filed by April 7, 2006. If you anticipate difficulty in submitting comments within that period, contact the person identified below as soon as possible.

ADDRESSES: Comments should be directed to Gregory P. Filas of EIA. To ensure receipt of the comments by the due date, submission by Fax (202–586–9753) or e-mail (*greg.filas@eia.doe.gov*) is recommended. Mr. Filas' mailing address is Energy Information Administration (EI–62), Financial Analysis Team, Forrestal Building, U.S. Department of Energy, Washington, DC 20585. Mr. Filas may be telephoned at (202) 586–1347.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Mr. Filas at the address listed above.

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Energy Administration Act of 1974 (Pub. L. No. 93–275, 15 U.S.C. 761 *et seq.*), and the Department of Energy Organization Act (Pub. L. No. 95–91, 42 U.S.C. 7101 *et seq.*), require the Energy Information Administration (EIA) to carry out a centralized, comprehensive, and unified energy information program. This program collects, evaluates, assembles, analyzes, and disseminates information on energy resource reserves, production, demand, technology, and related economic and statistical information. This information is used to assess the adequacy of energy resources to meet near and longer-term domestic demands.

The EIA, as part of its effort to comply with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35), provides the general public and other Federal agencies with opportunities to comment on collections of energy information conducted by or in conjunction with the EIA. Any comments received help the EIA to prepare data requests that maximize the utility of the information collected, and to assess the impact of collection requirements on the public. Also, the EIA will later seek approval by the Office of Management and Budget (OMB) of the collections under Section 3507(h) of the Paperwork Reduction Act of 1995.

Under Public Law 95–91, section 205(h), the Administrator of the EIA is required to "identify and designate" the major energy companies who must annually file Form EIA–28 to ensure that the data collected provide "a statistically accurate profile of each line of commerce in the energy industry in the United States." Data collected on Form EIA–28 are published and used in analyses of the energy industry.

II. Current Actions

EIA is proposing a three-year extension with changes to the previously approved Form EIA–28 for the FRS survey to be conducted in 2007 collecting information for 2006.

U.S. major energy companies report financial and operating information to the FRS survey each year on a consolidated corporate level, by individual lines of business, by major functions within each line of business, and by various geographic regions. From this information, EIA produces the annual publication Performance Profiles of Major Energy Producers. The data are also used for analyses and inquiries concerning earnings, profitability, investments, production and refining costs, reserve growth, and other issues related to the financial performance of major energy producers.

In 2004, EIA expanded the form to include the downstream natural gas and electric power lines of business. The expanded form increased the time and cost of processing the additional data. In addition, some of the new questions required very detailed information from the operational units of the FRS respondent companies, which increased the time required for companies to compile data for the form.

After working with the expanded form for two years, EIA reviewed the detailed elements of the form and the responses and is proposing to reduce the scope of the data collected in the downstream natural gas and electric power sections of the Form EIA–28. The reductions will eliminate some of the intra-line of business flows and some detailed operating information, which

will allow for more streamlined processing of the data and more effective use of resources, including providing more focus on information about profits, profitability, investment, and operating costs in these lines of business. Reducing the scope of the survey will also reduce the reporting burden on the survey respondents.

The proposed modifications include elimination of Schedule 5341, "Domestic Coal Operations, Reserves and Production Statistics," Schedule 5750, "Eliminations in Consolidation" for Downstream Natural Gas, and Schedule 5850, "Eliminations in Consolidation" for Electric Power. The following schedules for the downstream natural gas and electric power lines of business will be reduced in scope:

- Schedule 5711, Downstream Natural Gas Operating Expenses,
- Schedule 5712, Purchases and Sales of Natural Gas and Natural Gas Liquids,
- Schedule 5741, Downstream Natural Gas Capacity Measures, and Downstream Natural Gas Output Measures, and all of the Electric Power schedules, including:
- Schedule 5810, Consolidating Statement of Income,
- Schedule 5811, Electric Power Operating Expenses,
- Schedule 5812, Purchases and Sales of Fuel and Electric Power.
- Schedule 5841, Electric Power Capacity and Output Statistics.

Copies of the proposed new schedules and the instructions are available from Mr. Filas.

III. Request for Comments

Prospective respondents and other interested persons are invited to comment on the actions discussed in item II. The following guidelines are provided to assist in the preparation of comments.

General Issues

A. Is the proposed collection of information necessary for the proper performance of the functions of the agency and does the information have practical utility? Practical utility is defined as the actual usefulness of information to or for an agency, taking into account its accuracy, adequacy, reliability, timeliness, and the agency's ability to process the information it collects.

B. What enhancements can be made to the quality, utility, and clarity of the information to be collected?

As a Potential Respondent to the Request for Information

A. What actions could be taken to help ensure and maximize the quality, objectivity, utility, and integrity of the information to be collected?

B. Are the Form EIA–28 instructions and definitions clear and sufficient? If not, which instructions require clarification?

C. Can information be submitted by the due date?

D. Public reporting burden for the Form EIA–28 collection, including proposed changes, is estimated to average 450 hours per response. The estimated burden includes the total time, effort, or financial resources expended to generate, maintain, retain, disclose and provide the information. In your opinion, how accurate is this estimate?

E. The agency estimates that the only cost to a respondent is for the time it will take to complete the collection. Will a respondent incur any start-up costs for reporting, or any recurring costs for operation maintenance, and purchases of services associated with the information collection?

F. What additional actions could be taken to minimize the burden of this collection of information? Such actions may involve the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

G. Does any other Federal, State, or local agency collect similar information? If so, specify the agency, the data element(s), and the method(s) of collection.

As a Potential User of the Information to be Collected

A. What actions could be taken to help ensure and maximize the quality, objectivity, utility, and integrity of the information disseminated?

B. Is the information useful at the levels of detail to be collected?

C. For what purpose(s) would the information be used? Be specific.

D. Are there alternate sources for the information and are they useful? If so, what are their weaknesses and/or strengths?

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of the form. They also will become a matter of public record.

Statutory Authority: Section 3507(h)(1) of the Paperwork Reduction Act of 1995 (Pub. L. No. 104–13, 44 U.S.C. Chapter 35).

Issued in Washington, DC, January 31, 2006.

Jay H. Casselberry,

Agency Clearance Officer, Energy Information Administration.

[FR Doc. E6–1564 Filed 2–3–06; 8:45 am]

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DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER06–354–000; EL06–44–000]

Before Commissioners: Joseph T. Kelliher, Chairman; Nora Mead Brownell, and Suedeen G. Kelly; California Independent System Operator; Order Accepting and Modifying Tariff Filing and Instituting a Section 206 Proceeding

Issued January 13, 2006.

1. On December 21, 2005, the California Independent System Operator Corporation (CAISO) filed a tariff amendment (Amendment No. 73) proposing to change its current "soft" $250/MWh bid cap for real-time energy bids and adjustment bids to a "hard" $400/MWh bid cap, effective January 1, 2006 or as soon thereafter as possible. The CAISO asked the Commission to review its application on an expedited basis with a shortened comment period. In this order, the Commission accepts with modification, as described below, the CAISO's proposed tariff amendment, effective upon issuance of this order.

2. To remove any opportunity for market distortions created by the Commission's approval of an increase in the CAISO bid cap, we will institute, under section 206 of the Federal Power Act (FPA),[1] an investigation into the price cap in the WECC outside the CAISO. We also institute a section 206 investigation into the CAISO ancillary service capacity bid cap, in order to consider whether any incentives that distort a supplier's choice between offering energy or ancillary services will result from the rise in gas prices and the increase in the CAISO energy bid cap. We hereby establish a refund effective date pursuant to the provisions of section 206.

Background

The CAISO's Filing

3. The CAISO filed Amendment No. 73 requesting that the Commission accept its tariff revision altering the CAISO's current bid cap. Section 28 of the CAISO tariff establishes a bid cap that sets a limit on the level of bids submitted for the CAISO's energy and ancillary service capacity markets. According to the CAISO, this bid cap also applies to adjustment bids used in the day-ahead and hour-ahead congestion management markets. Amendment No. 73 proposes to modify section 28.1.2 to replace the current

[1] 16 U.S.C. 824e (2000).

"soft" bid cap [2] of $250/MWh for real-time energy bids and adjustment bids with a "hard" bid cap of $400/MWh.[3] The CAISO states that its proposal to change its bid cap from "soft" to "hard" is consistent with the Commission's directive that it change its bid cap to a "hard" cap when it implements the Market Redesign and Technology Upgrade (MRTU).[4] It does not propose to change the bid cap for ancillary services markets from the current "soft" $250/MWh cap.

4. The CAISO states that on November 9, 2005, in response to a request from its Department of Market Monitoring (DMM), the CAISO's Market Surveillance Committee (MSC) [5] recommended that the bid cap on the real-time energy market be increased prior to this winter, because "the likelihood of substantially higher natural gas prices during the winter of [2006] is sufficiently high to justify raising the bid cap at this time" in order to avoid "the risk of generation unit-level variable costs approaching or rising above the [current $250/MWh] cap level." The MSC recommended a new level of $400/MWh, based on its analysis of average values of Henry Hub futures prices for the upcoming winter.[6] The CAISO further notes that the DMM prepared a memorandum supporting the MSC's recommendation, citing changed market conditions and the significant benefits to the California energy markets that would result from raising the real-time energy bid cap under current market conditions.[7] The CAISO asserts that the DMM further recommended that the bid cap for adjustment bids used in day-ahead and hour-ahead congestion management markets be increased to $400/MWh, with the bid cap for ancillary services remaining at $250/MWh.[8]

5. The CAISO requested that, pursuant to section 35.11 of the Commission's regulations,[9] the Commission waive its notice requirements for Amendment No. 73. The CAISO states that good cause exists for this waiver because acceptance of a January 1, 2006 effective date will permit the California energy markets to realize the benefits described above as quickly as possible to address the substantial increase in natural gas prices that may potentially occur in the winter 2006. It also states that the January 1 date will assist in implementation of the bid-cap change in the CAISO settlements process and will permit interested stakeholders time to comment on this proposal on an expedited basis.

6. The CAISO requested expedited tariff revision procedures under the Commission's Expedited Tariff Revisions Guidance Order.[10] It asserts that Amendment No. 73 satisfies the requirements of the Expedited Tariff Revisions Guidance Order because the amendment is intended to remedy the risk that the CAISO real-time energy market may not be able to attract sufficient supply bids to maintain system reliability, particularly from resources outside of the CAISO Control Area due to significant increases in variable operation costs. The CAISO states that it has posted the filing on its website and sent an email notification to each market participant as is required by the Expedited Tariff Revisions Guidance Order.

7. Finally, the CAISO requested a shortened comment period of December 28, 2005 for Amendment No. 73. It states that this shorter comment period will allow the Commission to issue an order prior to the requested January 1, 2006 effective date.

Bid Cap Background

8. In a July 2002 Order,[11] the Commission established a bid cap of $250/MWh for the California real-time energy and ancillary services markets, to become effective on October 1, 2002, as recommended by the CAISO's MSC. The Commission also applied this bid cap to day-ahead markets when implemented by the CAISO. The July 2002 Order also imposed a price cap of $250/MWh for all spot market sales in the Western Electricity Coordinating Council (WECC), beginning October 1, 2002.[12]

9. On October 11, 2002, the Commission issued an order on rehearing and compliance filing.[13] The October 2002 Order clarified that sellers may continue to submit bids above the bid cap with the understanding that such bids cannot set the market clearing price and that these bids above the cap will be subject to justification and refund.[14]

10. On July 1, 2005, the Commission issued an order finding that the bid cap for California market energy bids should be increased to a hard $500/MWh cap on day one of MRTU implementation.[15] The July 2005 Order reaffirmed that the bid cap for ancillary services and Residual Unit Commitment (RUC) availability should remain at $250/MWh.[16]

Notice of Filing and Responsive Pleadings

11. Notice of the CAISO's December 21, 2005 filing was published in the **Federal Register**, 71 Fed. Reg. 98 (2006), with interventions and protests due on

[2] Section 28.1.1 of the CAISO's tariff currently permits market participants to submit bids above the cap, but any accepted bids above the cap are not eligible to set the market clearing price and are subject to cost justification and refund. A "soft" cap is one where market participants may submit bids above the bid cap with adequate justification, but without setting the market clearing price.

[3] A "hard" cap is one where market participants' bids are not permitted to exceed the cap, regardless of the seller's costs.

[4] *California Independent System Operator Corp.*, 112 FERC ¶ 61,013 at P 104 (2005) (July 2005 Order), *reh'g pending*.

[5] The CAISO's Web site notes that the MSC is an independent advisory group of industry experts who can suggest changes in rules and protocols to the CAISO Governing Board, MSC Description, available at *http://www.caiso.com/docs/2005/10/04/2005100410513010 81.html* (last visited Jan. 9, 2006).

[6] *See Raising the Level of the Bid Cap on the Real-Time Energy Market in California*, Market Surveillance Committee, Nov. 9, 2005 (MSC Recommendation Paper). According to the CAISO, the MSC also notes that gaining some experience with the current market design and a higher bid cap would be a preferred strategy for transitioning in the future to a $500/MWh bid cap. MSC Recommendation Paper at 5–6.

[7] *See Memorandum of Keith Casey*, Department of Market Monitoring, Dec. 9, 2005 (DMM Memorandum). According to the CAISO, the DMM Memorandum enumerates a number of reasons for raising the bid cap, including: (1) Promoting reliability by providing greater fixed-cost recovery for generating units during high demand periods when supply margins are tight and prices are at or near the bid cap; (2) providing greater incentives for load-servicing entities (LSEs) to continue to minimize their spot market exposure for signing additional long-term power contracts; (3) providing greater incentives for generation owners to maintain their units at a high level of availability; (4) providing greater incentives for further development of demand response programs such as real-time pricing; (5) if gas prices escalate over the winter months, a higher bid cap will not discourage suppliers from selling into the California real-time energy markets since such suppliers would be assured of bid cost recovery for accepted bids above $250/WMh; and (6) providing a measured transition to the $500/MWh energy bid cap scheduled to be implemented with the CAISO's new market design in 2007.

[8] The CAISO Amendment No. 73 Filing, Dec. 21, 2005 (citing DMM Memorandum at 5) (The CAISO Amendment No. 73 Filing).

[9] 18 CFR 35.11 (2005).

[10] *Guidance Order on Expedited Tariff Revisions for Regional Transmission Organizations and Independent System Operators*, 111 FERC ¶ 61,009 (2005).

[11] *California Independent System Operator Corp.*, 100 FERC ¶ 61,060 (July 2002 Order), *order on reh'g*, 101 FERC ¶ 61,061 (2002).

[12] Id. The Commission extended the October 1, 2002 deadline to October 30, 2002 in a subsequent order. *California Independent System Operator Corp.*, 100 FERC ¶ 61,351 (2002).

[13] *California Independent System Operator Corp.*, 101 FERC ¶ 61,061 (2002) (October 2002 Order).

[14] Id. at P 17.

[15] July 2005 Order, 112 FERC ¶ 61,013 at P 104.

[16] Id. at 111 (reaffirming the Commission's October 2003 and June 2004 orders which determined that the bid caps for ancillary services and RUC availability should be $250/MWh. *See California Independent System Operator Corp.*, 105 FERC ¶ 61,140, *reh'g denied*, 105 FERC ¶ 61,278 (2003); *California Independent System Operator Corp.*, 107 FERC ¶ 61,274, *order on reh'g*, 108 FERC ¶ 61,254 (2004)).

or before January 3, 2006. Southern California Edison Company (SCE), Sacramento Municipal Utility District (SMUD), the Northern California Power Agency (NCPA), Modesto Irrigation District (MID), the Mirant Parties,[17] and the California Department of Water Resources State Water Project filed motions to intervene. Williams Power Company, Inc. (Williams), Powerex Corp. (Powerex), Portland General Electric Company (Portland), Pacific Gas and Electric Company (PG&E), the Indicated Parties,[18] and Alliance for Retail Energy Markets (AReM) filed motions to intervene and comments. California Electricity Oversight Board (CEOB) filed a motion to intervene with comments supporting the CAISO's filing but made no other comments. Independent Energy Producers Association (IEP) filed a motion to intervene out-of-time and comments. City of Santa Clara, California (SVP) and Public Service Company of New Mexico (PSNM) filed motions to intervene and protests. The CAISO filed an answer on January 5, 2006.

Raising CAISO Bid Cap

12. PG&E, AReM, and Powerex generally support the CAISO's proposal. AReM states that the CAISO's proposal is rational and reasonable and has been sufficiently justified by the CAISO. AReM notes that the risk of electricity supply shortfalls in California remains high, particularly during the summer of 2006, and that given the dramatic increases in natural gas costs that have occurred over the past year, the current $250/MWh bid cap raises the risk of generator bid costs exceeding the current bid cap level. AReM cautions that this interim increase in the cap by the CAISO, however, should not be perceived to mitigate the necessity for the further "hard" bid cap increases mandated by the Commission.[19] Powerex cautions that it is important for the CAISO and the Commission to continue to give careful consideration in determining the bid cap levels associated with the various markets so that (1) there is a demonstrated need for the mitigation, and (2) the mitigation levels do not negatively impact the efficient operation of the market or the reliable operation of the grid both in California and West-wide. PSNM, SVP, Portland, and Williams support or do not oppose[20] the CAISO's proposal to raise the bid cap to $400/MWh. No intervenor opposed the CAISO's proposal to raise the bid cap level.

"Hard" vs. "Soft" Bid Cap

13. PSNM, SVP, Portland, and Williams oppose changing the CAISO's bid cap from a "soft" to a "hard" cap.

14. PSNM argues that although the Commission has directed the CAISO to replace the existing "soft" cap with an escalating "hard" cap starting in 2007, concurrent with implementation of the CAISO's MRTU, it would be unjust and unreasonable to implement a "hard" cap, particularly on such short notice, while still retaining the current market design structure. PSNM notes that, in our July 2005 Order, the Commission did not authorize adoption of a "hard" cap as part of the current market structure or otherwise suggest that the CAISO needs to or should adopt a "hard" bid cap prior to adoption of the MRTU in 2007. PSNM contends that implementing a "hard" cap now, at the proposed $400/MWh level, would limit suppliers' ability to recover their substantiated costs if congestion costs and natural gas prices cause the competitive market price to exceed $400/MWh, thereby creating a risk of supply curtailments. PSNM points out that if, as the CAISO claims, the $400/MWh price it has selected is unlikely to be exceeded during the one year period prior to adoption of the MRTU, then retention of the "soft" cap should be of little concern. By contrast, PSNM argues, if the CAISO's estimation of the market price produced by higher natural gas prices is incorrect, and actual prices exceed the $400/MWh level, the effect on California markets could be severe.

15. SVP argues that the CAISO's proposal to change from a "soft" cap to a "hard" cap is not supportable. They assert that the three CAISO departmental reports attached to the filing in support of the proposal recommended an increase to a $400/MWh "soft" cap, not a "hard" cap. SVP argues that the CAISO's studies conclude that, with current gas prices projected between $10 and $12 per Mcf, a "soft" cap of $400/MWh is roughly equivalent to the $250/MWh "soft" cap implemented when gas costs were approximately three to four dollars per Mcf. SVP contends that the CAISO studies do not provide any rationale to support a change from a "soft" cap to a "hard" cap, and in fact, assert that a $400/MWh "soft" cap is necessary to maintain the *status quo*. According to SVP, the CAISO's Board of Governors' resolution changed the CAISO's departmental recommendations to a "hard" cap without explanation or analysis. SVP points out that the CAISO's only comment on the change is that the Commission required the CAISO to change to a "hard" cap once MRTU is implemented, and that implementing a "hard" cap now will ease the transition to a $500/MWh "hard" cap when MRTU is implemented in 2007. According to SVP, without the structural changes MRTU is expected to bring about, there is no justification for the change to a "hard" cap, and the CAISO fails to justify any present need for a "hard" cap versus a "soft" cap and does not address the potential consequences of the change. SVP further argues that the escalation in natural gas prices and the recent bankruptcy filing of Calpine Corporation further strain the market and risk contributing to a shortfall of energy in California.

16. Portland argues that the "hard" nature of the new bid cap proposal does not adequately promote a transparent and workable market with the appropriate application of constraints and oversight. Specifically, Portland argues that a hard cap would force the CAISO to resort to out-of-market (OOM) purchases to acquire capacity resources when market prices within the CAISO market exceed the cap. By definition, according to Portland, such OOM purchases would involve capacity and associated pricing that would not be offered to all market participants in real time, and thus do not promote an efficient, transparent, and workable market. In contrast, Portland argues that a "soft" cap would achieve that goal because the current "soft" cap methodology provides a ceiling that market participants may not exceed without: (1) Demonstrating that their costs justify a higher bid; and (2) being subject to refund.

17. Williams similarly requests that the Commission reject the proposal to change the bid cap from a "soft" to a "hard" cap. Williams submits that the same concerns that resulted in the current "soft" cap continue to exist. Specifically, Williams expresses the concern that should fuel prices continue to rise, its operating costs may exceed $400/MWh, and with the must-offer obligation still in place, it may be

[17] The Mirant Parties consist of Mirant Americas Energy Marketing, LP, Mirant California, LLC, Mirant Delta, LLC, and Mirant Potrero, LLC.

[18] The Indicated Parties consist of Avista Energy, Inc., Puget Sound Energy, Inc., Coral Power, L.L.C., and Sempra Energy.

[19] *See* July 2005 Order, 112 FERC ¶ 61,013 at P 104.

[20] PSNM states it takes no explicit position regarding whether the $400/MWh bid cap selected by the CAISO is optimal or constitutes a sufficiently high price to eliminate risks of supply shortfalls, but agrees in principle with the CAISO's conclusion that higher natural gas prices necessitate an increase in the existing $250/MWh bid cap. Williams cautions that its comments in support of the CAISO's proposal should not be construed as an endorsement of price caps as it remains opposed to price caps for a number of reasons.

required to operate at a loss. Williams states that the CAISO seems to base its proposal for a "hard" cap on the Commission's directive in a separate proceeding to replace the current "soft" bid cap with a "hard" bid cap when the CAISO's MRTU market design is implemented.[21] However, Williams argues, the environment under which a generator will operate when MRTU is implemented will be significantly different than today's environment.[22] and accordingly the CAISO's attempt to justify the imposition of a "hard" cap at this time, by comparing the proposed cap with the initial MRTU "hard" cap of $500/MWh, is misplaced.

Price Cap in the WECC Outside the CAISO

18. Powerex and Indicated Parties contend that the CAISO-proposed bid cap increase should be applied throughout the West in order to prevent artificial distortions in the electricity markets that could result from different price caps between regions. They note that the expected increases in natural gas prices in the winter of 2006 will affect not only the CAISO markets, but all electricity markets in the West. As Indicated Parties further state, the West-wide market power mitigation program was established to meet the same goals as the CAISO market power mitigation, namely to address market power concerns without undermining incentives for new entry and long-term adequacy. Therefore, according to Indicated Parties, until the Commission releases the western markets from the temporary mitigation program, the West-wide price cap should be no less than the bid cap for the CAISO market. Indicated Parties request that the Commission take action under FPA section 206 to ensure that any elevation in the bid cap applicable to the CAISO markets is matched by an identical elevation in the price cap applicable to the remainder of the WECC. Powerex and Indicated Parties support the increase of the West-wide price cap to $400/MWh.

19. The Indicated Parties further assert that the Commission should hold that the bid cap in the non-California portion of the WECC will be a "soft" cap that permits cost justifications for sales above the level of the cap, and not a "hard" cap as the CAISO has proposed for its markets. They argue that if natural gas prices move even higher than their current levels, a "hard" cap of $400/MWh may not be sufficient to ensure full cost recovery for some generators. They assert that a "soft" cap at least permits generators to sell at prices above the cap as long as they can justify their elevated prices. Indicated Parties also request that the Commission clarify the type of documentation that sellers need to supply to justify prices above the applicable bid cap. According to Indicated Parties, this clarification will reduce the possibility of artificial constraints by making it easier for sellers with incremental costs above the level of the cap to decide whether to contribute their output into the market.

Ancillary Services

20. Powerex states that the cap on ancillary service capacity bids should be increased to $400/MWh. It asserts that neither the CAISO nor MSC has offered any reason for the failure to raise this bid cap. According to Powerex, different bid caps for energy and ancillary services could potentially distort electricity markets since not all possible markets scenarios can be foreseen.

Effective Date

21. SVP asserts that the CAISO violated the FPA by making an unauthorized tariff change. SVP states that the CAISO filed its proposed Amendment 73 on December 21, 2005, and requested expedited consideration in order to implement the proposal on January 1, 2006.[23] SVP notes that on December 22, 2005, the Commission established a comment date of January 3, 2006, for protests and interventions, and did not authorize a January 1, 2006 effective date.[24] According to SVP, despite the Commission's absence of approval, the CAISO announced its intention to make the proposed "hard" cap effective on January 1, 2006.[25] SVP states that the CAISO has no authority to unilaterally implement tariff changes before the Commission approves the changes. It states that the Commission should not tolerate such actions which violate the filed rate doctrine.[26] SVP states that the CAISO's unauthorized change in the tariff could cause bids to be rejected or could cause sellers to choose not to bid.

Discussion

Procedural Matters

22. Pursuant to Rule 214 of the Commission's Rules of Practice and Procedure, 18 CFR 385.214 (2005), the notices of intervention and timely, unopposed motions to intervene serve to make the entities that filed them parties to these proceedings. We will accept IEP's motion to intervene because it will not be prejudicial at this early stage in the proceeding.

23. Rule 213(a)(2) of the Commission's Rules of Practice and Procedure, 18 CFR 385.213(a)(2) (2005), prohibits an answer to a protest unless otherwise ordered by the decisional authority. We will accept the CAISO's answer because it has provided information that assisted us in our decision-making process.

24. IEP failed to file a timely Statement of Issues as required by Order No. 663.[27] Order No. 663 applies to all pleadings, including protests and comments,[28] and requires that any issues that a movant wishes the Commission to address must be specifically identified in a section entitled "Statement of Issues" that must list each issue presented to the Commission in a separately enumerated paragraph that includes representative Commission and court precedent on which the party is relying. Any issues not so listed in a separate section will be deemed to have been waived. Order No. 663 became effective September 23, 2005. IEP's late motion to intervene and comments, filed on January 4, 2006, omitted the Statement of Issues. For this reason, we deem IEP to have waived the issues in its comments. While Indicated Parties did include a "Statement of

[21] *See* The CAISO Amendment No. 73 Filing at 5 (citing July 2005 Order, 112 FERC ¶ 61,013 at P 104 (2005)).

[22] Williams notes that the "hard" cap directed by the Commission under MRTU is initially set at $500/MWh and ultimately increases to $1,000/MWh (a structure that Williams points out was approved by the Commission prior to the recent run-up in fuel prices), the must-offer obligation will not exist under MRTU as it does today, and the California Public Utility Commission's (CPUC) resource adequacy requirement should be in place when MRTU is implemented, resulting in less reliance by load on the CAISO's real-time market.

[23] *See* CAISO Amendment No. 73 Filing.

[24] *California Independent System Operator Corp.*, Notice of Filing, Docket No. ER06–354–000, Dec. 22, 2005.

[25] *See* CAISO Market Notice, Dec. 27, 2005.

[26] *See* FPA sections 205(c), 16 U.S.C. 824d(c) (2000), and 206(a), 16 U.S.C. 824e(a) (2000); *see also Arkansas Louisiana Gas Co.* v. *Hall*, 453 U.S. 571, 581 (1981) (explaining that "under the filed rate doctrine, the Commission alone is empowered to [accept proposed rate filings], and until it has done so, no rate other than the one on file may be charged."); *Williams Power Co.* v. *California Independent System Operator Corp.*, 110 FERC ¶ 61,231 at P 18, *clarification denied*, 111 FERC ¶ 61,348 (2005) (explaining that "[i]f the CAISO believes that additional tariff provisions are necessary to maintain operational control of its system and to minimize operating costs, it must request prior Commission authorization of the proposed tariff changes.").

[27] *Revision of Rules of Practice and Procedure Regarding Issue Identification*, Order No. 663, 70 FR 55,723 (Sept. 23, 2005), FERC Stats. & Regs. ¶31,193 (2005).

[28] Order No. 663 does not apply to comments on rulemakings or comments on offers of settlement. However, that exception does not apply here because IEP is commenting on a tariff filing. *See* Order No. 663.

Issues," any issue not specifically identified by Indicated Parties in their "Statement of Issues" is deemed waived.

Commission Determination

CAISO Bid Cap

25. The current $250/MWh "soft" bid cap in the CAISO's energy market was established in October 2002 when natural gas prices were between $3 and $4/MMBtu. As the CAISO noted in its filing, in recent months, concerns over tight natural gas supplies have resulted in high and volatile natural gas prices throughout the country. Natural gas spot prices in California recently reached as high as $14/MMBtu.[29] Since natural gas is the fuel source for a significant portion of generation used to meet California load, this price rise and volatility led the CAISO to have concerns that the current level of the bid cap may constrain the CAISO's ability to acquire sufficient power in real time. Given the current market design, which includes a must-offer obligation and a $250/MWh cap on energy, the Commission is concerned that generators may not have the opportunity to adequately recover their costs. We note that no intervenor has opposed the increase, and find that raising the bid cap is justified by the well-documented rise in gas prices. Accordingly, the Commission accepts the CAISO's proposal to raise the current bid cap from $250/MWh to $400/MWh.

26. The Commission rejects, however, the CAISO's proposal to change the current "soft" nature of the cap to a "hard" cap during this interim period prior to the implementation of MRTU and a resource adequacy mechanism. Neither the MSC nor DMM recommended changing the cap from a "soft" to a "hard" cap, and the CAISO has not adequately supported such a change. A "hard" cap, in combination with the CAISO's current must-offer obligation,[30] could result in confiscatory rates because it would raise the possibility that sellers could be forced to operate at a loss. Based on the current circumstances of rising and volatile gas prices, we will retain the cap as a "soft" cap during this interim period. The CAISO has filed an emergency request in response to an unusual situation of rapidly rising natural gas prices, and the Commission believes the importance of ensuring a market design that is both reliable and non-confiscatory outweighs the CAISO's desire to transition towards a "hard" cap directed by the Commission to begin at the implementation of MRTU in 2007.

Price Cap in the WECC Outside the CAISO

27. Our preliminary judgment is that the maximum price for spot market sales in the WECC outside the CAISO, as established by the Commission in our July 2002 Order, should also be raised to a $400/MWh "soft" cap. As we stated in that order, "California is an integral part of a trade and reliability region in the West. Because of this interdependency of market and infrastructure, conditions in and changes to the California market affect the entire region."[31] Accordingly, pursuant to our authority under section 206 of the FPA, we propose to increase the cap to a $400/MWh "soft" cap for all spot market sales in the WECC outside the CAISO, defined in our June 19, 2001 Order as sales in the WECC that are 24 hours or less and are entered into the day of or day prior to delivery.[32]

28. In light of issues raised by entities in this proceeding and the Commission's above proposal, we hereby institute, under section 206 of the FPA, 16 U.S.C. 824e (2000), an investigation into the price cap on spot market sales in the WECC outside the CAISO. We recognize the interest of entities regarding this investigation and, therefore, the Commission invites interested persons to submit comments on this issue within 10 days from the date of issuance of this order. We note that implementing a $400/MWh bid cap in the CAISO while the remainder of the WECC retains a $250/MWh cap could cause the non-CAISO WECC to have difficulties in attracting imbalance energy if gas prices were to rise substantially prior to Commission action. Because gas prices have leveled off since the CAISO's filing, we believe the potential for this to occur in the near term is small, however, the Commission intends to act expeditiously to address this WECC cap upon the expiration of the comment period.

29. In cases where the Commission institutes an investigation on its own motion, section 206(b) of the FPA, as amended by section 1285 of the Energy Policy Act of 2005,[33] requires that the Commission establish a refund effective date and that date must be no earlier than the publication date of the Commission's notice that it intends to initiate such proceeding but no later than five months after the publication date. Therefore, we find that the refund effective date, pursuant to section 206(b) of the FPA, as amended by section 1285 of the Energy Policy Act of 2005, is the date on which this order is published in the **Federal Register**.

Ancillary Services

30. Powerex argues that the bid caps should be the same for both the CAISO energy and ancillary services markets. Powerex asserts that neither the CAISO nor MSC has offered a rationale for not raising the ancillary services bid cap from its current $250/MWh level, and cites potential market distortions without giving details of how they might occur. In its answer, the CAISO dismisses this concern, pointing out that PJM has a $1,000/MWh energy bid cap and a $100/MWh regulation bid cap, and asserting that ancillary service capacity is a fixed cost and that gas prices do not affect the cost of ancillary services. The CAISO argues that to the extent the CAISO accepts an ancillary services capacity bid from a supplier, and then calls on the unit to provide energy, the supplier will be able to reflect any increased gas costs in its energy bid. Finally, the CAISO argues that the ancillary service capacity bid cap will continue to be a "soft" cap, thus allowing suppliers to submit bids in excess of $250/MWh, provided they can provide cost justification for such bids.

31. The Commission recognizes that until the implementation of MRTU in 2007, the current CAISO market design does not have a day-ahead market that co-optimizes energy and ancillary services. The CAISO relies on ancillary service capacity being offered by sellers directly to the CAISO for various categories of reserves. Sellers must make the decision to sell either energy or ancillary services. To the extent a seller chooses to make its capacity available for selling an ancillary service like spinning reserves, it could incur an opportunity cost by not selling energy. Thus, under the current market design, the price of energy could have an impact on the price of ancillary services and suppliers may thus choose to provide energy instead of ancillary

[29] *See Daily price survey* ($/MMBtu), Platts Gas Daily, Dec. 14, 2005, at p. 2 (listing the midpoint for "PG&E city-gate" at $14.325).

[30] We note that the current must-offer obligation in California (and the WECC), which lacks a separate capacity payment, is different from a must-offer obligation where sellers, as part of a resource adequacy program, voluntarily accept a must-offer obligation in exchange for receiving a capacity payment.

[31] July 2002 Order at P 2.

[32] *See San Diego Gas & Electric Company* v. *Sellers of Energy and Ancillary Services Into Markets Operated by the California Independent System Operator and the California Power Exchange*, 95 FERC ¶61,418 at n. 3 (2001).

[33] Pub. L. No. 109–58, § 1285, 119 Stat. 594, 980–81 (2005).

services if the ancillary service capacity bid cap is below this opportunity cost.

32. Given these concerns, we will address the issue of the appropriate level of the CAISO ancillary service capacity bid cap in the section 206 investigation instituted in this proceeding. We recognize the interest of entities regarding this issue, therefore, the Commission invites interested persons to submit comments on the appropriate level of the CAISO's ancillary service capacity bid cap within 10 days from the date of issuance of this order. As discussed above, we find that the refund effective date, pursuant to section 206(b) of the FPA, as amended by section 1285 of the Energy Policy Act of 2005, is the date on which this order is published in the **Federal Register**.

Effective Date

33. We note that in its answer, the CAISO states that it has not implemented Amendment No. 73 and it does not intend to make the $400/MWh bid cap effective until approved by the Commission. In fact, the CAISO asserts that it made repeated statements in its transmittal letter and market notice that it requested the amendment be made effective on January 1, 2006 or as soon thereafter as possible. As noted above, the Commission accepts the CAISO's proposal, as modified, effective as of the date of this order.

The Commission Orders

(A) The Commission accepts and modifies the CAISO's proposal to adjust its bid cap for real-time energy bids and adjustment bids to $400/MWh, as discussed within the body of the order, effective upon issuance of this order.

(B) Pursuant to the authority conferred upon the Commission by the FPA, particularly section 206 thereof, the Commission institutes an investigation into the price cap in the WECC outside the CAISO and the ancillary service capacity bid cap in the CAISO, as discussed in the body of this order. Entities may submit comments regarding these issues within 10 days from the date of issuance of this order.

(C) The refund effective date established pursuant to section 206(b) of the FPA, as amended by section 1285 of the Energy Policy Act of 2005, as discussed in the body of this order, is the date upon which this order is published in the **Federal Register**.

By the Commission.

Magalie R. Salas,

Secretary.

[FR Doc. 06–1090 Filed 2–3–06; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. EC06–68–000, et al.]

Morgan Stanley, et al. Electric Rate and Corporate Filings

January 30, 2006.

The following filings have been made with the Commission. The filings are listed in ascending order within each docket classification.

1. Morgan Stanley

[Docket No. EC06–68–000]

Take notice that on January 24, 2006, Morgan Stanley tendered for filing with the Commission an application pursuant to section 203 of the Federal power Act seeking blanket authorization for the acquisition, directly or indirectly, of securities of electric utility companies, transmitting utilities or of any holding company over any electric utility company or transmitting utility, subject to certain proposed limitations.

Comment Date: 5 p.m. eastern time on February 6, 2006.

2. Elkem Metals Company—Alloy, L.P., et al. and Alloy Power Inc., et al.

[Docket No. EC06–69–000]

Take notice that on January 25, 2006, Elkem Metals Company—Alloy, L.P. (Elkem) and Alloy Power Inc. (Alloy Power) (collectively, Parties) and D.E. Shaw & Co., L.L.C., D.E. Shaw & Co. II, Inc., D.E. Shaw & Co., L.P. and D.E. Shaw & Co., Inc. (collectively, the Shaw-Related Entities and, together with Parties, Applicants), submitted an application pursuant to section 203 of the Federal Power Act for authorization of a disposition of a jurisdictional facilities whereby one-third of the limited partnership interests in Elkem would be transferred to Alloy Power. In addition, Applicants seek authorization for the Shaw-Related Entities to indirectly acquire securities in Elkem.

Comment Date: 5 p.m. eastern time on February 15, 2006.

3. BBPOP Wind Equity LLC, et al.

[Docket No. EC06–70–000]

Take notice that on January 25, 2006, BBPOP Wind Equity LLC (BBPOP Wind Equity), Kumeyaay Wind, LLC (Kumeyaay), Wind Park Bear Creek, LLC (Bear Creek), and Jersey-Atlantic Wind, LLC (Jersey-Atlantic) (for the last three entities, collectively, the Project Companies), and Babcock & Brown Wind Partners—U.S. LLC (BBWPUS) (collectively, Applicants) filed with the Commission an application pursuant to section 203 of the Federal Power Act for an order authorizing the indirect disposition of jurisdictional facilities in connection with the transfer and sale of upstream ownership interests in the jurisdictional facilities of the Project Companies. BBPOP Wind Equity and BBWPUS state that they are subsidiaries or affiliates of Babcock & Brown International Pty. Ltd. (BBIPL). The Project Companies which currently are owned indirectly in part by BBPOP Wind Equity, further state that they own wind energy generating facilities in operation in California, Pennsylvania and New Jersey and the proposed transactions are the transfer of upstream ownership interests in the Project Companies from BBPOP Wind Equity to BBWP and the potential temporary transfer of the membership interests in one or more of the Project Companies from BBPOP 3 to another wholly-owned BBPOP Wind Equity subsidiary.

Comment Date: 5 p.m. eastern time on February 15, 2006.

4. FPL Energy Duane Arnold, LLC

[Docket No. EG06–31–000]

Take notice that on January 26, 2006, FPL Energy Duane Arnold, LLC (Applicant), tendered for filing with the Commission an application for determination of exempt wholesale generator status pursuant to part 365 of the Commission's regulations.

Applicant states that it is a nuclear-powered facility with a nameplate capacity rating of 645 MW and is located in Palo, Iowa.

Comment Date: 5 p.m. eastern time on February 16, 2006.

5. City of Anaheim, California

[Docket No. EL06–24–000]

Take notice that on January 26, 2006, the City of Anaheim, California filed revisions of Appendix I to the OATT.

Comment Date: 5 p.m. eastern time on February 9, 2006.

6. Braintree Electric Light Department

[Docket No. EL06–48–000]

Take notice that on January 19, 2006, Braintree Electric Light Department (Braintree) submitted a petition pursuant to Rule 207(a)(2) of the Commission's Rules of Practice and Procedure (18 CFR 385.207(a)(2)) for a declaratory order determining that rates and charges associated with the costs of a reliability must-run (RMR) agreement between Braintree and ISO New England, Inc. as to Braintree's Potter 2 generating unit will satisfy the "just and reasonable" criteria of section 205 of the Federal Power Act.

Comment Date: 5 p.m. eastern time on February 21, 2006.

Standard Paragraph

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Magalie R. Salas,

Secretary.

[FR Doc. E6–1550 Filed 2–3–06; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. EC06–71–000, et al.]

Duke Energy Trading and Marketing, L.L.C., et al.; Electric Rate and Corporate Filings

January 31, 2006.

The following filings have been made with the Commission. The filings are listed in ascending order within each docket classification.

1. Duke Energy Trading and Marketing, L.L.C.

[Docket No. EC06–71–000]

Take notice that on January 26, 2006, Duke Energy Trading and Marketing, L.L.C. (DETM) and Constellation Energy Commodities Group, Inc. (CCG) filed with the Commission an application pursuant to section 203 of the Federal Power Act for authorization of the transfer by DETM of two wholesale power transactions to CCG. DETM and CCG have requested privileged treatment for commercially sensitive information contained in the application.

Comment Date: 5 p.m. eastern time on February 16, 2006.

2. General Electric Capital Corporation; Deville Energy, LLC

[Docket No. EC06–72–000]

Take notice that on January 27, 2006, General Electric Capital Corporation and Deville Energy, LLC (Applicants) submitted an application pursuant to section 203 of the Federal Power Act for authorization of disposition of jurisdictional facilities resulting from a proposed sale of a biomass-fired qualifying small power production facility.

Comment Date: 5 p.m. eastern time on February 17, 2006.

3. Inland Empire Energy Center, LLC

[Docket No. EG06–30–000]

Take notice that on January 25, 2006, Inland Empire Energy Center, LLC (Inland Empire) tendered for filing pursuant to section 32(a)(1) of the Public Utility Holding Company Act of 1935 an application for determination of exempt wholesale generator status.

Comment Date: 5 p.m. eastern time on February 7, 2006.

4. Entergy Arkansas, Inc.

[Docket Nos. EL04–134–005 and EL05–15–007]

Take notice that on January 23, 2006, Entergy Arkansas, Inc. tendered for filing a refund report related to refunds to East Texas Electric Cooperative in compliance with Commission Order issued November 7, 2005, 113 FERC ¶ 61,137 (2005).

Comment Date: 5 p.m. eastern time on February 13, 2006.

5. City of Vernon, California

[Docket No. EL06–32–000]

Take notice that on January 20, 2006, the City Vernon, California tendered for filing verification of the calculations to its revised Transmission Revenue Balancing Account Adjustment submitted on December 15, 2005, for the calendar year 2006.

Comment Date: 5 p.m. eastern time on February 6, 2006.

6. Thumb Electric Cooperative

[Docket Nos. OA05–1–000 and TS05–17–000]

Take notice that on July 28, 2005, Thumb Electric Cooperative (Thumb) requests the Commission waive the Open Access Same Time Information Systems requirements and functional separation requirements of the Standards of Conduct for Transmission Providers established by Order 889 and amended by Order 2004.

Comment Date: 5 p.m. eastern time on February 15, 2006.

7. Attala Transmission LLC

[Docket No. TS05–18–000]

Take notice that on June 29, 2005, Attala Transmission LLC (Attala), submitted for filing copies of the executed Interconnection and Service Charge Agreement, dated June 28, 2005, between Attala and Entergy Mississippi, Inc.

Comment Date: 5 p.m. eastern time on February 15, 2006.

8. Hardee Power Partners Limited

[Docket No. TS06–6–000]

Take notice that on December 15, 2005, Hardee Power Partners Limited tendered for filing with the Commission request for waiver of Orders Nos. 888 and 889 and Part 358 of the Commission's regulations.

Comment Date: 5 p.m. eastern time on February 7, 2006.

Standard Paragraph

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the

Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Magalie R. Salas,

Secretary.

[FR Doc. E6–1552 Filed 2–3–06; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OA–2006–0074; FRL–8028–5]

Agency Information Collection Activities: Proposed Collection; Comment Request; Voluntary Customer Satisfaction Surveys; EPA ICR Number 1711.05, OMB Control Number 2090–0019

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), this document announces that EPA is planning to submit a request to renew an existing approved Information Collection Request (ICR) to the Office of Management and Budget (OMB). This ICR is scheduled to expire on June 30, 2006. Before submitting the ICR to OMB for review and approval, EPA is soliciting comments on specific aspects of the proposed information collection as described below.

DATES: Comments must be submitted on or before April 7, 2006.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OA–2006–0074 by one of the following methods:

- *Http://www.regulations.gov*: Follow the on-line instructions for submitting comments.
- E-mail: *docket.oei@epa.gov*.
- Fax: 202–566–1753.
- Mail: OEI Docket, Environmental Protection Agency, Mailcode: 2822T, 1200 Pennsylvania Ave., NW., Washington, DC 20460.
- Hand Delivery: OEI Docket in the EPA Docket Center (EPA/DC), EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room is open from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–OA–2006–0074. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or e-mail. The *http://www.regulations.gov* Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through www.regulations.gov your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.*

FOR FURTHER INFORMATION CONTACT: Patricia Bonner, Office of Environmental Policy Innovation, (MC 1807T), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: 202–566–2204; fax number: 202–566–2200; e-mail address: *bonner.patricia@epa.gov.*

SUPPLEMENTARY INFORMATION:

How Can I Access the Docket and/or Submit Comments?

EPA has established a public docket for this ICR under Docket ID No. EPA–HQ–OA–2006–0074, which is available for online viewing at *http://www.regulations.gov*, or in person viewing at the OEI Docket in the EPA Docket Center (EPA/DC), EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room is open from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is 202–566–1744, and the telephone number for the OEI Docket is 202–566–1752.

Use *http://www.regulations.gov* to obtain a copy of the draft collection of information, submit or view public comments, access the index listing of the contents of the docket, and to access those documents in the public docket that are available electronically. Once in the system, select "search," then key in the docket ID number identified in this document.

What Information Is EPA Particularly Interested in?

Pursuant to section 3506(c)(2)(A) of the PRA, EPA specifically solicits comments and information to enable it to:

(i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(ii) Evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(iii) Enhance the quality, utility, and clarity of the information to be collected; and

(iv) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses. In particular, EPA is requesting comments from very small businesses (those that employ less than 25) on examples of specific additional efforts that EPA could make to reduce the paperwork burden for very small businesses affected by this collection.

What Should I Consider When I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible and provide specific examples.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Offer alternative ways to improve the collection activity.
6. Make sure to submit your comments by the deadline identified under DATES.
7. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

What Information Collection Activity or ICR Does This Apply To?

Docket ID No. EPA–HQ–OA–2006–0074.

Affected entities: Entities potentially affected by this action are primarily individuals or households.

Title: Voluntary Customer Satisfaction Surveys.

ICR numbers: EPA ICR No. 1711.05, OMB Control No. 2090–0019.

ICR status: This ICR is currently scheduled to expire on June 30, 2006. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register** when approved, are listed in 40 CFR part 9, are displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers in certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: EPA uses voluntary surveys to learn how satisfied EPA customers are with our services, and how we can improve services, products and processes. EPA surveys individuals who use services or could have. During the next three years, EPA plans up to 50 surveys, and will use results to target/measure service delivery improvements. By seeking renewal of the generic clearance for customer surveys, EPA will have the flexibility to gather the views of our customers to better determine the extent to which our services, products and processes satisfy their needs or need to be improved. The generic clearance will speed the review and approval of customer surveys that solicit opinions from EPA customers on a voluntary basis, and do not involve "fact-finding" for the purposes of regulatory development or enforcement.

An Agency may conduct or sponsor, and a person is not required to respond to, a collection of information unless it has a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR chapter 15.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average five minutes to two hours per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements which have subsequently changed; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

The ICR provides a detailed explanation of the Agency's estimate, which is only briefly summarized here:

Estimated total number of potential respondents: 8,640.

Frequency of response: On occasion.

Estimated total annual burden hours: 550 hours.

Estimated total annual costs: $9,075. This includes an estimated burden cost of $9,075 and an estimated cost of $0 for capital investment or maintenance and operational costs.

What Is the Next Step in the Process for This ICR?

EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval pursuant to 5 CFR 1320.12. At that time, EPA will issue another **Federal Register** notice pursuant to 5 CFR 1320.5(a)(1)(iv) to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB. If you have any questions about this ICR or the approval process, please contact the technical person listed under **FOR FURTHER INFORMATION CONTACT.**

Dated: January 31, 2006.

Elizabeth A. Shaw,

Director, Office of Environmental Policy Innovation, Office of Policy, Economics and Innovation, Office of the Administrator.

[FR Doc. E6–1581 Filed 2–3–06; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7760–5]

Establishment of Human Studies Review Board

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; Establishment of Advisory Committee.

SUMMARY: As required by section 9(a)(2) of the Federal Advisory Committee Act, the United States Environmental Protection Agency (EPA or Agency) is giving notice that it is establishing the Human Studies Review Board (HSRB). The purpose of this Board is to provide advice and recommendations to EPA on issues related to the scientific and ethical review of human subjects research. EPA has determined that this advisory committee is in the public interest and will assist the Agency in performing its duties as directed in the 2006 EPA Appropriations Act. Further, the Agency included the establishment of such a Board in a final rule for protection of subjects in human research. The Agency is publishing, in a separate **Federal Register** notice, the final rule that strengthens the protections for subjects in human research, including a provision addressing the establishment and operation of the HSRB. In addition, in a report requested by the Agency, the National Academy of Sciences recommended that EPA establish such a Board. See: "Department of Interior, Environment, and Related Agencies Appropriations Act, 2006," Public Law 109–54; and "Intentional Human Dosing Studies for EPA Regulatory Purposes," Washington, DC: National Academy Press. 2004. Balanced membership will be driven by a number of considerations characterized by: inclusion of the necessary areas of technical expertise, different scientific perspectives within each technical discipline, and the collective breadth of experience needed to address the Agency's charge. Copies of the Committee Charter will be filed with the appropriate congressional committees and the Library of Congress.

FOR FUTHER INFORMATION CONTACT: Paul I. Lewis, Office of the Science Advisor, Mail Code 8105R, Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; telephone number: (202) 564–8381; fax number (202) 564–2070; e-mail: lewis.paul@epa.gov.

Dated: January 25, 2006.

William H. Farland,

Chief Scientist, Office of the Science Advisor.

[FR Doc. 06–1046 Filed 2–3–06; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–EPA–HQ–2005–0252; FRL–7762–3]

Iodomethane Risk Assessment; Notice of Availability; Extension of Comment Period

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; extension of comment period.

SUMMARY: EPA issued a notice in the Federal Register of January 6, 2006, concerning the availability of EPA's human health risk assessment and related documents for the fumigant iodomethane. These documents can be viewed in the docket. This document is extending the comment period for 15 days, from February 6, 2006 to February 21, 2006.

DATES: Comments, identified by the docket identification number OPP–EPA–HQ–2005–0252, must be received on or before February 21, 2006.

ADDRESSES: Follow the detailed instructions as provided under **ADDRESSES** in the **Federal Register** document of January 6, 2006.

FOR FURTHER INFORMATION CONTACT: Mary L. Waller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9354; fax number: (703) 308–1825; e-mail address: *waller.mary @epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

The Agency included in the proposed rule a list of those who may be potentially affected by this action. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under the **FOR FURTHER INFORMATION CONTACT.**

B. How Can I Access Electronic Copies of this Document and Other Related Information?

Electronic access. You may access this **Federal Register** document electronically through the EPA Internet under "**Federal Register**" listings at http://www.epa.gov/fedrgstr/.

In addition to using EDOCKET *http://www.epa.gov/edocket/*, you may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at *http://www.epa.gov/fedrgstr/.* A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/.*

EDOCKET, EPA's electronic public docket and comment system was replaced on November 25,2005, by an enhanced Federal-wide electronic docket management and comment system located at *http://www.regulations.gov/.* Follow the on-line instructions.

II. What Action is EPA taking?

This document extends the public comment period established in the **Federal Register** issued on January 6, 2006 (71 FR 930). In that document, EPA made available the human health risk assessment for iodomethane. Iodomethane is a new chemical proposed for use as a pre-plant fumigant to control soil borne pests including weed seeds, nematodes, insects, and diseases in fields intended for commercial production of strawberries, tomatoes, peppers, turf, ornamentals (flowers grown for cutting; bulbs, and nursery plants), trees and vines. EPA is hereby extending the comment period, which was set to end on February 6, 2006. to February 21, 2006.

III. What is the Agency's Authority for Taking this Action?

Section 3 of FIFRA directs that "the Administrator may by regulation limit the distribution, sale, or use in any State of any pesticide that is not registered under this Act and that is not the subject of an experimental use permit under section 4 or an emergency exemption under section 18.

IV. Do Any Statutory and Executive Order Reviews Apply to this Action?

No. This action is not a rulemaking, it merely extends the date by which public comments on a risk assessment must be submitted to EPA as announced in a Notice of Availability that previously published in the **Federal Register** of January 6, 2006 (71 FR 930).

List of Subjects

Environmental protection, Pesticides and pests.

Dated: February 1, 2006.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 06–1082 Filed 2–1–06; 8:45 am]

BILLING CODE 6560–50–S

FEDERAL ELECTION COMMISSION

Sunshine Act; Meeting

DATE & TIME: Thursday, February 9, 2006 at 10 a.m.

PLACE: 999 E Street, NW., Washington, DC (Ninth Floor).

STATUS: This meeting will be open to the public.

ITEMS TO BE DISCUSSED:

Correction and Approval of Minutes.
Final Rules for Definition of Federal Election Activity.
Routine Administrative Matters.

FOR FURTHER INFORMATION CONTACT: Mr. Robert Biersack, Press Officer, Telephone: (202) 694–1200.

Mary W. Dove,

Secretary of the Commission.

[FR Doc. 06–1112 Filed 2–2–06; 2:45 pm]

BILLING CODE 6715–01–M

FEDERAL MARITIME COMMISSION

[Docket No. 06–03]

Premier Automotive Serices, Inc. v. Robert L. Flanagan and F. Brooks Royster, III; Notice of Filing of Complaint and Assignment

Notice is given that a complaint has been filed with the Federal Maritime Commission ("Commission") by Premier Automotive Services, Inc., ("Complainant"), against Robert L. Flanagan and F. Brooks Royster, III, ("Respondents"). Complainant asserts that it is a Baltimore based import/export vehicle processing center that operates as a marine terminal operator under The Shipping Act of 1984 ("the Act"). Complainant contends that Respondent Robert L. Flanagan is the Secretary of the Department of Transportation of the State of Maryland and the Chairman of the Maryland Port Commission, and Respondent F. Brooks Royster, III, is the Executive Director of the Maryland Port Administration. Complainant asserts that it has been a tenant of the Maryland Port Authority ("MPA") since 1992, renewing the lease once in 1998 and then leasing month-to-

month since 2002. The Complainant further contends the MPA has demanded that Complainant vacate the premises after refusing to negotiate a commercially reasonable lease. Complainant alleges that the MPA and its Directors have violated Section 10(d)(1) of the Act (46 U.S.C. App. 1709(d)(1)) by failing to establish, observe, and enforce just and reasonable regulations and practices relating to or connected with receiving, handling, storing, or delivering property. In addition, Complainant alleges that Respondents violated Sections 10(d)(3) of the Act (46 USA App. § 1709(d)(3)) by unreasonably refusing to deal with a tenant, and 10(d)(4) of the Act (46 U.S.C. App. 1709(d)(4)) by giving undue or unreasonable preference or advantage or imposing undue or unreasonable prejudice or disadvantage with respect to any person. Respondent asserts that the Commission has found that it might have jurisdiction to adjudicate a "* * * privately-initiated complaint proceeding against the directors of a state-run port rather than against the port." Respondent prays that the Commission: seek a temporary restraining order and preliminary injunction enjoining the Respondents to cease their unlawful treatment of Complainant and from leasing the lot to another company; declare that the Respondents have violated the Act as detailed above and direct the Respondents to cease all such violations; direct Respondents to offer Complainant a commercially viable lease for the lot in question; award Complainant reparations for actual injuries, pre and post-judgment interest, and litigation and attorney fees; and award such other and further relief as deemed just and proper.

This proceeding has been assigned to the Office of Administrative Law Judges. Hearing in this matter, if any is held, shall commence within the time limitations prescribed in 46 CFR 502.61, and only after consideration has been given by the parties and the presiding officer to the use of alternative forms of dispute resolution. The hearing shall include oral testimony and cross-examination in the discretion of the presiding officer only upon proper showing that there are genuine issues of material fact that cannot be resolved on the basis of sworn statements, affidavits, depositions, or other documents or that the nature of the matter in issue is such that an oral hearing and cross-examination are necessary for the development of an adequate record. Pursuant to the further terms of 46 CFR 502.61, the initial decision of the presiding officer in this proceeding shall be issued by January 31, 2007, and the final decision of the Commission shall be issued by May 31, 2007.

Bryant L. VanBrakle,

Secretary.

[FR Doc. E6–1589 Filed 2–3–06; 8:45 am]

BILLING CODE 6730–01–P

GENERAL SERVICES ADMINISTRATION

Office of Small Business Utilization; Small Business Advisory Committee; Notification of a Public Meeting of the Small Business Advisory Committee

AGENCY: Office of Small Business Utilization, GSA.

ACTION: Notice.

SUMMARY: The General Services Administration (GSA) is announcing a public meeting of the GSA Small Business Advisory Committee (the Committee).

DATES: The meeting will take place February 21–22. The meeting will begin 1 p.m. Tuesday February 21 and conclude no later than 5 p.m. that day. The meeting will resume 9 a.m. Wednesday February 22 and conclude no later than 3 p.m. that day. The Committee will accept oral public comments at this meeting and has reserved a total of sixty minutes for this purpose. Members of the public wishing to reserve speaking time must contact Denis Peck in writing at: *denis.peck@gsa.gov* or by fax at (202) 208–5938, no later than one week prior to the meeting.

ADDRESS: GSA Central Office Auditorium, 1800 F Street, NW., Washington, DC 20405.

FOR FURTHER INFORMATION CONTACT: Denis Peck, Room 6021, GSA Building, 1800 F Street, NW., Washington, DC 20405 (202) 501–1021 or e-mail at *denis.peck@gsa.gov*.

SUPPLEMENTARY INFORMATION: This notice is published in accordance with the provisions of the Federal Advisory Committee Act (FACA) (Pub. L. 92–463).

Background:

The purpose of this meeting is to develop the topics generated during the previous meeting September 1, 2005; to receive briefings from small business topical experts, and to hear from interested members of the public on proposals to improve GSA's small business contracting performance.

Dated: January 13, 2006.

Felipe Mendoza,

Associate Administrator, Office of Small Business Utilization, General Services Administration.

[FR Doc. E6–1525 Filed 2–3–06; 8:45 am]

BILLING CODE 6820–34–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee on Childhood Lead Poisoning Prevention

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the National Center for Environmental Health (NCEH) of the Centers for Disease Control and Prevention (CDC) announces the following committee meeting.

Name: Advisory Committee on Childhood Lead Poisoning Prevention (ACCLPP).

Times and Dates: 8:30 a.m.–5 p.m., March 21, 2006. 8:30 a.m.–12:30 p.m., March 22, 2006.

Place: Magnolia Hotel, 1100 Texas Avenue, Houston, Texas 77002.

Telephone: (281)657–2664 or toll free 1–888–915–1110.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 75 people.

Purpose: The committee shall provide advice and guidance to the Secretary, Department of Health and Human Services; the Assistant Secretary for Health; and the Director, CDC, regarding new scientific knowledge and technological developments and their practical implications for childhood lead poisoning prevention efforts. The committee shall also review and report regularly on childhood lead poisoning prevention practices and recommend improvements in national childhood lead poisoning prevention efforts.

Matters to be Discussed: Update on the Primary Prevention Workgroup document; update on the Adverse Health Effects of Blood Lead Levels less than 10 Report; update from the Lead and Pregnancy Workgroup; update of strategic planning process by state and local childhood lead poisoning prevention programs; update on cooperation with the U.S. Department of Housing and Urban Development and the U.S. Environmental Protection Agency enforcement of the Lead Disclosure Rule; and an update on research and program evaluation activities ongoing in the Lead Poisoning Prevention Branch.

Agenda items are subject to change as priorities dictate.

Opportunities will be provided during the meeting for oral comments. Depending on the time available and the number of requests, it may be necessary to limit the time of each presenter.

Contact Person For More Information: Claudine Johnson, Lead Poisoning Prevention Branch, Division of Emergency and Environmental Health Services, NCEH, CDC, 4770 Buford Hwy, NE., M/S F–40, Atlanta, Georgia 30341, telephone (770) 488–3629, fax (770) 488–3625.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: January 30, 2006.

Diane Allen,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E6–1557 Filed 2–3–06; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Guide to Community Preventive Services Task Force

Name: Task Force on Community Preventive Services.

Times and Dates: 8 a.m.–7 p.m., February 15, 2006; 9 a.m.–1:30 p.m., February 16, 2006.

Place: Centers for Disease Control and Prevention (CDC), Roybal Campus, Building 19, Room 232 (Auditorium B), 1600 Clifton Road, Atlanta, Georgia 30333, telephone (404) 639–3311.

Status: Open to the public, limited only by the space available.

Purpose: The mission of the Task Force is to develop and publish the Guide to Community Preventive Services (GCPS), which is based on the best available scientific evidence and current expertise regarding essential public health and what works in the delivery of those services.

Matters To Be Discussed: (1) Briefings on administrative information; (2) Violence prevention; (3) Enhanced enforcement of laws prohibiting sale of alcohol to minors; (4) Worksite health promotion and the assessment of health risks with feedback; (5) Update on worksite setting and obesity; (6) Adolescent health; (7) Provider reminders and provider incentives for cancer screening; and (8) Dissemination activities and projects in which the Community Guide is utilized.

Agenda items are subject to change as priorities dictate.

Persons interested in reserving a space for this meeting should call (770) 488–8376 by close of business on February 10, 2006.

Contact Person or Additional Information: Peter Briss, M.D., Chief, Community Guide Branch, Coordinating Center for Health Information and Service, National Center for Health Marketing, Division of Scientific Communications, 4770 Buford Highway, M/S K–95, Atlanta, Georgia 30333, telephone (770) 488–8338.

The Director, Management Analysis and Services Office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: January 30, 2006.

Diane Allen,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E6–1556 Filed 2–3–06; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Institute for Occupational Safety and Health, Safety and Occupational Health Study Section

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting.

Name: Safety and Occupational Health Study Section (SOHSS), National Institute for Occupational Safety and Health (NIOSH).

Times and Dates: 8 a.m.–5 p.m., February 21, 2006. 8:30 a.m.–5 p.m., February 22, 2006.

Place: Embassy Suites Hotel, 1900 Diagonal Road, Alexandria, Virginia 22314, telephone 703–684–5900, fax 703–684–1403.

Status: Open 8 a.m.–8:30 a.m., February 21, 2006. Closed 8:30 a.m.–5 p.m., February 21, 2006. Closed 8:30 a.m.–5 p.m., February 22, 2006.

Purpose: The SOHSS will review, discuss, and evaluate grant application(s) received in response to the Institute's standard grants review and funding cycles pertaining to research issues in occupational safety and health, and allied areas.

It is the intent of NIOSH to support broad-based research endeavors in keeping with the Institute's program goals. This will lead to improved understanding and appreciation for the magnitude of the aggregate health burden associated with occupational injuries and illnesses, as well as to support more focused research projects, which will lead to improvements in the delivery of occupational safety and health services, and the prevention of work-related injury and illness. It is anticipated that research funded will promote these program goals.

Matters to be Discussed: The meeting will convene in open session from 8–8:30 a.m. on February 21, 2006, to address matters related to the conduct of study section business. The remainder of the meeting will proceed in closed session. The purpose of the closed session is for the study section to consider safety and occupational health-related grant applications. These portions of the meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), Title 5 U.S.C., and the determination of the Director, Management Analysis and Services Office, CDC, pursuant to section 10(d), Public Law 92–463.

Agenda items are subject to change as priorities dictate.

FOR FURTHER INFORMATION CONTACT: Price Connor, Ph.D., NIOSH Health Scientist, 1600 Clifton Road, NE., Mailstop E–20, Atlanta, Georgia 30333, telephone 404–498–2511, fax 404–498–2569.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: January 29, 2006.

Diane Allen,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E6–1559 Filed 2–3–06; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0038]

Agency Information Collection Activities; Proposed Collection; Comment Request; Irradiation in the Production, Processing, and Handling of Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the reporting and recordkeeping requirements for food irradiation processors.

DATES: Submit written or electronic comments on the collection of information by April 7, 2006.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Irradiation in the Production, Processing, and Handling of Food—21 CFR Part 179 (OMB Control Number 0910–0186)—Extension

Under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(s) and 348), food irradiation is subject to regulation under the food additive premarket approval provisions of the act. The regulations providing for uses of irradiation in the production, processing, and handling of food are found in part 179 (21 CFR part 179). To ensure safe use of a radiation source, § 179.21(b)(1) requires that the label of sources bear appropriate and accurate information identifying the source of radiation and the maximum energy of radiation emitted by x ray tube sources. Section 179.21(b)(2)(i) requires that the label or accompanying labeling bear adequate directions for installation and use. Section 179.25(e) requires that food processors who treat food with radiation make and retain, for 1 year past the expected shelf life of the products up to a maximum of 3 years, specified records relating to the irradiation process (e.g., the food treated, lot identification, scheduled process, etc.). The records required by § 179.25(e) are used by FDA inspectors to assess compliance with the regulation that establishes limits within which radiation may be safely used to treat food. The agency cannot ensure safe use without a method to assess compliance with the dose limits, and there are no practicable methods for analyzing most foods to determine whether they have been treated with ionizing radiation and are within the limitations set forth in part 179. Records inspection is the only way to determine whether firms are complying with the regulations for treatment of foods with ionizing radiation.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of recordkeepers	Annual frequency per recordkeeping	Total annual records	Hours per record	Total hours
179.25(e)	6	120	720	1	720

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

The number of firms who process food using irradiation is extremely limited. FDA estimates that there are two irradiation plants whose business is devoted primarily (i.e., approximately 100 percent) to irradiation of food and other agricultural products. Four other firms also irradiate small quantities of food. FDA estimates that this irradiation accounts for no more than 10 percent of the business for each of these firms. Therefore, the average estimated burden is based on: Two facilities devoting 100 percent of their business (or 600 hours for recordkeeping annually) to food irradiation; four facilities devoting 10 percent of their business or 120 hours (4 x 30 hours) for recordkeeping annually to food irradiation.

No burden has been estimated for the labeling requirements in §§ 179.21(b)(2)(i) and (b)(2)(ii) and 179.26(c) because the information to be disclosed is information that has been supplied by FDA. Under 5 CFR 1320.3(c)(2), the public disclosure of

information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public is not a collection of information.

Dated: January 30, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–1516 Filed 2–3–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0037]

Agency Information Collection Activities; Proposed Collection; Comment Request; Proposed Experimental Study of Trans Fat Claims on Foods

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on a proposed experimental study of *trans* fat claims on foods to evaluate the effects of various possible disclosure requirements intended to help consumers understand and apply *trans* fat claims they might see on food products. The proposed experimental study will estimate the communication effectiveness of these disclosure requirements in realistic label usage situations for a range of products that may bear *trans* fat claims.

DATES: Submit written or electronic comments on the collection of information by April 7, 2006.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Proposed Experimental Study of Trans Fat Claims on Foods (OMB Control Number 0910–0533)—Reinstatement

FDA is requesting OMB approval of a proposed experimental study of *trans* fat claims on food products intended to help FDA's Center for Food Safety and Applied Nutrition formulate decisions and policies affecting labeling requirements for *trans* fat claims on foods.

In the **Federal Register** of July 11, 2003 (68 FR 41507), FDA issued an advance notice of proposed rulemaking entitled "Food Labeling: Trans Fatty Acids in Nutrition Labeling; Consumer Research to Consider Nutrient Content and Health Claims and Possible Footnote or Disclosure Statements," which requested comments about possible disclosure requirements to accompany nutrient content claims about *trans* fatty acids that could help consumers make heart-healthy food choices. The proposed experimental study will evaluate the ability of several such disclosure requirements to help consumers make heart-healthy food choices. The results of the proposed experimental study will provide empirical support for possible policy decisions about the need for such disclosures and the appropriate form they should take.

FDA or its contractor will collect and use information gathered from Internet panel samples to evaluate how consumers understand and respond to possible disclosure requirements for *trans* fat content claims. The distinctive features of Internet panel and shopping mall methodologies for the purpose of the proposed experimental study are that they allow for controlled visual presentation of study materials, experimental manipulation of study materials, and the random assignment of subjects to condition. Experimental manipulation of labels and random assignment to condition makes it possible to estimate the effects of the various possible disclosure requirements while controlling for individual differences. Random assignment ensures that mean differences between conditions can be tested using well-known techniques such as analysis of variance or regression analysis to yield statistically valid estimates of treatment effect size. The proposed study will be conducted from a sample drawn from a large, nationally representative consumer panel with 800,000 households. The sample size and population pool are adequate to ensure that results can be generalized.

Participants will be adults, age 18 and older, who are recruited for a study about foods and food labels. Each participant will be randomly assigned to one of the 144 experimental conditions consisting of fully crossing 8 disclosure conditions, 3 product types, 3 fatty acid profiles and 2 prior knowledge conditions.

FDA will use the information from the proposed experimental study to evaluate regulatory policy options. The agency often lacks empirical data about how consumers understand and respond to statements they might see in product labeling. The information gathered from this proposed experimental study will be used by the agency to assess likely consumer responses to various disclosure

requirements for nutrient content claims.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Type of survey	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Internet Survey	2880	1	2880	.25	720
Total					720

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA's burden estimate is based on prior experience with Internet panel experiments similar to the study proposed here.

Dated: January 30, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–1517 Filed 2–3–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0317]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Record Retention Requirements for the Soy Protein and Risk of Coronary Heart Disease Health Claim

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Record Retention Requirements for the Soy Protein and Risk of Coronary Heart Disease Health Claim" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 15, 2005 (FR 70 69344), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0428. The approval expires on January 31, 2009. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets.*

Dated: January 30, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–1518 Filed 2–3–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2000N–1269] (formerly Docket No. 00N–1269)

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Product Labels

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Product Labels" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Karen Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 22, 2000 (65 FR 81082), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0572. The approval expires on January 31, 2009. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets.*

Dated: January 30, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–1519 Filed 2–3–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0029]

Agency Information Collection Activities; Proposed Collection; Comment Request; Impact of Coupons on Consumer Perceptions of Products in Prescription Drugs in Direct-to-Consumer Prescription Drug Print Advertisements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on a proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on a study of the impact of coupons (such as price incentives or rebate offers) on consumers' perceptions of product risks and benefits in direct-to-consumer (DTC) print ads.

DATES: Submit written or electronic comments on the collection of information by April 7, 2006.

ADDRESSES: Submit electric comments on the collection of information to: *http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Karen Nelson, Office Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collections of information set forth in this document.

With respect to each of the following collections of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Impact of Coupons on Consumer Perceptions of Products in Direct-to-Consumer Prescription Drug Print Advertisements

The Federal Food, Drug, and Cosmetic Act (the act) requires that manufacturers, packers, and distributors (sponsors) who advertise prescription human and animal drugs, including biological products for humans, disclose in advertisements certain information about the advertised product's uses and risks. For prescription drugs and biologics, the act requires advertisements to contain "information in brief summary relating to side effects, contraindications, and effectiveness" (21 U.S.C. 352(n)). FDA is responsible for enforcing the act and implementing regulations.

FDA regulations require that prescription drug advertisements that make claims about a product must also include risk information in a "balanced" manner (21 CFR 202.1(e)(5)(ii)), both in terms of the content and presentation of the information. Advertisements that draw attention to the name of the product but do not make representations about the product's indication(s) or dosage recommendations are called reminder advertisements. Reminder ads may mention the proprietary and established name of the product and (optionally) contain information about the product's ingredients, dosage form, quantity, price, or manufacturer (21 CFR 202.1(e)(2)(i)). Graphic presentation and information is not prohibited in reminder ads as long as that information does not make a representation or suggestion about the product beyond those permitted.

The exemption for reminder ads was originally intended to allow distribution of price sheets, pens, notepads and other minor giveaways featuring the name of the drug product to physicians and other healthcare professionals without requiring a full disclosure of the product's risks. As DTC promotion has increased, sponsors have chosen to create reminder ads for consumers.

Sponsors may use ads as a vehicle to offer price incentives or coupons to consumers (e.g., "free trial," "buy six get one free"). Coupon promotions are widely used in many product categories and have been the topic of many academic studies. Coupons are primarily offered to increase the sales of the brand relative to their level without coupons.[1] Certain types of coupons, most notably those that appear in the body of an advertisement itself, can positively impact perceptions of the brand.

People tend to rate owned objects more favorably than those they do not own, even when those objects have been assigned to them at random.[2] This has been termed the "mere ownership" or "mere possession" effect. An interesting extension of this effect is provided in research by Sen and Johnson[3] which has shown that consumers rate a product more favorably when they are simply given a gift certificate or a coupon for that product or service. Other research has examined the effect of warranties. People who viewed an ad with a high warranty perceived the product as being less risky compared to people who saw an ad with a medium or low warranty.[4]

Based on this body of consumer research, the inclusion of coupons or other price incentives in DTC ads may impact consumers' perceptions of the risks and benefits of the prescription drug. For "simple" consumer products, coupons and free trial offers may enable the customer to test new products while minimizing their financial risk of testing the product. For products that consumers can readily test and ones where performance can be adequately verified (termed "search" goods by economists), coupons and free trial offers provide both the consumer and manufacturer an efficient mechanism for matching consumers and products. For more complex products such as prescription drugs where supervision of a physician is required to evaluate both appropriateness and performance, coupons and free trial offers may send different signals. These signals may foster consumer misperceptions about the advertised prescription drug product by exploiting general beliefs. Thus, prescription drugs promoted with coupons or free trial offers may be seen as more widely indicated, more appropriate and/or less risky than they really are. Inclusion of a mechanism that affects consumers' perception of the product's risks is especially problematic in reminder ads because this type of ad contains no accompanying risk information. Furthermore, coupons and price promotions may imply superior drug efficacy.

The proposed study will examine the impact coupons have on consumers' perceptions of risks and benefits and the overall impression of the product in DTC full-product and reminder

[1] LeClerc, France and John D.C. Little "Can advertising copy make FSI coupons more effective?" *Journal of Marketing Research*, 34(4), 473-484, 1997.

[2] Beggan, James K., "On the social nature of nonsocial perception: The mere ownership effect," *Journal of Personality and Social Psychology*, 62(2), 229-237, 1992.

[3] Sen, Sankar and Eric J. Johnson, "Mere-possession effects without possession in consumer choice," *Journal of Consumer Research*, 24 (June), 105-117, 1997.

[4] Shimp, Terrence A. and William O. Bearden, "Warranty and other extrinsic cue effects on consumers' risk perceptions," *Journal of Consumer Research*, 9 (June), 38-47, 1982.

advertisements. To justify future regulatory changes, we need to have better empirical data about consumers' perceptions of the information in both types of ads and how inclusion of such promotional devices can impact consumers' perceptions of the risks and benefits of advertised prescription drugs.

Design Overview: This study will employ a between-subjects crossed factorial design and will focus on consumer print advertising. Fifteen print advertisements will be created using three levels of ad type and five levels of promotional offer. Thus, the factors will be ad type (DTC print reminder; DTC print full product; over-the-counter print full product) and offer type (free trial offer; buy one, get one free; money off prescription/purchase cost; money back guarantee; no promotion). Product name and indication will be constant across conditions. Side effect and risk information will be constant across full product DTC ad conditions. Participants will be asked to read a single print advertisement for a new drug. After reading the advertisement, they will be asked questions about their evaluation of the information presented in the advertisement.

Factors: (*1*) *Participants*. Consumers will be screened and recruited by the contractor to be currently diagnosed with insomnia or at risk of developing insomnia. Participants will be randomly assigned to experimental cells. Each condition will be balanced with respect to gender.

Because this is the first investigation of this issue with DTC ads, we chose to limit our investigation to one disease condition. We chose to accept this decrease in generality to maximize our ability to detect a subtle difference between promotion types. Participants will be screened to represent a range of education levels (some college or less vs. completed college or more). Because the task presumes basic reading abilities, all participants will have English as their primary language and, as appropriate, be required to have reading glasses when participating in the study.

(*2*) *Type of Ad*. Three types of ads will be tested: A full-product ad for a prescription drug, a reminder ad for a prescription drug, and an ad for an over-the-counter (OTC) drug. An ad for an OTC drug, which typically includes benefit but not risk information, is included to see if prior research findings in the area of consumer package goods can be replicated. It is expected that consumer processing of information in the ad may vary by presence of a promotion. For instance, consumers may assign more weight to benefit claims in cases where a promotional coupon is included.

(*3*) *Type of Promotion*. Five types of promotion will be tested: Free trial offer, buy one, get one free, money-off prescription/purchase cost, money back guarantee, and a no promotion condition. With the exception of buy one, get one free, these are promotional variations that have been used in drug advertising. We ask for comment on other promotional types that could be tested.

Procedure: Participants will be shown one ad, for example, a reminder ad for a prescription drug with a free-trial offer coupon attached. Then the participant will be asked to answer questions examining a number of important perceptions about the product, including perceived riskiness of the drug, likelihood of benefits, and behavioral intent (talking to doctor, product purchase). Finally, demographic and health care utilization information will be collected. Interviews are expected to last approximately 15 minutes. A total of 1,350 participants will be involved. This will be a one time (rather than annual) collection of information.

FDA estimates the burden of this collection of information as follows:

FDA estimates that 2,025 individuals will need to be screened to obtain a respondent sample of 1,350. The screener is expected to take 30 seconds, for a total screener burden of 17 hours. The 1,350 respondents will then be asked to respond to a series of questions about the advertisement. We estimate the response burden for the consumer part of the survey to be 15 minutes, for a burden of 337.5 hours. The estimated total burden for this data collection effort is 354.5 hours. The respondent burden chart is listed below:

ESTIMATED ANNUAL REPORTING BURDEN

No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
2,025 (screener)	1	2,025	.008	17
1,350 (questionnaire)	1	1,350	.25	337.5
Total		3,375		354.5

Footnote: there are no capital costs or operating and maintenance costs associated with this data collection.

Dated: January 30, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–1521 Filed 2–3–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0036]

Agency Information Collection Activities; Proposed Collection; Comment Request; Experimental Study of Possible Footnotes and Cueing Schemes to Help Consumers Interpret Quantitative Trans Fat Disclosure on the Nutrition Facts Panel

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on

an experimental study of possible footnotes and cueing schemes intended to help consumers understand and apply quantitative *trans* fat information they might see on the Nutrition Facts Panel of a food product. The experimental study will estimate the communication effectiveness of quantitative *trans* fat information in terms of its ability to help consumers make heart-healthy product decisions in realistic label usage situations for a range of products.

DATES: Submit written or electronic comments on the collection of information by April 7, 2006.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) The accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Experimental Study of Possible Footnotes and Cueing Schemes to Help Consumers Interpret Quantitative Trans Fat Disclosure on the Nutrition Facts Panel (OMB Control Number 0910–0532)—Reinstatement

FDA is requesting OMB approval of an experimental study of possible footnotes and cueing schemes intended to help consumers interpret quantitative *trans* fat information on the Nutrition Facts Panel of a food product. The purpose of the experimental study is to help FDA's Center for Food Safety and Applied Nutrition formulate decisions and policies affecting labeling requirements for *trans* fat disclosure.

In the **Federal Register** of July 11, 2003 (68 FR 41434), FDA issued a final rule requiring disclosure on the Nutrition Facts Panel of quantitative *trans* fat information on a separate line without any accompanying footnote. At the same time, the agency issued an advance notice of proposed rulemaking entitled, "Food Labeling: *Trans* Fatty Acids in Nutrition Labeling; Consumer Research to Consider Nutrient Content and Health Claims and Possible Footnote or Disclosure Statements," (68 FR 41507) which requested comments about possible footnotes to help consumers better understand *trans* fat declarations on the product label. The agency sought comments about whether it should consider requiring statements about *trans* fat, either alone or in combination with saturated fat and cholesterol, as a footnote on the Nutrition Facts Panel to enhance consumers' understanding about such cholesterol-raising lipids and how to use information on the label to make healthy food choices. Comments received in response to the notice contained suggested footnotes and cueing schemes. The proposed experimental study will evaluate the ability of several possible footnotes and cueing schemes to help consumers make heart-healthy food choices. The results of the experimental study will provide empirical support for possible policy decisions about the need for such requirements and the appropriate form they should take.

FDA or its contractor will use information gathered from Internet panel samples to evaluate how consumers understand and respond to possible footnote and cueing schemes. The distinctive features of Internet panels for the purpose of the experimental study are that they allow for controlled visual presentation of study materials, experimental manipulation of study materials, and the random assignment of subjects to condition. Experimental manipulation of labels and random assignment to condition makes it possible to estimate the effects of the various possible footnotes and cueing schemes while controlling for individual differences between subjects. Random assignment ensures that mean differences between conditions can be tested using well-known techniques such as analysis of variance or regression analysis to yield statistically valid estimates of effect size. The study will be conducted from a sample drawn from a large, nationally representative consumer panel with 800,000 households. The sample size and population pool are adequate to ensure that results can be generalized.

Participants will be adults, age 18 and older, who are recruited for a study about foods and food labels. Each participant will be randomly assigned to one of the 42 experimental conditions derived from fully crossing 7 possible footnotes/cueing schemes, 3 product types, and 2 prior knowledge conditions.

FDA will use the information from the experimental study to evaluate regulatory and policy options. The agency often lacks empirical data about how consumers understand and respond to statements they might see in product labeling. The information gathered from this experimental study will be used to estimate consumer comprehension and the behavioral impact of various footnotes and cueing schemes intended to help consumers better understand quantitative *trans* fat information.

The experimental study data will be collected using participants of an Internet panel of approximately 600,000 people. Participation in the experimental study is voluntary.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Type of survey	No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Internet survey	3,240	1	3,240	.25	810
Total					810

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA's burden estimate is based on prior experience with Internet panel experiments similar to the study proposed in this document.

Dated: January 30, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–1522 Filed 2–3–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0032]

Referral of ZINECARD (dexrazoxane) and RELPAX (eletriptan) Written Requests for the Conduct of Pediatric Studies

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the referral of ZINECARD (dexrazoxane) and RELPAX (eletriptan) Written Requests for the conduct of pediatric studies to the Foundation for the National Institutes of Health (the Foundation). FDA referred the ZINECARD (dexrazoxane) and RELPAX (eletriptan) Written Requests to the Foundation on August 29, 2005, and is publishing this notice of the referrals in accordance with the Best Pharmaceuticals for Children Act (BPCA).

FOR FURTHER INFORMATION CONTACT: Grace Carmouze, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, rm. 1613, Silver Spring, MD 20993–0002, 301–796–2200, e-mail: *carmouzeg@cder.fda.gov.*

SUPPLEMENTARY INFORMATION: In accordance with section 4 of the BPCA (Public Law 107–109), FDA is announcing the referral to the Foundation of the written requests for the conduct of pediatric studies for ZINECARD (dexrazoxane) and RELPAX (eletriptan). Enacted on January 4, 2002, the BPCA reauthorizes, with certain important changes, the exclusivity incentive program described in section 505A of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355a). Section 505A of the act permits certain applications to obtain 6 months of exclusivity if, in accordance with the requirements of the statute, the sponsor submits requested information relating to the use of the drug in the pediatric population.

The BPCA established additional mechanisms for obtaining information on the safe and effective use of drugs in pediatric patients. Specifically, section 4 of the BPCA amends section 505A(d) of the act to create a referral process to obtain studies for drugs that have patent or exclusivity protection, but for which the sponsor has declined to conduct the pediatric studies in response to a written request by FDA. Under section 4 of the BPCA, if the Secretary of Health and Human Services (the Secretary) determines that there is a continuing need for the pediatric studies described in the written request and the sponsors of the products with patent or exclusivity protection have declined to conduct the studies, the Secretary shall refer the drug to the Foundation, established under section 499 of the Public Health Service Act (42 U.S.C. 290(b)), for the conduct of the pediatric studies described in the written request (21 U.S.C. 355a(d)(4)(B)(i)). In addition, the BPCA requires public notice of the name of the drug, name of the manufacturer, and indications to be studied under the referrals (21 U.S.C. 355a(d)(4)(B)(ii)).

In accordance with section 4 of the BPCA, FDA is announcing that on August 29, 2005, it referred to the Foundation the written requests for pediatric studies for ZINECARD (dexrazoxane) and RELPAX (eletriptan). On July 14, 2004, FDA issued a written request for pediatric studies to Pfizer, Inc., the holder of approved applications for RELPAX (eletriptan) that have market exclusivity. The studies described in the written request were for the acute treatment of migraines in adolescents. Pfizer, Inc., declined to conduct the requested studies. FDA has determined that there is a continuing need for information relating to the use of RELPAX (eletriptan) in the pediatric population.

On June 17, 2004, FDA issued a written request for pediatric studies to Pfizer, Inc., the holder of approved applications for ZINECARD (dexrazoxane) that have market exclusivity. The studies described in the written request were for cardioprotection in children receiving doxorubicin therapy. Pfizer, Inc., declined to conduct the requested studies. FDA has determined that there is a continuing need for information relating to the use of ZINECARD (dexrazoxane) in the pediatric population.

Dated: January 27, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–1520 Filed 2–3–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the

quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Social Network Analysis of a Service System for Transition Aged Youth—New

SAMHSA's, Center for Mental Health Services will seek information about the change in the network of social services in one community, Clark County Washington, as a result of a Center for Mental Health Services funded grant initiative, the Options Program. The Options program was one of 5 funded sites across the country. Each site received four years of funding to build comprehensive supports that help adolescents with serious emotional disturbance and their families make the difficult transition from adolescent to adult functioning through the age of 25. This grant program, called the Partnerships for Youth Transition, aims to remediate some of the most difficult system barriers that interfere with transition system building by providing community leaders and advocates funding for direct services and infrastructure building, technical assistance to help shape the vision, and time to establish programs and interagency relationships. Since no single site in the country has ever successfully built a transition support system we do not know whether combining the resources of this grant, with the resources of the community are sufficient to make significant strides in transition system building. It is imperative to answer this question systematically and rigorously in order to guide future efforts.

There have been 110 agencies identified in Clark County that could potentially serve youth or young adults with serious mental, emotional and behavioral disorders. This study will conduct network analysis by interviewing one key informant from each of these programs about their organization's professional relationship with other social services. The Social Network Questionnaire was previously developed for use in several studies in mental health and homeless services. Questions focus on aspects of professional relationship such as how often clients are referred to another agency and how often staff meet for client planning purposes with staff from another agency, as well as some background information about the agency and the quality of services offered. An additional 10 items focus on whether the program is following guidelines for exemplary practice with transition aged youth. Findings will be compared to data collected prior to program initiation.

The following table summarizes the estimated response burden for this project.

Respondent	Number of respondents	Responses/ respondent	Total responses	Hours per response	Total hour burden
Key informants from social services in Clark County	110	1	110	1.25	137.5

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 7–1044, One Choke Cherry Road, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: January 27, 2006.

Anna Marsh,

Executive Officer, SAMHSA.

[FR Doc. E6–1561 Filed 2–3–06; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Notice and request for comments.

SUMMARY: The Federal Emergency Management Agency, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on a proposed revision of a currently approved information collection. In accordance with the Paperwork Reduction Act of 1995, this notice seeks comments concerning the National Urban Search and Rescue (US&R) grant program.

SUPPLEMENTARY INFORMATION: Section 303 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act), 42 U.S.C. 5144, authorizes the President of the United States to form emergency Support teams of Federal personnel to be deployed in an area affected by a major disaster or emergency. Under Section 403(a)(3)(B) of the Stafford Act provides that the President may authorize Federal agencies to perform work on public or private lands essential to save lives and protect property, including search and rescue and emergency medical care, and other essential needs. FEMA established the National Urban Search and Rescue Response System (US&R) under these authorities. The President amended E.O. 121448 to transfer the FEMA Director's delegated authority to the Secretary of Homeland Security.

Collection of Information

Title: National Urban Search and Rescue Program Agreement, Application, Reporting, and Audit Requirement.

Type of Information Collection: Revision of a currently approved collection.

OMB Number: 1660–0073.

Form Numbers: None.

Abstract: The information collection activity is the collection of financial, program and administrative information for US&R Sponsoring Organizations relating to preparedness and response grant awards. This information includes a narrative statement that FEMA uses to evaluate a grantee's proposed use of funds, progress reports to monitor overall progress on managing FEMA grant program, extension or change requests used to consider changing or extending the time or the performance period of the preparedness or response cooperative agreement and a memorandum of agreement between DHS/FEMA and the Sponsoring Organizations of US&R task forces as described below.

Narrative Statement: FEMA uses narrative statements to evaluate a grantee's proposed use of funds. Examples of information a grantee needs to provide FEMA for preparedness and response cooperative agreements are a description of the types of eligible activities the grantee will undertake, a plan for expending and monitoring funds, and an estimate of the percentage or amount of funds the grantee will pass through to sub-grantees. Sponsoring

Organizations make this information available to FEMA only when we request it. If a Sponsoring Organization has remaining preparedness or response cooperation agreement funds after completing specific disaster or preparedness work, we will require a second narrative statement describing the grantee's proposed use of the remaining funds.

Progress Reports: FEMA program officers use progress reports to monitor overall progress on managing FEMA grant programs. We do not prescribe a particular format; however, we ensure that the OMB standard elements outlined in the common rule, 44 CFR part 13, are in any report or suggested format.

Extension or Change Requests: Grantees that want FEMA to consider changing or extending the time or the performance period of the preparedness or response cooperative agreement will need to request such changes or extensions in writing. FEMA will use the information to ensure that the Sponsoring Organization spends funds consistent with the intent of the appropriations an in accordance with applicable laws and guidance. This type of information is available to FEMA only when we request it.

Affected Public: State, local, or tribal government.

Estimated Total Annual Burden Hours:

ANNUAL BURDEN HOURS

Project/activity (survey, form(s), focus group, etc.)	No. of respondents (A)	Frequency of responses (B)	Burden hours per respondent (C)	Annual responses (A × B)	Total annual burden hours (A × B × C)
Narrative Statement	28	2	4	56	224
Progress Reports	28	2	2	56	112
Extension or Change Requests	5	1	1	5	5
Memorandum of Agreements	28	1	4	28	112
Total	28		11	229	453

Estimated Cost: The average cost for each respondent would be approximately $660. This would include the burden hour costs for extensions or change requests, revisions to existing memorandum of agreements and progress reports.

Comments: Written comments are solicited to: (a) Evaluate whether the proposed data collection is necessary for the proper performance of the agency, including whether the information shall have practical utility; (b) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) enhance the quality, utility, and clarity of the information to be collected; and (d) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses. Comments must be submitted on or beforeApril 7, 2006.

ADDRESSES: Interested persons should submit written comments to Chief, Records Management Section, Information Resources Management Branch, Information Technology Services Division, Federal Emergency Management Agency, 500 C Street, SW., Room 316, Washington, DC 20472.

FOR FURTHER INFORMATION CONTACT: Contact Wanda Casey, Program Specialist, National Urban Search and Rescue Program, (202) 646–4013 for additional information. You may contact the Records Management Branch for copies of the proposed collection of information at facsimile number (202) 646–3347 or e-mail address: *FEMA-Information-Collections@dhs.gov*.

Dated: January 31, 2006.

George S. Trotter,

Acting Branch Chief, Information Resources Management Branch, Information Technology Services Division.

[FR Doc. E6–1565 Filed 2–3–06; 8:45 am]

BILLING CODE 9110–69–P

DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

Extension Agency Information Collection Activity Under OMB Review: Corporate Security Review (CSR)

AGENCY: Transportation Security Administration (TSA), DHS.

ACTION: Notice.

SUMMARY: This notice announces that TSA has forwarded the new Information Collection Request (ICR) abstracted below to the Office of Management and Budget (OMB) for review and approval of an extension of the currently approved collection under the Paperwork Reduction Act. The ICR describes the nature of information collection and its expected burden. TSA published a **Federal Register** notice, with a 60-day comment period soliciting comments, of the following collection of information on October 2, 2005, 70 FR 66454. In response to this notice, TSA received comments from NiSource, a natural gas pipeline company operating in several states.

DATES: Send your comments by March 8, 2006. A comment to OMB is most effective if OMB receives it within 30 days of publication.

ADDRESSES: Comments may be faxed to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: DHS–TSA Desk Officer, at (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Katrina Wawer, Information Collection Specialist, Office of Transportation Security Policy, TSA–9, Transportation Security Administration, 601 South 12th Street, Arlington, VA 22202–4220.

SUPPLEMENTARY INFORMATION:

Comments Invited

In accordance with the Paperwork Reduction Act of 1995, (44 U.S.C. 3501 et seq.), an agency may not conduct or sponsor, and a person is not required to respond to a collection of information, unless it displays a valid OMB control number. Therefore, in preparation for OMB review and approval of the following information collection, TSA is soliciting comments to—

(1) Evaluate whether the proposed information requirement is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Information Collection Requirement

Title: Corporate Security Review (CSR).

Type of Request: Extension of a currently approved collection.

OMB Control Number: 1652–0036.

Forms(s): Corporate Security Review Form.

Affected Public: Surface transportation system owners and operators.

Abstract: The Aviation and Transportation Security Act (ATSA) (Pub. L. 107–71, 115 Stat. 597, Nov. 19, 2001) requires TSA to oversee the security of the nation's surface transportation system. Specifically, ATSA grants TSA authority to execute its responsibilities for:

- Enhancing security in all modes of transportation (49 U.S.C. 114(d));
- Assessing intelligence and other information in order to identify individuals who pose a threat to transportation security and to coordinate countermeasures with other Federal agencies to address such threats (49 U.S.C. 114(f)(1)–(5), (h)(1)–(4)); and
- Identifying and coordinating countermeasures to address threats to the transportation system (49 U.S.C. 114(f)(4)), including the authority to receive, assess, and distribute intelligence information related to transportation security; (49 U.S.C. 114(f)(1)–(4)).

To support these requirements, TSA assesses the current security practices in the surface transportation sector by way of site visits and interviews through its Corporate Security Review (CSR) program, one piece of a much larger domain awareness, prevention, and protection program in support of TSA's and Department of Homeland Security's missions. TSA is requesting continued approval for this collection to allow TSA to continue to ascertain minimum-security standards and identify coverage gaps, activities that are critical to its mission of ensuring transportation security. TSA assures respondents that the portion of their responses TSA deems Sensitive Security Information will be handled as such, as described in 49 CFR parts 15 and 1520.

Number of Respondents: 500.

Estimated Annual Burden Hours: An estimated 1,200 hours annually.

Issued in Arlington, Virginia, on January 25, 2006.

Lisa S. Dean,

Privacy Officer.

[FR Doc. E6–1526 Filed 2–3–06; 8:45 am]

BILLING CODE 4910–62–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

Agency Information Collection Activities: Extension of a Currently Approved Information Collection; Comment Request

ACTION: 30-Day Notice of Information Collection Under Review; Application for Suspension of Deportation or Special Rule Cancellation of Removal (Pursuant to Section 203 of Public Law 105–100); Form I–881. OMB Control No. 1615–0072.

The Department of Homeland Security, U.S. Citizenship and Immigration Services (USCIS) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously published in the **Federal Register** on December 5, 2005, at 70 FR 72461. The notice allowed for a 60-day public comment period. No comments were received on this information collection.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until March 8, 2006. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Department of Homeland Security (DHS), USCIS, Director, Regulatory Management Division, Clearance Office, 111 Massachusetts Avenue, 3rd floor, Washington, DC 20529. Comments may also be submitted to DHS via facsimile to 202–272–8352 or via e-mail at *rfs.regs@dhs.gov*. When submitting comments by e-mail please make sure to add OMB Control Number 1615–0072 in the subject box. Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Overview of this information collection:

(1) *Type of Information Collection:* Extension of existing information collection.

(2) *Title of the Form/Collection:* Application for Suspension of Deportation or Special Rule Cancellation of Removal (Pursuant to Section 203 of Public Law 105–100).

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Form I–881. U.S. Citizenship and Immigration Services.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals and households. This form is used by a nonimmigrant to apply for suspension of deportation or special rule cancellation of removal. The information collected on this form is necessary in order for USCIS to determine if it has jurisdiction over an individual applying for this release as well as to elicit information regarding the eligibility of an individual applying for release pursuant to section 203 of the Nicaraguan Adjustment and Central American Relief Act (NACARA); Pub. L. 105–100.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 55,000 responses at 12 hours per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 660,000 annual burden hours.

If you have additional comments, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please visit the

USCIS Web site at: *http://uscis.gov/graphics/formsfee/forms/pra/index.htm.*

If additional information is required contact: USCIS, Regulatory Management Division, 111 Massachusetts Avenue, 3rd Floor, Washington, DC 20529, (202) 272–8377.

Dated: January 30, 2006.

Stephen Tarragon,

Deputy Director, Regulatory Management Division, U.S. Citizenship and Immigration Services.

[FR Doc. 06–985 Filed 2–3–06; 8:45 am]

BILLING CODE 4410–10–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

Agency Information Collection Activities; Extension of Existing Information Collection Comment Request

ACTION: 30-Day Notice of Information Collection under Review: Application for Posthumous Citizenship; Form N–644. OMB Control No. 1615–0059.

The Department of Homeland Security, U.S. Citizenship and Immigration Services (USCIS) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously published in the **Federal Register** on December 5, 2005, at 70 FR 72461. The notice allowed for a 60-day public comment period. No comments were received on this information collection.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until March 8, 2006. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Department of Homeland Security (DHS), USCIS, Director, Regulatory Management Division, Clearance Office, 111 Massachusetts Avenue, 3rd floor, Washington, DC 20529. Comments may also be submitted to DHS via facsimile to 202–272–8352 or via e-mail at *rfs.regs@dhs.gov*. When submitting comments by e-mail please make sure to add OMB Control Number 1615–0059 in the subject box. Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Overview of this information collection:

(1) Type of Information Collection: *Extension of a currently approved collection.*

(2) Title of the Form/Collection: Application for Posthumous Citizenship.

(3) Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection: Form N–644. USCIS.

(4) Affected public who will be asked or required to respond, as well as a brief abstract: Primary: Individual or households. The information collected will be used to determine an applicant's eligibility to request posthumous citizenship status for a decedent and to determine the decedent's eligibility for such status.

(5) An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond: 50 responses at 1 hour and 50 minutes (1.83 hours) per response.

(6) An estimate of the total public burden (in hours) associated with the collection: 92 annual burden hours.

If you have additional comments, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please visit the USCIS Web site at: *http://uscis.gov/graphics/formsfee/forms/pra/index.htm.*

If additional information is required contact: USCIS, Regulatory Management Division, 111 Massachusetts Avenue, 3rd Floor, Washington, DC 20529, (202) 272–8377.

Dated: January 30, 2006.

Stephen Tarragon,

Deputy Director, Regulatory Management Division, U.S. Citizenship and Immigration Services.

[FR Doc. 06–986 Filed 2–3–06; 8:45 am]

BILLING CODE 4410–10–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of Federal Housing Enterprise Oversight

Privacy Act of 1974: Notice of Establishment of New Systems of Records

AGENCY: Office of Federal Housing Enterprise Oversight, HUD.

ACTION: Notice of New Systems of Records.

SUMMARY: In accordance with the Privacy Act of 1974, as amended, 5 U.S.C. 552a (Privacy Act), the Office of Federal Housing Enterprise Oversight (OFHEO) is issuing public notice of its intent to establish three new Privacy Act systems of records. The three systems are titled Emergency Contingency Plan and Personnel Locator System, Mortgage Fraud System, and Computer Systems Activity and Access Records System. OFHEO seeks comment on the new systems of records described in this notice.

The Emergency Contingency Plan and Personnel Locator System will be established to maintain emergency contact information for use in developing and implementing an emergency plan, including a continuity of operations and essential functions plan, and to maintain a facilities evacuation plan. This system will enable OFHEO to adequately coordinate a plan for preparedness and facilities evacuation in the event of an emergency. The Mortgage Fraud System will maintain information of mortgage fraud or possible mortgage fraud involving the Federal National Mortgage Association and the Federal Home Loan Mortgage Association (collectively referred to as the "Enterprises"). This system is being established so that OFHEO may respond appropriately to mortgage fraud in furtherance of the safe and sound operations of the Enterprises. The Computer Systems Activity and Access Records System will be established to maintain, plan, and manage computer system services. It is necessary to ensure security and proper use of OFHEO electronic information and computer systems and services.

DATES: Written comments must be received before March 8, 2006. The proposed new systems of records will become effective on March 20, 2006 unless OFHEO receives comments that would result in changes to the system of records.

ADDRESSES: You may submit your comments on the proposed new Privacy Act systems of records, identified by "Systems of Records," by any of the following methods:

- *U.S. Mail, United Parcel Post, Federal Express, or Other Mail Service:* The mailing address for comments is: David A. Felt, Acting General Counsel, Attention: Comments/Systems of Records, Office of Federal Housing Enterprise Oversight, Fourth Floor, 1700 G Street, NW., Washington, DC 20552.
- *Hand Delivery/Courier:* The hand delivery address is: David A. Felt, Acting General Counsel, Attention: Comments/Systems of Records, Office of Federal Housing Enterprise Oversight, Fourth Floor, 1700 G Street, NW., Washington, DC 20552. The package should be logged at the Guard Desk, First Floor, on business days between 9 a.m. and 5 p.m.
- *E-mail: RegComments@OFHEO.gov.* Comments to David A. Felt, Acting General Counsel, may be sent by e-mail at *RegComments@OFHEO.gov.* Please include "Systems of Records" in the subject line of the message.

Posting of comments: All comments received will be posted without change to *http://www.ofheo.gov,* including any personal information provided. Copies of all comments received will be available for examination by the public on business days between the hours of 10 a.m. and 3 p.m., at the Office of Federal Housing Enterprise Oversight, Fourth Floor, 1700 G Street NW., Washington, DC 20552. To make an appointment to inspect comments, please call the Office of General Counsel at (202) 414–3751. See **SUPPLEMENTARY INFORMATION** for additional information on posting of comments.

FOR FURTHER INFORMATION CONTACT: Mary Alice Donner, Senior Counsel, telephone (202) 343–1319 (not a toll-free number); Office of Federal Housing Enterprise Oversight, Fourth Floor, 1700 G Street, NW., Washington, DC 20552. The telephone number for the Telecommunications Device for the Deaf is (800) 877–8339.

SUPPLEMENTARY INFORMATION

Instructions: OFHEO requests that comments to the proposed new systems include the reference "Systems of Records" as well as your name and other contact information in the body of your comment. OFHEO further requests that comments submitted in hard copy also be accompanied by the electronic version in Microsoft® Word or in portable document format (PDF) on 3.5" disk or CD–ROM. If OFHEO cannot read your comment due to technical difficulties and cannot contact you for clarification, OFHEO may not be able to consider your comment. Electronic files should avoid the use of special characters, and any form of encryption, and be free of any defects or viruses.

Introduction: This notice informs the public that OFHEO proposes to establish and maintain three new systems of records. This notice satisfies the Privacy Act requirement that an agency publish a system of records notice in the **Federal Register** when there is a revision, change, or addition to an agency's system of records. The proposed new systems of records are as follows:

OFHEO–06—Emergency Contingency Plan and Personnel Locator System
OFHEO–07—Mortgage Fraud System
OFHEO–08—Computer Systems Activity and Access Records System

As required by 5 U.S.C. 552a(r) of the Privacy Act and OMB Circular A–130, OFHEO has submitted a report describing the new systems of records covered by this notice to the Office of Management and Budget and to Congress. The three proposed new systems of records described above are set forth in their entirety below.

Stephen A. Blumenthal,
Acting Director.

OFHEO–06

SYSTEM NAME:

Emergency Contingency Plan and Personnel Locator System.

SYSTEM LOCATION:

The Emergency Contingency Plan and Personnel Locator System is located in the Office of Federal Housing Enterprise Oversight, 1700 G Street, NW., Fourth Floor, Washington, DC 20552, and any alternate work site utilized by employees of the Office of Federal Housing Enterprise Oversight (OFHEO) or individuals assisting such employees.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The Emergency Contingency Plan and Personnel Locator System contains information about:

1. Current employees and contractors of OFHEO;

2. Private or Federal employees and contractors located at any OFHEO facility (headquarters, alternate work sites utilized by OFHEO employees, and off-site or emergency facility); and,

3. Other individuals including but not limited to employees of the Federal National Mortgage Association and the Federal Home Loan Mortgage Association (collectively referred to as the "Enterprises"), employees of the District of Columbia, and other key governmental and non-governmental persons essential to the successful implementation of an emergency preparedness and security plan.

CATEGORIES OF RECORDS IN THE SYSTEM:

The Emergency Contingency Plan and Personnel Locator System includes emergency notification rosters, fliers, files, and emergency assignments. It includes records of personal information on covered individuals including name, job title, work and home addresses, work and home phone and facsimile machine numbers, cell phone numbers, pager numbers, personal electronic mail addresses, and other emergency contact information (including personal local and out of area telephone numbers of Federal employees and their emergency contacts). System records may also include finger prints, and special needs and health information such as medical, mobility, and transportation requirements of individuals, and names of physicians of OFHEO employees and contractors and other information associated with identifying and contacting personnel in event of an emergency.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The system is established and maintained pursuant to 12 U.S.C. 4513(b)(9), and Executive Order 12656.

PURPOSES:

The purpose of this system of records is to maintain emergency contact and other information for use in developing, maintaining, and implementing emergency plans, including a continuity of operations (COOP) and essential functions plan; and to maintain a facilities evacuation plan for OFHEO. The records maintained in this system will be used to notify, locate, and mobilize individuals as necessary, and evacuate facilities as necessary during emergency and threat situations.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to the conditions of disclosure under 5 U.S.C. 552a(b) and in addition to the general routine uses identified in the Prefatory Statement of General Routine Uses, 63 FR 9007 (February 23, 1998), OFHEO staff may provide information in these records to:

1. Any Federal or local government authority responsible for responding to an emergency situation;

2. Facilities management personnel for all OFHEO locations (headquarters, alternate work sites utilized by OFHEO employees, and off-site or emergency facilities);

3. Other individuals, including employees of the Enterprises and other employees located at OFHEO facilities, as necessary to coordinate, review, implement, or practice OFHEO's COOP and essential functions plan or other emergency preparedness or security plan developed in response to security threats or Department of Homeland Security alerts.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

None.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored in electronic and paper format. Paper records are maintained in file folders, index cards, rolodex-type files, notebooks, or files. Computer files are maintained on magnetic tape, diskette, or other machine readable format.

RETRIEVABILITY:

Records are retrievable by name, location, or other personal identifier listed above under "Categories of Records in the System."

SAFEGUARDS:

Access to the records is restricted to those who require the records for the purpose for which the system is maintained.

RETENTION AND DISPOSAL:

Records are retained and disposed of in accordance with the appropriate National Archives and Records Administration General Records Schedule, and will be updated as appropriate.

SYSTEM MANAGER AND ADDRESS:

Executive Director, Office of Federal Housing Enterprise Oversight, 1700 G Street, NW., Washington, DC 20552.

NOTIFICATION PROCEDURE:

Contact the Privacy Act Officer, Office of Federal Housing Enterprise Oversight, 1700 G Street, NW., Fourth Floor, Washington, DC 20552.

RECORD ACCESS PROCEDURE:

The OFHEO regulation for providing access to records appears at 12 CFR part 1702. If additional information or assistance is required, contact the Privacy Act Officer, Office of Federal Housing Enterprise Oversight, 1700 G Street, NW., Fourth Floor, Washington, DC 20552.

CONTESTING RECORD PROCEDURES:

The OFHEO regulation for contesting records procedures appears at 12 CFR part 1702. If additional information or assistance is required, contact the Privacy Act Appeals Officer, Office of Federal Housing Enterprise Oversight, 1700 G Street, NW., Fourth Floor, Washington, DC 20552.

RECORD SOURCE CATEGORIES:

The information contained in these records is provided by or verified by the individual who is the subject of the record, the individual's supervisors, or official personnel or employment records.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

OFHEO—07

SYSTEM NAME:

Mortgage Fraud System.

SYSTEM LOCATION:

The Mortgage Fraud System is located in the Office of Federal Housing Enterprise Oversight, 1700 G Street, NW., Fourth Floor, Washington, DC 20552, and in any alternate work site utilized by employees of the Office of Federal Housing Enterprise Oversight (OFHEO) or individuals assisting such employees.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The Mortgage Fraud System contains information about:

1. Individuals or entities that are known perpetrators or suspected perpetrators of a known or possible mortgage fraud committed or attempted against the Federal National Mortgage Association (Fannie Mae) or the Federal Home Loan Mortgage Corporation (Freddie Mac) (collectively, the Enterprises).

2. In connection with any such known or possible mortgage fraud:

(a) Individuals who are directors, officers, employees, agents, of an Enterprise;

(b) Individuals or entities that are actual or potential victims of mortgage fraud;

(c) Individuals or entities involved;

(d) Individuals who are named as possible witnesses;

(e) Individuals or entities who have or might have information about reported matters;

(f) Individuals or entities named as preparers of any reports; or

(g) Individuals or entities named as persons to be contacted for assistance by OFHEO.

CATEGORIES OF RECORDS IN THE SYSTEM:

The records in the Mortgage Fraud System contain information about the categories of persons or entities specified in "Categories of Individuals Covered by the System." The records may also contain information pertaining to criminal prosecutions, civil actions, enforcement proceedings, and investigations resulting from or relating to the records.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The system is established and maintained pursuant to 12 U.S.C. 4513 and 12 CFR part 1731.

PURPOSES:

Mortgage fraud or possible mortgage fraud information is used by OFHEO in furtherance of its supervisory responsibilities to ensure the safe and sound operations of the Enterprises.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to the conditions of disclosure under 5 U.S.C. 552a(b), and in addition to the general routine uses identified in the Prefatory Statement of General Routine Uses in 63 FR 9007 (February 23, 1998), OFHEO may use the records contained in Mortgage Fraud System, to:

1. Provide information derived from the system to the Financial Crimes Enforcement Network, the Department of Housing and Urban Development, and other government authorities, as determined by OFHEO to be appropriate;

2. Disclose information or records to individuals or entities in furtherance of eliciting information pertinent to the supervisory responsibilities of OFHEO; and

3. Furnish analytic and statistical reports to government authorities and the public providing information about trends and patterns derived from information contained in the system, in a form in which individual identities are not revealed.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

None.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored in electronic and paper format. Paper records are

maintained in file folders, index cards, rolodex-type files, notebooks, or files. Computer files are maintained on magnetic tape, diskette, or other machine readable format.

RETRIEVABILITY:

Data in the Mortgage Fraud System may be retrieved by sectionalized data fields or by the use of search and selection criteria, such as an individual's name.

SAFEGUARDS:

The system is located in a guarded building that has restricted access. Access to the computer facilities and any paper records is subject to additional physical safeguards that restrict access. Access to any electronic records in the system is restricted by means of passwords and non-transferable identifiers. Back-up magnetic tapes are kept in an off-site storage facility in Sterling, VA. Records in hard copy are maintained in locked file cabinets. Access is limited to those individuals who have an official need to know.

RETENTION AND DISPOSAL:

Records in this system will be updated periodically to reflect changes, and will be maintained in electronic form as long as needed for the purpose for which the information was collected. Records will be disposed of in accordance with applicable law.

SYSTEM MANAGER(S) AND ADDRESS:

Chief Information Officer, Office of Technology and Information Management, Office of Federal Housing Enterprise Oversight, 1700 G Street, NW., Fourth Floor, Washington, DC 20552.

NOTIFICATION PROCEDURE:

Contact the Privacy Act Officer, OFHEO, 1700 G Street, NW., Fourth Floor, Washington, DC 20552.

RECORD ACCESS PROCEDURE:

The OFHEO regulation for providing access to records appears at 12 CFR part 1702. If additional information or assistance is required, contact the Privacy Act Officer at OFHEO, 1700 G Street, NW., Fourth Floor, Washington, DC 20552.

CONTESTING RECORD PROCEDURES:

The procedures for contesting initial denials for access to or amendment of records appears at 12 CFR part 1702. If additional information or assistance is required, contact the Privacy Act Appeals Officer at OFHEO, 1700 G Street, NW., Fourth Floor, Washington, DC 20552.

RECORD SOURCE CATEGORIES:

Records in this system may be provided by the Enterprises and members of the public.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

OFHEO–08

SYSTEM NAME:

Computer Systems Activity and Access Records System.

SYSTEM LOCATION:

The Computer Systems Activity and Access Records System is located in the Office of Federal Housing Enterprise Oversight, 1700 G Street, NW., Fourth Floor, Washington, DC 20552, and in any alternate work site utilized by employees of the Office of Federal Housing Enterprise Oversight (OFHEO) or individuals assisting such employees.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

All individuals who access, with or without authorization, OFHEO personal computers or mainframe servers, including individuals who send and receive electronic communications from or to OFHEO computers, access Internet/Intranet sites, or access system databases, files, or applications from OFHEO computers; and including individuals who access OFHEO systems from their personal residence or other remote location (remote access).

CATEGORIES OF RECORDS IN THE SYSTEM:

Records and reports in the Computer Systems Activity and Access Records System may include:

1. The source Internet Protocol (IP) address to the computer used to access the system and date and time of log-on and log-off to the system;

2. The destination IP address of the site visited, which could include the Uniform Resource Locator (URL) address, date and time of the connection and disconnection, and size of the transmission;

3. Keywords propagated by Internet/Intranet Web sites;

4. Technical machine data as the system may generate, such as machine-name field and media access control address;

5. Electronic mail systems, including the e-mail address of sender and receiver of the electronic mail message, subject, date, and time;

6. Records on user access to OFHEO office automation networks as well as denials of access;

7. Records relating to mainframe/enterprise server access;

8. Verification and authorization records, such as user identifications, passwords, user names, title, and agency; and

9. Telecommunications logs and other information necessary to monitor and spot-check an individual's use of the OFHEO access systems and services and compliance with the OFHEO information systems guidelines and procedures, including those for remote access.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The system is established and maintained pursuant to 12 U.S.C. 4513(b)(9) and 44 U.S.C. 3544.

PURPOSES:

The underlying data in this system of records is used by OFHEO computer systems and security employees or persons authorized to assist these employees to plan and manage computer system services and to otherwise perform their official duties. Authorized OFHEO employees or contractors may use the records in the system to monitor an individual's use of the OFHEO access services, and to ensure compliance with the OFHEO information systems guidelines and procedures, including those for remote access. Authorized OFHEO employees or contractors may use the records in this system to investigate improper access or use related to the computer system; to initiate disciplinary or other actions related to improper access or use; or, where the record(s) may appear to indicate a violation or potential violation of law, to refer such record(s) to the appropriate investigative office within OFHEO or law enforcement agencies for investigation.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Routine uses shall be, in addition to the conditions of disclosure under 5 U.S.C. 552a(b), the general routine uses identified in the Prefatory Statement of General Routine Uses in 63 FR 9007 (February 23, 1998).

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

None.

POLICES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM STORAGE:

Records are stored in electronic and paper format. Paper records are maintained in file folders, index cards, rolodex-type files, notebooks, or files. Computer files are maintained on magnetic tape, diskette, or other machine readable format.

RETRIEVABILITY:

The information can be retrieved by user name, user identification (ID), e-mail address, or other identifying search term employed, depending on the record category. OFHEO does not usually connect Internet Protocol (IP) addresses with a person, or retrieve information by user ID. However, in some instances, for official government business and law enforcement purposes, or to ensure compliance with the OFHEO information systems guidelines and procedures, including those for remote access, OFHEO may connect the IP address with an individual and may retrieve records by IP address, and information by user ID.

SAFEGUARDS:

Access is limited to those who have an official need to know. Only computer systems and security employees or individuals authorized to assist such employees have access to automated records and magnetic storage media. These records are kept in a locked room with controlled entry. The use of password protection identification features and other automated data processing system protection methods also restrict access. The back-up magnetic tapes are kept in an off-site storage facility in Sterling, VA. Records in hard copy are maintained in locked file cabinets and access is limited to those individuals who have an official need to know.

RETENTION AND DISPOSAL:

Records are retained and disposed of in accordance with the appropriate National Archives and Records Administration General Records Schedule, and will be updated as appropriate.

SYSTEM MANAGER(S) AND ADDRESS:

Chief Information Officer, Office of Technology and lnformation Management, Office of Federal Housing Enterprise Oversight, 1700 G Street, NW., Fourth Floor, Washington, DC 20552.

NOTIFICATION PROCEDURE:

Contact the Privacy Act Officer, OFHEO, 1700 G Street, NW., Fourth Floor, Washington, DC 20552.

RECORD ACCESS PROCEDURE:

The OFHEO regulation for providing access to records appears at 12 CFR part 1702. If additional information or assistance is required, contact the Privacy Act Officer at OFHEO, 1700 G Street, NW., Fourth Floor, Washington, DC 20552.

CONTESTING RECORD PROCEDURES:

The procedures for contesting initial denials for access to or amendment of records appears at 12 CFR part 1702. If additional information or assistance is required, contact the Privacy Act Appeals Officer at OFHEO, 1700 G Street, NW., Fourth Floor, Washington, DC 20552.

RECORD SOURCE CATEGORIES:

Information is collected from OFHEO personal computers and file servers. Most records are generated internally, such as by computer activity logs, individuals covered by the system, and management officials.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. E6–1548 Filed 2–3–06; 8:45 am]
BILLING CODE 4210–27–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Pea Island National Wildlife Refuge

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability of the Draft Comprehensive Conservation Plan and Environmental Assessment for Pea Island National Wildlife Refuge in Dare County, NC.

SUMMARY: This notice announces that a Draft Comprehensive Conservation Plan and Environmental Assessment for Pea Island National Wildlife Refuge are available for review and comment. The National Wildlife Refuge System Administration Act of 1966, as amended by the National Wildlife Refuge System Improvement Act of 1997, requires the Service to develop a comprehensive conservation plan for each national wildlife refuge. The purpose in developing a comprehensive conservation plan is to provide refuge managers with a 15-year strategy for achieving refuge purposes and contributing toward the mission of the National Wildlife Refuge System, consistent with sound principles of fish and wildlife management, conservation, legal mandates, and Service policies. In addition to outlining broad management direction on conserving wildlife and their habitats, the plan identifies wildlife-dependent recreational opportunities available to the public, including opportunities for hunting, fishing, wildlife observation, wildlife photography, and environmental education and interpretation.

DATES: Open house style meeting will be held in early 2006 in Hatteras Island and Manteo, North Carolina, to present the plan to the public. Mailings, newspaper articles, and postings on the refuge Web site will be the avenues to inform the public of the dates and times of the meetings. Individuals wishing to comment on the Draft Comprehensive Conservation Plan and Environmental Assessment for Pea Island National Wildlife Refuge should do so no later than March 8, 2006. Public comments were requested, considered, and incorporated throughout the planning process in numerous ways. Public outreach has included scoping meetings, a review of the biological program, an ecosystem planning newsletter, and a **Federal Register** notice.

ADDRESSES: Request for copies of the draft comprehensive conservation plan and environmental assessment should be addressed to Bonnie Strawser, P.O. Box 1969, Manteo, North Carolina 27954. Comments on the draft plan may also be submitted via electronic mail to: *bonnie_strawser@fw.gov*. Our practice is to make comments, including names and home addresses of respondents, available for public review during regular business hours. Individual respondents may request that we withhold their home addresses from the record, which we will honor to the extent allowed by law.

SUPPLEMENTARY INFORMATION: The Service analyzed five alternatives for future management and chose Alternative 2, an alternative that addresses the refuge's highest priorities.

Proposed goals for the refuge include:

- Protect, maintain, and enhance healthy and viable populations of indigenous migratory birds, wildlife, fish, and plants, including Federal and State threatened and endangered species.
- Restore, maintain, and enhance the health and biodiversity of barrier island upland and wetland habitats to ensure optimum ecological productivity.
- Provide the public with safe, quality wildlife-dependent recreational and educational opportunities that focus on barrier island wildlife and habitats of the refuge.
- Continue to participate in local efforts to sustain economic health through nature-based tourism.
- Protect refuge resources by limiting the adverse impacts of human activities and development.
- Acquire and manage adequate funding, human resources, facilities, equipment, and infrastructure to accomplish the other refuge goals.

Also available for review are draft compatibility determinations for

recreational hunting, fishing, wildlife observation, wildlife photography, and environmental education and interpretation.

Alternatives

Alternative 1 proposes to maintain the status quo. The refuge would manage very intensively the water levels of the impoundments and the vegetation to create optimum habitat for migrating waterfowl, shorebirds, wading birds, and aquatic organisms. It would manage marshes with prescribed fire. The staff would survey sea turtles, waterfowl, shorebirds, and wading birds on a routine basis. The refuge would allow five of the six priority public use activities: Fishing, wildlife observation, wildlife photography, and environmental education and interpretation. The staff would conduct extensive environmental education and interpretation programs with the assistance of 25,000 hours of volunteer service every year. There would be one staff public use specialist stationed at the refuge. Staff from the Alligator River National Wildlife Refuge would manage the refuge, administer budgets and contracts, maintain the facilities, manage impoundment and marsh habitats, and conduct wildlife surveys.

Alternative 2 proposes moderate program increases. The refuge would continue to manage very intensively the water levels of the impoundments and the vegetation to create optimum habitat for migrating waterfowl, shorebirds, wading birds, and aquatic organisms. It would manage for fall shorebird habitat. It would also manage marshes with prescribed fire. The staff would survey a wider range of wildlife on the refuge, adding regular surveys of land birds. The refuge would continue to allow five of the six priority public use activities, but would have the capacity to increase the number of opportunities. The staff would continue to conduct extensive environmental education and interpretation programs with the assistance of 30,000 hours of volunteer service every year. There would be five staff members stationed at the refuge, including an assistance refuge manager, biologist, two public use specialists, and a maintenance worker. Staff from the Alligator River National Wildlife Refuge would still administer budgets and contracts and manage impoundment and marsh habitats.

Alternative 3 proposes optimum program increases. The refuge would continue to manage very intensively the water levels of the impoundments and the vegetation to create optimum habitat for migrating waterfowl, shorebirds, wading birds, and aquatic organisms. It would manage for fall shorebird habitat. It would also manager marshes with prescribed fire. The staff would survey a wider range of wildlife on the refuge, adding regular surveys of land birds, wading birds, mammals, invertebrates, reptiles, and amphibians. The refuge would continue to allow five of the six priority public use activities, but would have the capacity to increase the number of opportunities. The staff would continue to conduct extensive environmental education and interpretation programs with the assistance of 35,000 hours of volunteer service every year. There would be twelve staff members stationed at the refuge, including an assistant refuge manager, biologist, three biological technicians, two public use specialists, and five maintenance workers. Staff from the Alligator River National Wildlife Refuge would still administer budgets and contracts and manage marsh habitat.

Alternative 4 assumes vehicular access to the refuge on a paved road would be eliminated from the north, but access would be maintained from the south as far north as the visitor center. The alternative assumes that natural processes would dominate the area north of the visitor center and habitat for colonial nesting shorebirds would increase. The refuge would continue to manage impoundments and marshes. The staff would survey all wildlife on the refuge. The refuge would provide public use opportunities, but the number of visitors would decrease due to the limited access. Staffing would be the same as Alternative 3.

Alternative 5 assumes access to the refuge on a paved road would be totally eliminated. The Service would provide other means of accessing the refuge. The alternative assumes that natural processes would dominate the entire refuge and habitat for colonial nesting shorebirds would increase substantially. The refuge would continue to manage impoundments and marshes. The staff would survey all wildlife on the refuge. The refuge would provide public use opportunities, but the number of visitors would decrease due to the limited access. Staffing would be the same as Alternative 3.

Actions Common to All Alternatives

All five alternatives share the following concepts and techniques for achieving the goals of the refuge:

- Cooperating with State and Federal agencies, and non-government organizations, to evaluate the effects of dredging on Oregon Inlet and placement of dredge material on the refuge beaches;
- Cooperating with State and Federal agencies, and non-government organizations, to evaluate the effects of the maintenance of North Carolina Highway 12 on the refuge resources;
- Utilizing volunteers to execute the public use, biological, and maintenance programs on the refuge;
- Providing extensive public use opportunities in fishing, environmental education, interpretation, wildlife observation, and wildlife photography;
- Monitoring populations of waterfowl, shorebirds, and wading birds, and vegetation in the refuge impoundments;
- Maintaining the vegetation in the marsh with prescribed fire; and
- Encouraging scientific research on the refuge.

Pea Island National Wildlife Refuge, in northeastern North Carolina, consists of 5,000 acres, or which 1,375 acres are salt marsh, 790 acres are managed wetlands (impoundments), 565 acres are maritime scrub/shrub, and 450 acres are dune. These habitats support a variety of wildlife species including waterfowl, shorebirds, wading birds, sea turtles, and neotropical migratory songbirds.

The refuge hosts more than two million visitors annually, who participate in fishing, wildlife observation, wildlife photography, and environmental education and interpretation.

Authority: This notice is published under the authority of the National Wildlife Refuge System Improvement Act of 1997, Public Law 105–57.

Dated: April 1, 2005.

Cynthia K. Dohner,

Acting Regional Director.

Note: This document was received at the office of the Federal Register February 1, 2006.

[FR Doc. 06–1047 Filed 2–3–06; 8:45 am]

BILLING CODE 4310–55–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[OR–027–1020–PI–020H; G–06–0060]

Notice of Public Meetings for the Steens Mountain Advisory Council

AGENCY: Bureau of Land Management, Department of the Interior.

ACTION: Notice of public meetings.

SUMMARY: In accordance with the Steens Mountain Cooperative Management and Protection Act of 2000, the Federal Land Policy and Management Act, and the Federal Advisory Committee Act of

1972, the U.S. Department of the Interior, Bureau of Land Management; Steens Mountain Advisory Council will meet as indicated below.

DATES: The Steens Mountain Advisory Council will meet at the Bureau of Land Management Burns District Office, 28910 Highway 20 West, Hines, Oregon, 97738, on March 16 and 17, 2006; August 24 and 25, 2006; October 12 and 13, 2006; and December 7 and 8, 2006. A meeting in Bend, Oregon, at the Comfort Inn and Suites, 62065 SE 27th Street, will be held May 11 and 12, 2006. All meeting sessions will begin at 8 a.m., local time, and will end at approximately 4:30 p.m., local time.

SUPPLEMENTARY INFORMATION: The Steens Mountain Advisory Council was appointed by the Secretary of the Interior on August 14, 2001 pursuant to the Steens Mountain Cooperative Management and Protection Act of 2000 (Pub. L. 106–399) and re-chartered in August 2003 and again in August 2005. The Steens Mountain Advisory Council's purpose is to provide representative counsel and advice to the Bureau of Land Management regarding: new and unique approaches to management of the land within the bounds of the Steens Mountain Cooperative Management and Protection Area; cooperative programs and incentives for landscape management that meet human needs, maintain and improve the ecological and economic integrity of the area; and preparation and implementation of a management plan for the Steens Mountain Cooperative Management and Protection Area.

Topics to be discussed by the Steens Mountain Advisory Council at these meetings include the Steens Mountain Cooperative Management and Protection Area Travel, Comprehensive Recreation, Implementation, and Monitoring Plans; North Steens Ecosystem Restoration Project Environmental Impact Statement and project implementation; Wildlands Juniper Management Area projects and partnerships; Steens Mountain Wilderness and Wild and Scenic Rivers Plan; categories of interest such as wildlife, special designated areas, partnerships/programs, cultural resources, education, volunteer-based information, adaptive management, and socioeconomics; and other matters that may reasonably come before the Steens Mountain Advisory Council.

All meetings are open to the public in their entirety. Information to be distributed to the Steens Mountain Advisory Council is requested prior to the start of each Steens Mountain Advisory Council meeting. Public comment is generally scheduled for 11 a.m. to 11:30 a.m., local time, both days of each meeting session. The amount of time scheduled for public presentations and meeting times may be extended when the authorized representative considers it necessary to accommodate all who seek to be heard regarding matters on the agenda.

FOR FURTHER INFORMATION CONTACT: Rhonda Karges, Management Support Specialist, Burns District Office, 28910 Highway 20 West, Hines, Oregon, 97738, (541) 573–4400 or *Rhonda_Karges@or.blm.gov*.

Dated: January 30, 2006.

Dana R. Shuford,

Burns District Manager.

[FR Doc. E6–1576 Filed 2–3–06; 8:45 am]

BILLING CODE 4310–33–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

Notice of Proposed Reinstatement of Terminated Oil and Gas Lease WYW152678

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: Under the provisions of Section 371(a) of the Energy Policy Act of 2005, the lessee, Walter S. Fees, Jr. and Son Oil and Gas LLC, timely field a petition for reinstatement of competitive oil and gas lease WYW152678 in Carbon County, Wyoming. The lessee paid the required rental accruing from the date of termination, May 1, 2002.

No leases were issued that affect these lands. The lessee agrees to new lease terms for rentals of $10.00 per acre and royalties of 16⅔ percent or 4 percentages above the existing competitive royalty rate. The lessee has paid the required $500 administrative fee for the reinstatement of the lease and $166 cost for publishing this Notice.

The lessee has met all the requirements for reinstatement of the lease per Sec. 31(e) of the Mineral Leasing Act of 1920 (30 U.S.C. 188(e)). We are proposing to reinstate the lease, effective the date of termination subject to:

- The original terms and conditions of the lease;
- The increased rental of $10.00 per acre; and
- The increased royalty of 16⅔ percent or 4 percentages above the existing competitive royalty rate.

FOR FURTHER INFORMATION CONTACT: Bureau of Land Management, Pamela J. Lewis, Chief, Branch of Fluid Minerals Adjudication, at (307) 775–6176.

Pamela J. Lewis,

Chief, Branch of Fluid Minerals Adjudication.

[FR Doc. 06–1065 Filed 2–3–06; 8:45 am]

BILLING CODE 4310–22–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

Notice of Proposed Reinstatement of Terminated Oil and Gas Lease WYW130285

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: Under the provisions of Section 371(a) of the Energy Policy Act of 2005, the lessee, Pennaco Energy, Inc., timely filed a petition for reinstatement of noncompetitive oil and gas lease WYW130285 in Campbell County, Wyoming. The lessee paid the required rental accruing from the date of termination, September 1, 2003.

No leases were issued that affect these lands. The lessee agrees to new lease terms for rentals of $5.00 per acre and royalties of 16⅔ percent or 4 percentages above the existing competitive royalty rate. The lessee has paid the required $500 administrative fee for the reinstatement of the lease and $166 cost for publishing this Notice.

The lessee has met all the requirements for reinstatement of the lease per Sec. 31(e) of the Mineral Leasing Act of 1920 (30 U.S.C. 188(e)). We are proposing to reinstate the lease, effective the date of termination subject to:

- The original terms and conditions of the lease;
- The increased rental of $5.00 per acre; and
- The increased royalty of 16⅔ percent or 4 percentages above the existing competitive royalty rate.

FOR FURTHER INFORMATION CONTACT: Bureau of Land Management, Pamela J. Lewis, Chief, Branch of Fluid Minerals Adjudication, at (307) 775–6176.

Pamela J. Lewis,

Chief, Branch of Fluid Minerals Adjudication.

[FR Doc. E6–1573 Filed 2–3–06; 8:45 am]

BILLING CODE 4310–22–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

Notice of Proposed Reinstatement of Terminated Oil and Gas Lease WYW141728

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: Under the provisions of Section 371(a) of the Energy Policy Act of 2005, the lessee, Terry S. Miller, timely filed a petition for reinstatement of competitive oil and gas lease WYW141728 in Weston County, Wyoming. The lessee paid the required rental accruing from the date of termination, May 1, 2002.

No leases were issued that affect these lands. The lessee agrees to new lease terms for rentals of $10.00 per acre and royalties of 16⅔ percent or 4 percentages above the existing competitive royalty rate. The lessee has paid the required $500 administrative fee for the reinstatement of the lease and $166 cost for publishing this Notice.

The lessee has met all the requirements for reinstatement of the lease per Sec. 31(e) of the Mineral Leasing Act of 1920 (30 U.S.C. 188(e)). We are proposing to reinstate the lease, effective the date of termination subject to:

- The original terms and conditions of the lease;
- The increased rental of $10.00 per acre; and
- The increased royalty of 16⅔ percent or 4 percentages above the existing competitive royalty rate.

FOR FURTHER INFORMATION CONTACT: Bureau of Land Management, Pamela J. Lewis, Chief, Branch of Fluid Minerals Adjudication, at (307) 775–6176.

Pamela J. Lewis,

Chief, Branch of Fluid Minerals Adjudication.

[FR Doc. E6–1577 Filed 2–3–06; 8:45 am]

BILLING CODE 4310–22–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

Notice of Proposed Reinstatement of Terminated Oil and Gas Lease WYW142145

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: Under the provisions of Section 371(a) of the Energy Policy Act of 2005, the lessee, Rocksource Energy Corporation, timely filed a petition for reinstatement of competitive oil and gas lease WYW142145 in Fremont County, Wyoming. The lessee paid the required rental accruing from the date of termination, August 1, 2002.

No leases were issued that affect these lands. The lessee agrees to new lease terms for rentals of $10.00 per acre and royalties of 16⅔ percent or 4 percentages above the existing competitive royalty rate. The lessee has paid the required $500 administrative fee for the reinstatement of the lease and $166 cost for publishing this Notice.

The lessee has met all the requirements for reinstatement of the lease per Sec. 31(e) of the Mineral Leasing Act of 1920 (30 U.S.C. 188(e)). We are proposing to reinstate the lease, effective the date of termination subject to:

- The original terms and conditions of the lease;
- The increased rental of $10.00 per acre; and
- The increased royalty of 16⅔ or 4 percentages above the existing competitive royalty rate.

FOR FURTHER INFORMATION CONTACT: Bureau of Land Management, Pamela J. Lewis, Chief, Branch of Fluid Minerals Adjudication, at (307) 775–6176.

Pamela J. Lewis,

Chief, Branch of Fluid Minerals Adjudication.

[FR Doc. E6–1578 Filed 2–3–06; 8:45 am]

BILLING CODE 4310–22–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

Notice of Proposed Reinstatement of Terminated Oil and Gas Lease WYW131797

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: Under the provisions of Section 371(a) of the Energy Policy Act of 2005, the lessee, Tippens Oil Investments, timely filed a petition for reinstatement of competitive oil and gas lease WYW131797 in Fremont County, Wyoming. The lessee paid the required rental accruing from the date of termination, April 1, 2002.

No leases were issued that affect these lands. The lessee agrees to new lease terms for rentals of $10.00 per acre and royalties of 16⅔ percent or 4 percentages above the existing competitive royalty rate. The lessee has paid the required $500 administrative fee for the reinstatement of the lease and $166 cost for publishing this Notice.

The lessee has met all the requirements for reinstatement of the lease per Sec. 31(e) of the Mineral Leasing Act of 1920 (30 U.S.C. 188(e)). We are proposing to reinstate the lease, effective the date of termination subject to:

- The original terms and conditions of the lease;
- The increased rental of $10.00 per acre; and
- The increased royalty of 16⅔ percent or 4 percentages above the existing competitive royalty rate.

FOR FURTHER INFORMATION CONTACT: Bureau of Land Management, Pamela J. Lewis, Chief, Branch of Fluid Minerals Adjudication, at (307) 775–6176.

Pamela J. Lewis,

Chief, Branch of Fluid Minerals Adjudication.

[FR Doc. E6–1579 Filed 2–3–06; 8:45 am]

BILLING CODE 4310–22–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

Notice of Proposed Reinstatement of Terminated Oil and Gas Lease WYW132338

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: Under the provisions of section 371(a) of the Energy Policy Act of 2005, the lessee, Palo Production Corporation, timely filed a petition for reinstatement of competitive oil and gas lease WYW132338 in Fremont County, Wyoming. The lessee paid the required rental accruing from the date of termination, June 1, 2002.

No leases were issued that affect these lands. The lessee agrees to new lease terms for rentals of $10.00 per acre and royalties of 16⅔ percent or 4 percentages above the existing competitive royalty rate. The lessee has paid the required $500 administrative fee for the reinstatement of the lease and $166 cost for publishing this Notice.

The lessee has met all the requirements for reinstatement of the lease per Sec. 31(e) of the Mineral Leasing Act of 1920 (30 U.S.C. 188(e)). We are proposing to reinstate the lease, effective the date of termination subject to:

- The original terms and conditions of the lease;
- The increased rental of $10.00 per acre; and
- The increased royalty of 16⅔ percent or 4 percentages above the existing competitive royalty rate.

FOR FURTHER INFORMATION CONTACT: Bureau of Land Management, Pamela J. Lewis, Chief, Branch of Fluid Minerals Adjudication, at (307) 775–6176.

Pamela J. Lewis,

Chief, Branch of Fluid Minerals Adjudication.

[FR Doc. E6–1580 Filed 2–3–06; 8:45 am]

BILLING CODE 4310–22–P

DEPARTMENT OF THE INTERIOR

Notice of Proposed Reinstatement of Terminated Oil and Gas Lease WYW135686

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: Under the provisions of Section 371(a) of the Energy Policy Act of 2005, the lessee, Tippens Oil Investments, timely filed a petition for reinstatement of competitive oil and gas lease WYW135686 in Fremont County, Wyoming. The lessee paid the required rental accruing from the date of termination, April 1, 2002.

No leases were issued that affect these lands. The lessee agrees to new lease terms for rentals of $10.00 per acre and royalties of 16⅔ percent or 4 percentages above the existing competitive royalty rate. The lessee has paid the required $500 administrative fee for the reinstatement of the lease and $166 cost for publishing this Notice.

The lessee has met all the requirements for reinstatement of the lease per Sec. 31(e) of the Mineral Leasing Act of 1920 (30 U.S.C. 188(e)). We are proposing to reinstate the lease, effective the date of termination subject to:

- The original terms and conditions of the lease;
- The increased rental of $10.00 per acre; and
- The increased royalty of 16⅔ percent or 4 percentages above the existing competitive royalty rate.

FOR FURTHER INFORMATION CONTACT: Bureau of Land Management, Pamela J. Lewis, Chief, Branch of Fluid Minerals Adjudication, at (307) 775–6176.

Pamela J. Lewis,

Chief, Branch of Fluid Minerals Adjudication.

[FR Doc. E6–1582 Filed 2–3–06; 8:45 am]

BILLING CODE 4310–22–P

DEPARTMENT OF THE INTERIOR

Notice of Proposed Reinstatement of Terminated Oil and Gas Lease WYW138627

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: Under the provisions of Section 371(a) of the Energy Policy Act of 2005, the lessee, SHADCO, timely filed a petition for reinstatement of noncompetitive oil and gas lease WYW138627 in Natrona County, Wyoming. The lessee paid the required rental accruing from the date of termination, April 1, 2002.

No leases were issued that affect these lands. The lessee agrees to new lease terms for rentals of $5.00 per acre and royalties of 16⅔ percent or 4 percentages above the existing competitive royalty rate. The lessee has paid the required $500 administrative fee for the reinstatement of the lease and $166 cost for publishing this Notice.

The lessee has met all the requirements for reinstatement of the lease per Sec. 31(e) of the Mineral Leasing Act of 1920 (30 U.S.C. 188(e)). We are proposing to reinstate the lease, effective the date of termination subject to:

- The original terms and conditions of the lease;
- The increased rental of $5.00 per acre; and
- The increased royalty of 16⅔ percent or 4 percentages above the existing competitive royalty rate.

FOR FURTHER INFORMATION CONTACT: Bureau of Land Management, Pamela J. Lewis, Chief, Branch of Fluid Minerals Adjudication, at (307) 775–6176.

Pamela J. Lewis,

Chief, Branch of Fluid Minerals Adjudication.

[FR Doc. E6–1583 Filed 2–3–06; 8:45 am]

BILLING CODE 4310–22–P

DEPARTMENT OF THE INTERIOR

Notice of Proposed Reinstatement of Terminated Oil and Gas Lease WYW141678

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: Under the provisions of Section 371(a) of the Energy Policy Act of 2005, the lessee, Bill Barrett Production Company, timely filed a petition for reinstatement of competitive oil and gas lease WYW141678 in Natrona County, Wyoming. The lessee paid the required rental accruing from the date of termination, May 1, 2002.

No leases were issued that affect these lands. The lessee agrees to new lease terms for rentals of $10.00 per acre and royalties of 16⅔ percent or 4 percentages above the existing competitive royalty rate. The lessee has paid the required $500 administrative fee for the reinstatement of the lease and $166 cost for publishing this Notice.

The lessee has met all the requirements for reinstatement of the lease per Sec. 31(e) of the Mineral Leasing Act of 1920 (30 U.S.C. 188(e)). We are proposing to reinstate the lease, effective the date of termination subject to:

- The original terms and conditions of the lease;
- The increased rental of $10.00 per acre; and
- The increased royalty of 16⅔ percent or 4 percentages above the existing competitive royalty rate.

FOR FURTHER INFORMATION CONTACT: Bureau of Land Management, Pamela J. Lewis, Chief, Branch of Fluid Minerals Adjudication, at (307) 775–6176.

Pamela J. Lewis,

Chief, Branch of Fluid Minerals Adjudication.

[FR Doc. E6–1584 Filed 2–3–06; 8:45 am]

BILLING CODE 4310–22–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CO–800–1430–EU, COC 67637]

Notice of Realty Action: Proposed Noncompetitive Sale of Public Land, Archuleta County, CO

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Realty Action.

SUMMARY: The Bureau of Land Management (BLM) hereby provides notice that it will offer a 40-acre parcel of public land located in Archuleta County, Colorado, for sale at not less than the appraised fair market value to Thomas H. and Margie E. Smith, the sale proponents. The BLM Pagosa Field Manager has determined that because the parcel is completely surrounded by private lands owned by the sale proponents and has no legal access via any public road, it will be offered to the sale proponents under noncompetitive (direct) sale procedures.

DATES: Comments regarding the proposed sale must be in writing and received by BLM not later than March 23, 2006.

ADDRESSES: Address all written comments regarding the proposed sale to Field Manager, BLM, Pagosa Field Office, Box 310, Pagosa Springs, Colorado 81147. Comments received in electronic form such as e-mail or facsimile will not be considered.

FOR FURTHER INFORMATION CONTACT: Charlie Higby, Realty Specialist, at (970) 385–1374.

SUPPLEMENTARY INFORMATION: In accordance with the provisions of 43 CFR parts 2710 and 2720, the following described land in Archuleta County, Colorado, is proposed to be sold pursuant to authority provided in sections 203 and 209 of the Federal Land Policy and Management Act of 1976 (FLPMA), as amended (43 U.S.C. 1713, 1719). The parcel to be sold is identified as suitable for disposal in the San Juan/San Miguel Resource Area Management Plan (1985). Proceeds from the sale of the public land will be deposited in the Federal Land Disposal Account under section 206 of the Federal Land Transaction Facilitation Act (43 U.S.C. 2305).

Publication of this notice in the **Federal Register** shall segregate the land described below from appropriation under the public land laws, including the mining laws. The segregative effect of this notice shall terminate upon issuance of patent or upon expiration of 270 days from the date of publication in the **Federal Register**, whichever occurs first.

Noncompetitive Sale

New Mexico Principal Meridian, Colorado

T. 36 N., R. 2 W.,
sec. 28, SW¼SW¼.

The area described contains 40.00 acres.

The appraised fair market value of the parcel is $170,000. This parcel cannot be legally accessed by any public road. It is completely surrounded by the private property of the sale proponent (Thomas and Margie Smith) and is isolated from other public lands. There are no encumbrances of record.

The following reservation, right, and condition will be included in the patent that may be issued for the above parcel of federal land: A reservation to the United States for a right-of-way for ditches and canals constructed by the authority of the United States. Act of August 30, 1890 (43 U.S.C. 945).

No warranty of any kind, express or implied, is given by the United States as to the title, physical condition, or potential uses of the parcel proposed for sale.

The Federal mineral interest underlying the parcel has minimal mineral value and will be conveyed with the parcel. Acceptance in writing of the offer to purchase the above described parcel will constitute an application for conveyance of the mineral interest for the parcel. In addition to the full purchase price, the purchaser must pay a separate nonrefundable filing fee of $50 for the mineral interest to be conveyed simultaneously with the sale of the land.

Failure to timely submit full payment for the parcel within 180 days of the sale will constitute a withdrawal of the request for noncompetitive sale of the public land.

Public Comments

Detailed information concerning the proposed land sale, including reservations, sale procedures, appraisals, planning and environmental documents, Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) 120(h) findings, and mineral report, is available for review at the BLM, Pagosa Field Office, 180 Second Street, Pagosa Springs, Colorado. Normal business hours are 7:45 a.m. to 4:30 p.m. MST, Monday through Friday, except Federal holidays.

The general public and interested parties may submit written comments regarding the proposed sale to the Field Manager, BLM, Pagosa Field Office, not later than March 23, 2006. Comments received during this process, including respondent's name, address, and other contact information, will be available for public review. Individual respondents may request confidentiality. If you wish to request that BLM consider withholding your name, address, and other contact information from public review or disclosure under the Freedom of Information Act, you must state this prominently at the beginning of your comment. The BLM will honor requests for confidentiality on a case-by-case basis to the extent allowed by law. The BLM will make available for public review, in their entirety, all comments submitted by businesses or organizations, including comments by individuals in their capacity as an official or representative of a business or organization.

Any adverse comments will be reviewed by the BLM State Director, Colorado, who may sustain, vacate, or modify this realty action in whole or in part. In the absence of any adverse comments, this realty action will become the final determination of the Department of the Interior.

Authority: 43 CFR 2711.1–2(a).

Steven A. Hartvigsen,
Acting Field Manager, Pagosa Field Office.

[FR Doc. E6–1572 Filed 2–3–06; 8:45 am]
BILLING CODE 4310–JB–P

DEPARTMENT OF JUSTICE

Office of Justice Programs

Agency Information Collection Activities: Proposed Collection; Comment Request

ACTION: 60-Day Notice of Information Collection Under Review: Equal Employment Opportunity Plan Certification and Short Form.

The U.S. Department of Justice, Office of Justice Programs (OJP), Office for Civil Rights has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for "sixty days" until April 7, 2006. This process is conducted in accordance with 5 CFR 1320.10.

If you have comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Daphne Felten-Green, (202) 307–0690, Office for Civil Rights, Office of Justice Programs, U.S. Department of Justice, 810 Seventh Street, NW., Washington, DC 20531.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility;
—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
—Enhance the quality, utility, and clarity of the information to be collected; and
—Minimize the burden of the collection of information on those who are to

respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology; *e.g.*, permitting electronic submission of responses.

Overview of this information:

(1) *Type of Information Collection:* Extension of previously approved collection.

(2) *Title of the Form/Collection:* Equal Employment Opportunity Plan Certification and Short Form.

(3) *Agency form number, if any, and the applicable component of the U.S. Department of Justice sponsoring the collection:* Office for Civil Rights, Office of Justice Programs, United States Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* State, and local, government instrumentalities. Other: For-profit Institutions. 28 CFR 42.301 et seq. authorizes the Department of Justice to collect information regarding employment practices from State or Local units of government, agencies of State and Local governments, and Private entities, institutions or organizations to which OJP, Community Oriented Policing Services, and the Office for Violence Against Women extend Federal financial assistance.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* There are 6,371 respondents. It is estimated that it will take 1,290 respondents receiving a grant of $500,000 or more, one hour to complete an Equal Employment Opportunity Plan Short Form and submit it to the Office of Justice Programs. In addition, an estimated 5,081 of respondents seeking grants ranging from $25,000 up to $500,000 will be required to complete Certification stating that they are maintaining a current Equal Employment Opportunity Plan on file and submit the certification to OJP. Completion and submission of the Certification will take approximately 15 minutes.

(6) *An estimate of the total public burden (in hours) associated with the collection:* For the 6,371 respondents, there are an estimated 2,560 total annual burden hours associated with this collection.

If additional information is required, contact Brenda E. Dyer, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Patrick Henry Building, Suite 1600, 601 D Street, NW., Washington, DC 20530.

Dated: January 31, 2006.

Brenda E. Dyer,

Department Clearance Officer, United States Department of Justice.

[FR Doc. E6–1543 Filed 2–3–06; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF JUSTICE

Office of Justice Programs

Agency Information Collection Activities: Proposed Collection; Comments Requested

ACTION: 60-Day Notice of Information Collection under Review: Accounting System and Financial Capability Questionnaire.

The Department of Justice (DOJ), Office of Justice Programs (OJP), Office of the Comptroller has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for "sixty days" until April 7, 2006. The process is conducted in accordance with 5 CFR 1320.10.

If you have comments, especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Cynthia J. Schwimer, Comptroller, Office of Justice Programs, U.S. Department of Justice, 810 7th Street, NW., Washington, DC 20531.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluation the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used:

—Enhance the quality, utility, and clarity of the information to be collected; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Overview of this information collection:

(1) Type of information collection: Extension of a currently approved collection.

(2) Title of the form/collection: Accounting System and Financial Capability Questionnaire.

(3) Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection: The agency form number is 7120/1 Office of Justice Programs, United States Department of Justice.

(4) Affected public who will be asked or required to respond, as well as a brief abstract: Primary: Not-for-profit institutions, for-profit entities. Other: none. The information is required for assessing the financial risk of a potential recipient in administrating federal funds in accordance with OMB Circular A–110 and 28 CFR part 70.

(5) An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond: It is estimated that 100 respondents will complete the form within approximately 4 hours.

(6) An estimate of the total public burden (in hours) associated with the collection: There are an estimated 400 total hour burden hours associated with this collection.

If additional information is required contact: Mrs. Brenda E. Dyer, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Patrick Henry Building, Suite 1600, 601 D Street, NW., Washington, DC 20530.

Dated: January 31, 2006.

Brenda E. Dyer,

Department Clearance Officer, Department of Justice.

[FR Doc. E6–1544 Filed 2–3–06; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF JUSTICE

Office of Justice Programs

Agency Information Collection Activities: Proposed Collection; Comments Requested

ACTION: 60-Day Notice of Information Collection under Review: Budget Detail Worksheet.

The Department of Justice (DOJ), Office of Justice Programs (OJP), Office of the Comptroller has submitted the following information collection request to the Office of Management and Budget (OBM) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for "sixty days" until April 7, 2006. The process is conducted in accordance with 5 CFR 1320.10.

If you have comments, especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Cynthia J. Schwimer, Comptroller, Office of Justice Programs, U.S. Department of Justice, 810 7th Street, NW., Washington, DC 20531.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used:

—Enhance the quality, utility, and clarity of the information to be collected; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Overview of this information collection:

(1) *Type of information collection:* Extension of a currently approved collection.

(2) *Title of the form/collection:* Budget Detail Worksheet.

(3) *Agency form number, if any and the applicable component of the Department of Justice sponsoring the collection:* The agency form number: None. Office of Justice Programs, United States Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: State and local government, Indian tribes, profit entities, non-profit entities, educational institutions, and individuals. The voluntary form is recommended as a guide to assist the recipient in preparing the budget narrative as authorized 28 CFR parts 66 and 70 titled Subpart B, Pre-Award Requirements.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* It is estimated that 2,500 respondents will complete a form within 4 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The estimated total burden hours associated with this collection is 10,000 hours.

If additional information is required contact: Mrs. Brenda E. Dyer, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Patrick Henry Building, Suite 1600, 601 D Street, NW., Washington, DC 20530.

Dated: January 31, 2006.

Brenda E. Dyer,

Department Clearance Officer, Department of Justice.

[FR Doc. E6–1545 Filed 2–3–06; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF LABOR

Office of the Secretary

Submission for OMB Review: Comment Request

January 31, 2006.

The Department of Labor (DOL) has submitted the following public information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. chapter 35). A copy of this ICR, with applicable supporting documentation, may be obtained by contacting the Department of Labor (DOL). To obtain documentation, contact Darrin King on 202–693–4129 (this is not a toll-free number) or e-mail: *king.darrin@dol.gov.*

Comments should be sent to Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the Occupational Safety and Health Administration (OSHA), Office of Management and Budget, Room 10235, Washington, DC 20503, 202–395–7316 (this is not a toll-free number), within 30 days from the date of this publication in the **Federal Register**.

The OMB is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Agency: Occupational Safety and Health Administration.

Type of Review: Extension of currently approved collection.

Title: OSHA Strategic Partnership Program for Worker Safety and Health (OSPP).

OMB Number: 1218–0244.

Frequency: On occasion and Annually

Type of Response: Reporting.

Affected Public: Business or other for-profit and Federal Government.

Number of Respondents: 5,113.

Number of Annual Responses: 5,113.

Estimated Time Per Respondent: 11 hours.

Total Burden Hours: 57,923.

Total Annualized capital/startup costs: $0.

Total Annual Costs (operating/maintaining systems or purchasing services): $0.

Description: The agency requires OSPP information to monitor and to assess the impact of a partnership. An OSHA Strategic Partnership aims to have a measurable positive impact on workplace safety and health that goes beyond what historically has been achievable through traditional

enforcement method and focus on individual worksites.

Darrin A. King,

Acting Departmental Clearance Officer.

[FR Doc. E6–1554 Filed 2–3–06; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF LABOR

Employment and Training Administration

SCSEP Performance Measurement System

ACTION: Notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) [44 U.S.C. 3506(c)(A)]. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Employment and Training Administration, Division of Older Worker Programs, is soliciting comments concerning the proposed extension of the collection for the Senior Community Service Employment Program. The proposed information collection request (ICR) documents can be obtained at this Web site: *http://www.doleta.gov/Performance/guidance/OMBControlNumber.cfm.*

DATES: Written comments must be submitted to the office listed in the addressee's section below on or before 60 days after the date of publication in the **Federal Register.**

ADDRESSES: Gale B. Gibson, U.S. Department of Labor, Employment and Training Administration, Room S–4206, 200 Constitution Avenue, NW., Washington, DC 20210; Telephone: (202) 693–3758 (This is not a toll-free number); Fax: (202) 693–3817, e-mail: *gibson.gale@dol.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

This package contains revised performance reports for the Senior Community Service Employment Program (SCSEP). The previously approved package permitted implementation of the Older Americans Act (OAA) Amendments of 2000. That request reflected information collection requirements contained in the Final Rule submitted to OMB on December 24, 2003. The current request is for approval of modified forms required for implementation of an Internet-based SCSEP Performance and Results QPR (SPARQ) system that became effective on July 1, 2005.

The SCSEP is funded for approximately $439 million and provides over 61,000 community service positions in which over 93,000 low-income persons aged 55 or older are employed each year. About 20,000 people will be placed from the program into unsubsidized employment in the private or public sector.

To ensure that the Senior Community Service Employment Program is properly administered, and to implement the performance measures and sanctions authorized by the 2000 Amendments to the OAA, it has become necessary to expand and change the existing Quarterly Progress Report (QPR). In addition, a collection of information is required under OMB Memorandum M–02–06, which has been adopted by the Department of Labor (the Department). This requirement necessitates a collection of information to implement the Administration's common performance measures. The legal authority for the collection of additional information may be found at sections 503(a)(1), 503(e)(4), 507, 508, 513, and 514 of the 2000 Amendments to the OAA.

Data collection forms have also required enhancements to allow tracking the co-enrollment of SCSEP participants in the SCSEP 502(e) training grants that were awarded in October of 2004. The 502(e) grants are a sub-set of the SCSEP designed to involve private, for-profit businesses in training SCSEP participants.

II. Review Focus:

The Department of Labor is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

III. Current Actions

Type of Review: Revision of a currently approved collection.

Agency: Employment and Training Administration.

Title: SCSEP Performance Measurement System.

OMB Number: 1205–0040.

Agency Form Numbers: ETA–9120, ETA–9121, ETA–9122, ETA–9123, ETA–9124A, ETA–9124B, ETA–9124C, ETA–8705, and OMB Forms SF269, SF424, and SF424A

Recordkeeping: N/A

Affected Public: Not-for-profit institutions; state, local and tribal governments; business or other for-profit; organizations; the Federal government; and individuals

Total Respondents: 324,940.

Estimated Total Burden Hours:

ESTIMATED TOTAL BURDEN HOURS

Cite reference	Total respondents [1]	Frequency	Total responses	Average time per response	Burden hours
Participant Form—ETA–9120	69	Ongoing	106,000	11 mins	19,433
Community Service Assignment Form—ETA–9121	69	Ongoing	110,000	5 mins	9,167
Unsubsidized Employment Form—ETA–9122	69	Ongoing	22,000	11 mins	4,033
Exit Form—ETA–9123	69	Ongoing	55,000	2 mins	1,833
Equitable Distribution Report Form—ETA–8705	56	Annually	56	12 hrs	672
Participant Customer Satisfaction—ETA–9124A	14,000	Annually	14,000	10 mins	2,333
Host Agency Customer Satisfaction—ETA–9124B	13,000	Annually	13,000	10 mins	2,167

ESTIMATED TOTAL BURDEN HOURS—Continued

Cite reference	Total respondents [1]	Frequency	Total responses	Average time per response	Burden hours
Employer Customer Satisfaction—ETA–9124C	4,400	Ongoing	4,400	8 mins	587
Financial Status Report (SF–269)	69	Quarterly and Final.	345	1 hour 15 mins.	431
Grant Planning—SF–424A	69	Annually	69	3 hours	207
Grant Planning—SF–424	69	Annually	69	45 hours	1,725
Sub Total ETA Forms			324,940	8 mins	42,590

[1] The total respondents will likely vary from year to year.

Total Burden Cost (capital/startup): $0.

Total Burden Cost (operating/maintaining): $0.

Comments submitted in response to this comment request will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated: January 27, 2006.

John R. Beverly, III,

Administrator, Office of National Programs.

[FR Doc. E6–1555 Filed 2–3–06; 8:45 am]

BILLING CODE 4510–30–P

NUCLEAR REGULATORY COMMISSION

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: U.S. Nuclear Regulatory Commission (NRC).

ACTION: Notice of pending NRC action to submit an information collection. request to OMB and solicitation of public comment.

SUMMARY: The NRC is preparing a submittal to OMB for review of continued approval of information collections under the provisions of the Paperwork Reduction Act of 1995 (44 U.S. Chapter 35).

Information pertaining to the requirement to be submitted:

1. *The title of the information collection:* 10 CFR Part 55, Operators Licenses.

2. *Current OMB approval number:* 3150–0018.

3. *How often the collection is required:* As necessary for NRC to meet its responsibilities to determine the eligibility of applicants for operators' licenses, prepare or review initial operator licensing and requalification examinations, and review applications for and performance of simulation facilities.

4. *Who is required or asked to report:* Holders of and applicants for facility (i.e., nuclear power, research, and test reactor) operating licenses and individual operators' licenses.

5. *The number of annual respondents:* 240.

6. *The number of hours needed annually to complete the requirement or request:* 67,060.

7. *Abstract:* 10 CFR Part 55, "Operators' Licenses," of the NRC's regulations, specifies information and data to be provided by applicants and facility licenses so that the NRC may make determinations concerning the licensing and requalification of operators for nuclear reactors, as necessary to promote public health and safety. The reporting and recordkeeping requirements contained in 10 CFR Part 55 are mandatory for the licensees and applicants affected.

Submit, by April 7, 2006, comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?

2. Is the burden estimate accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection be minimized, including the use of automated collection techniques or other forms of information technology?

A copy of the draft supporting statement may be viewed free of charge at the NRC Public Document Room, One White Flint North, 11555 Rockville Pike, Room O–1 F21, Rockville, MD 20852. OMB clearance requests are available at the NRC worldwide Web site: *http://www.nrc.gov/public-involve/doc-comment/omb/index.html.* The document will be available on the NRC home page site for 60 days after the signature date of this notice.

Comments and questions about the information collection requirements may be directed to the NRC Clearance Officer, Brenda Jo. Shelton (T–5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, by telephone at 301–415–7233, or by Internet electronic mail to *INFOCOLLECTS@NRC.GOV.*

Dated at Rockville, Maryland, this 30th day of January 2006.

For the Nuclear Regulatory Commission.

Brenda Jo. Shelton,

NRC Clearance Officer, Office of Information Services.

[FR Doc. E6–1586 Filed 2–3–06; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[EA 05–110]

In the Matter of Alfred C. Burris, Senior, M.D.; Confirmatory Order (Effective Immediately)

Alfred C. Burris, Senior, M.D. (Dr. Burris) is a self-employed cardiologist, who is licensed to practice medicine in the State of Maryland and the District of Columbia. Dr. Burris submitted an application for an NRC license dated February 2, 2004, to authorize use of byproduct material for diagnostic nuclear medicine.

An investigation was initiated by the NRC Office of Investigations (OI) on May 24, 2004, (OI Case No. 1–2004–028) to determine if Dr. Burris submitted inaccurate and/or misleading information to the NRC in his NRC application to be the sole authorized user (AU) as well as the Radiation Safety Officer (RSO) on a license for use of byproduct material for medical imaging and diagnostic purposes. During the course of this investigation, OI identified that an NRC licensee, a mobile cardiac imaging company, may have provided the same inaccurate information in support of their amendment request to add Dr. Burris and another physician to its NRC materials license as Authorized Users. On August 6, 2004, OI initiated a separate investigation (OI Case No. 1–2004–034) to determine if Dr. Burris submitted false information to an NRC

licensee to become an AU on their existing NRC license. Based on the evidence developed during its investigations, OI concluded that Dr. Burris deliberately submitted false and/or inaccurate information (1) to the NRC as an applicant for an NRC license and (2) to an NRC licensee with the purpose to become an AU on their existing NRC license. The results of the two investigations were completed by OI on April 15, 2005 and June 15, 2005, and were sent to Dr. Burris in two letters dated September 15, 2005.

Subsequent to becoming aware of the details of the apparent violation, Dr. Burris took several prompt actions to assure that these events would not recur. These actions included: (a) Correcting inaccurate information for the record in a letter dated July 26, 2004; (b) providing details of the violation to associates in the process of getting character references; (c) supplementing his work experience in May 2004, when he began working with the nuclear medicine technologists at Greater Southeast Community Hospital; and (d) undertaking efforts to better understand regulatory requirements through self study and review of his consultant's letter of May 4, 2004.

In response to the NRC's September 15, 2005 letters, Dr. Burris requested the use of Alternative Dispute Resolution (ADR) to resolve this apparent violation and pending enforcement action. ADR is a process in which a neutral mediator, with no decision-making authority, assists the NRC and the individual to resolve any disagreements on whether a violation occurred, the appropriate enforcement action, and the appropriate corrective actions. An ADR session was held between Dr. Burris and the NRC in Rockville, MD, on December 1, 2005, and was mediated by a professional mediator, arranged through Cornell University's Institute of Conflict Management. During that ADR session, a settlement agreement was reached. The elements of the settlement agreement consisted of the following:

1. Dr. Burris agreed that he was in violation of NRC requirements when, in an application for a new NRC license, dated February 2, 2004, Dr. Burris submitted inaccurate information contrary to 10 CFR 30.9(a). Specifically, his application indicated that Dr. Burris was listed as an authorized user (AU) on the Greater Southeast Community Hospital license, when he was not. In addition, the preceptor statement, prepared by a radiologist and attached to his application, inaccurately described required supervised work experience in handling nuclear materials.

2. While NRC and Dr. Burris agreed the violation was not deliberate, NRC maintained that it was in careless disregard of NRC's regulation.

3. Dr. Burris, subsequent to becoming aware of the details of the violation, took prompt actions to assure that he learned from this violation and provided the NRC with assurance that it would not recur. These actions included: (a) Correcting inaccurate information for the record in a letter dated July 26, 2004; (b) providing details of the violation to associates in the process of getting character references; (c) supplementing his work experience in May 2004, when Dr. Burris began working with the nuclear medicine technologists at Greater Southeast Community Hospital; and (d) undertaking efforts to better understand regulatory requirements through self study and review of his consultant's letter of May 4, 2004.

4. During the ADR mediation session, Dr. Burris recognized an opportunity for other potential Authorized Users/Radiation Safety Officers in the industry to learn from his participation in the NRC enforcement process and his experiences regarding the necessity to provide complete and accurate information to the NRC. Therefore, Dr. Burris agreed to take the following future corrective actions: (a) Submit an article for consideration to an appropriate medical journal that reaches an audience of cardiologists; (b) offer to speak at a training session at a meeting of the American Society of Nuclear Cardiology, a similar society, or at a Nuclear Cardiology symposium; and (c) write a letter to local cardiologists describing his experiences. In addition, Dr. Burris agreed to meet with a hospital RSO who has a knowledge of imaging and localization studies in order to review NRC requirements.

5. Dr. Burris agreed to complete the additional actions in Item 4 within 12 months of the date of the Order, and send a letter to the NRC informing the NRC that these actions are completed. Dr. Burris agreed to send this letter to the NRC within 30 days of completion of all actions.

6. In light of the actions Dr. Burris took as described in Item 3, those actions Dr. Burris has committed to take as described in Item 4, and his cooperation in providing information during the ADR session, the NRC agreed to issue a Severity Level III Notice of Violation (10 CFR 30.9) to Dr. Burris with no civil penalty. This action will be publicly available in ADAMS, will appear on the NRC "Significant Enforcement Actions—Individuals" Web site for a period of 1 year, and will be discussed in a press release announcing the ADR agreement between Dr. Burris and the NRC.

7. Any license application received from Dr. Burris will be reviewed without prejudice.

8. Dr. Burris agreed to issuance of a Confirmatory Order confirming this agreement.

In light of the actions Dr. Burris has taken and agreed to take to correct the violation and prevent recurrence, as set forth in Section III above, the NRC has concluded that its concerns regarding the violation can be resolved through the NRC's confirmation of the commitments as outlined in this Confirmatory Order.

I find that Dr. Burris' commitments as set forth in Section III above are acceptable. However, in view of the foregoing, I have determined that these commitments shall be confirmed by this Confirmatory Order. Based on the above, and Dr. Burris' consent, this Confirmatory Order is immediately effective upon issuance.

Accordingly, pursuant to Sections 103, 161b, 161i, 161o, 182, and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202 and 10 CFR part 30 and 35, *it is hereby ordered, that:*

1. Dr. Burris will (a) submit an article for consideration to an appropriate medical journal that reaches an audience of cardiologists; (b) offer to speak at a training session at a meeting of the American Society of Nuclear Cardiology, a similar society, or at a Nuclear Cardiology symposium; and (c) write a letter to local cardiologists describing his experiences. In addition, Dr. Burris agreed to meet with a hospital RSO who has a knowledge of imaging and localization studies in order to review NRC requirements.

2. Dr. Burris will complete the actions in Section V.1 within 12 months of the date of this Order, and send a letter to the NRC informing the NRC that these actions are completed within 30 days of completion of all actions.

The Director, Office of Enforcement, may relax or rescind, in writing, any of the above conditions upon a showing by Dr. Burris of good cause.

Any person adversely affected by this Confirmatory Order, other than Dr. Burris, may request a hearing within 20 days of its issuance. Where good cause is shown, consideration will be given to extending the time to request a hearing. A request for extension of time must be made in writing to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and must include a statement of good cause for the extension. Any request for

a hearing shall be submitted to the Secretary, U.S. Nuclear Regulatory Commission, ATTN: Chief, Rulemaking and Adjudications Staff, Washington, DC 20555. Copies of the hearing request shall also be sent to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, to the Assistant General Counsel for Materials Litigation and Enforcement, and to the Director of the Division of Regulatory Improvement Programs at the same address. Because of continuing disruptions in delivery of mail to United States Government offices, it is requested that answers and requests for hearing be transmitted to the Secretary of the Commission either by means of facsimile transmission to 301–415–1101 or by e-mail to *hearingdocket@nrc.gov* and also to the Office of the General Counsel by means of facsimile transmission to 301–415–3725 or e-mail to *OGCMailCenter@nrc.gov*. If such a person requests a hearing, that person shall set forth with particularity the manner in which his interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR § 2.309(d) and (f).

If a hearing is requested by a person whose interest is adversely affected, the Commission will issue an Order designating the time and place of any hearing. If a hearing is held, the issue to be considered at such hearing shall be whether this Confirmatory Order shall be sustained. An answer or a request for a hearing shall not stay the effectiveness date of this order.

Dated this 27th day of January, 2006.

For the Nuclear Regulatory Commission.

Michael Johnson,

Director, Office of Enforcement.

[FR Doc. E6–1570 Filed 2–3–06; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[EA–05–136]

In the Matter of Digirad Imaging Solutions, Inc.; Confirmatory Order (Effective Immediately)

Digirad Imaging Solutions, Incorporated (DIGIRAD or Licensee) is the holder of Byproduct Material License 31–30666–01 issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Parts 30 and 35. This mobile medical license authorizes possession of radionuclides for medical diagnosis, including uptake, dilution and excretion studies permitted by 10 CFR 35.100; and imaging and localization studies permitted by 10 CFR 35.200. The license further authorizes possession and use of byproduct material at specified facilities located in Indiana, Michigan, Missouri, New Jersey, Pennsylvania, Virginia, and West Virginia. The license also authorizes use of byproduct material at temporary jobsites of the licensee anywhere in the United States where the NRC maintains jurisdiction for regulating the use of licensed material, including areas of exclusive Federal jurisdiction within Agreement States. The license was originally issued on August 21, 2001, was due to expire on July 31, 2005, and is currently under timely renewal pursuant to 10 CFR 30.36(a)(1).

On August 6, 2004, the NRC Office of Investigations (OI) initiated an investigation (OI Case No. 1–2004–034) to determine if a physician listed on the DIGIRAD NRC license submitted false information to DIGIRAD in October 2003 to become an Authorized User (AU) on its existing NRC license. Based on the evidence developed during its investigations, OI substantiated that false and/or inaccurate information was submitted to DIGIRAD by the physician for the purpose of adding that physician as an AU on the existing DIGIRAD NRC license. The results of the investigation completed on June 15, 2005, were sent . to DIGIRAD in a letter dated September 15, 2005. This letter stated that a physician listed as an AU on DIGIRAD's NRC license deliberately provided inaccurate information to DIGIRAD to become an AU on DIGIRAD's license, but that DIGIRAD did not knowingly submit the false information to the NRC in an amendment request dated October 16, 2003, that it submitted to the NRC to add the physician to the list of AUs on the license.

Subsequent to becoming aware of the NRC investigation and of the apparent violation, DIGIRAD took several actions to assure that these events would not recur. These actions included: (a) Immediately removing two AUs from its license; (b) cancelling a contract it had with one of the physicians; (c) attaching to physicians and preceptors statement form a notice equivalent to the following: "*Notice to Physician and Preceptor:* 10 CFR 30.9(a) and 30.10(a) require that all information provided to the Nuclear Regulatory Commission by a licensee or its agents shall be complete and accurate in all material respects. The submission of false information constitutes a serious violation of applicable regulations and may cause you or us to be fined, to lose licensing privileges, or to suffer other significant penalties."; and (d) requiring any physician that is added to its license to sign and date a document containing a statement equivalent to the following: "In connection with my application to be named as an Authorized User on Digirad Imaging Solution's ("DIS") radioactive materials license, I am aware that the submission of information that is not complete and accurate in all material respects is a violation of 10 CFR Sections 30.9(a) and 30.10(a). I hereby represent and warrant that, to the best of my knowledge, the information I have submitted to DIS in connection with my application to be named as an Authorized User is complete and accurate in all material respects."

Also, in response to the NRC's September 15, 2005, letter, DIGIRAD requested the use of Alternative Dispute Resolution (ADR) to resolve this apparent violation and pending enforcement action. ADR is a process in which a neutral mediator, with no decision-making authority, assists the NRC and DIGIRAD to resolve any disagreements on whether a violation occurred, the appropriate enforcement action, and the appropriate corrective actions. An ADR session was held between DIGIRAD and the NRC in King of Prussia, PA, on November 14, 2005, and was mediated by a professional mediator, arranged through Cornell University's Institute of Conflict Management. Based on discussions at the ADR mediation session, as well as subsequent discussions held on December 14 and 15, 2005, between Vera Pardee, Vice President and General Counsel for DIGIRAD, and Karl Farrar, Region I Counsel, a settlement agreement was reached. The elements of the settlement agreement consisted of the following:

1. The NRC and DIGIRAD agreed to disagree on the violation being in careless disregard of NRC requirements.

2. DIGIRAD took the corrective actions described in Section II above prior to attending the ADR Mediation Session on November 14, 2005.

3. As a means to provide added assurance to meet the requirements of 10 CFR 30.9(a) and 30.10(a), DIGIRAD agreed that for all future NRC AU applicants, on a yearly basis, it will audit the training and experience credentials of the first 10 AU applicants and 25% of any applications received after the first 10. DIGIRAD will audit by endeavoring to locate and call preceptors as well as Continuing Medical Education providers to verify the information given by the AU applicants. This does not eliminate the requirement that DIGIRAD provide complete and accurate information to the NRC on all AU applicants. The

results of this audit will be documented and submitted to the NRC at the end of a two-year period. However, DIGIRAD will notify the NRC as soon as practicable after identification of any discrepancies identified as a result of the audit. If no falsifications are uncovered during the two-year period, DIGIRAD will discontinue the practice.

4. In addition, DIGIRAD will take other actions to ensure that similar violations will not recur. These actions will include the Vice President and Corporate Radiation Safety Officer preparing and submitting a commentary to (a) the Journal of Nuclear Medicine, (b) the Journal of Nuclear Medicine Technology, and (c) the Journal of Medical Physics to provide an opportunity for other licensees in the industry to learn from this incident. DIGIRAD will advise NRC upon completion of these items and not later than one year from the date of this agreement.

5. In light of the corrective actions that DIGIRAD has taken or has committed to take as described in Items 2, 3 and 4, the NRC agreed to issue a Severity Level III Notice of Violation to DIGIRAD (10 CFR 30.9(a)), but to not issue a Civil Penalty. This action will be publicly available in ADAMS and on the NRC "Significant Enforcement Actions" Web site, and the NRC will issue a press release announcing this action, as well as the actions DIGIRAD has taken and committed to take to address the violation.

6. DIGIRAD agreed to issuance of a Confirmatory Order confirming this agreement.

In light of the actions DIGIRAD has taken and agreed to take to correct the violation and prevent recurrence, as set forth in section III above, the NRC has concluded that its concerns regarding the violation can be resolved through the NRC's confirmation of the commitments as outlined in this Confirmatory Order.

I find that DIGIRAD's commitments as set forth in section III above are acceptable. However, in view of the foregoing, I have determined that these commitments shall be confirmed by this Confirmatory Order. Based on the above and DIGIRAD's consent, this Confirmatory Order is immediately effective upon issuance.

Accordingly, pursuant to Sections 103, 161b, 161i, 161o, 182, and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202 and 10 CFR part 30 and 35, *it is hereby ordered, that by August 23, 2006:*

1. DIGIRAD will audit, for all future NRC AU applicants, on a yearly basis, the training and experience credentials of the first 10 AU applicants and 25% of any applications received after the first 10. DIGIRAD will audit by endeavoring to locate and call preceptors as well as Continuing Medical Education providers to verify the information given by the AU applicants. This does not eliminate the requirement that DIGIRAD provide complete and accurate information to the NRC on all AU applicants. The results of this audit will be documented and submitted to the NRC at the end of a two-year period. However, DIGIRAD will notify the NRC as soon as practicable after identification of any discrepancies identified as a result of the audit. If no falsifications are uncovered during the two-year period, DIGIRAD will discontinue the practice.

2. The DIGIRAD Vice President and Corporate Radiation Safety Officer will prepare and submit a commentary regarding this violation to the Journals of Nuclear Medicine, Nuclear Medicine Technology, and Medical Physics to provide an opportunity for other licensees in the industry to learn from this incident.

3. DIGIRAD will advise NRC upon completion of these items and not later than one year from the date of this agreement.

The Director, Office of Enforcement, may relax or rescind, in writing, any of the above conditions upon a showing by DIGIRAD of good cause.

Any person adversely affected by this Confirmatory Order, other than DIGIRAD, may request a hearing within 20 days of its issuance. Where good cause is shown, consideration will be given to extending the time to request a hearing. A request for extension of time must be made in writing to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and must include a statement of good cause for the extension. Any request for a hearing shall be submitted to the Secretary, U.S. Nuclear Regulatory Commission, ATTN: Chief, Rulemaking and Adjudications Staff, Washington, DC 20555. Copies of the hearing request shall also be sent to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, to the Assistant General Counsel for Materials Litigation and Enforcement, to the Director of the Division of Regulatory Improvement Programs at the same address, and to MSHMC. Because of continuing disruptions in delivery of mail to United States Government offices, it is requested that answers and requests for hearing be transmitted to the Secretary of the Commission either by means of facsimile transmission to 301–415–1101 or by e-mail to *hearingdocket@nrc.gov* and also to the Office of the General Counsel by means of facsimile transmission to 301–415–3725 or e-mail to *OGCMailCenter@nrc.gov*. If such a person requests a hearing, that person shall set forth with particularity the manner in which his interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.714(d).

If a hearing is requested by a person whose interest is adversely affected, the Commission will issue an Order designating the time and place of any hearing. If a hearing is held, the issue to be considered at such hearing shall be whether this Confirmatory Order shall be sustained. *An answer or a request for a hearing shall not stay the effectiveness date of this order.*

Dated this 27th day of January 2006.

For the Nuclear Regulatory Commission.

Michael Johnson,

Office of Enforcement.

[FR Doc. E6–1568 Filed 2–3–06; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–293]

Entergy Nuclear Operations, Inc.; Notice of Receipt and Availability of Application for Renewal of Pilgrim Nuclear Power Station Facility Operating License No. DPR–35 for an Additional 20-Year Period

The U.S. Nuclear Regulatory Commission (NRC or Commission) has received an application, dated January 25, 2006, from Entergy Nuclear Operations, Inc., filed pursuant to Section 104b (DPR–35) of the Atomic Energy Act of 1954, as amended, and 10 CFR part 54, to renew the operating license for the Pilgrim Nuclear Power Station. Renewal of the license would authorize the applicant to operate the facility for an additional 20-year period beyond the period specified in the current operating license. The current operating license for the Pilgrim Nuclear Power Station (DPR–35) expires on June 8, 2012. The Pilgrim Nuclear Power Station is a Boiling Water Reactor designed by General Electric. The unit is located in Plymouth, MA. The acceptability of the tendered application for docketing, and other matters including an opportunity to request a hearing, will be the subject of subsequent **Federal Register** notices.

Copies of the application are available for public inspection at the

Commission's Public Document Room (PDR), located at One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland 20582 or electronically from the NRC's Agencywide Documents Access and Management System (ADAMS) Public Electronic Reading Room under accession number ML060300024. The ADAMS Public Electronic Reading Room is accessible from the NRC's Web site at *http://www.nrc.gov/reading-rm/adams.html*. In addition, the application is available at *http://www.nrc.gov/reactors/operating/licensing/renewal/applications.html*, on the NRC's Web page, while the application is under review. Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS should contact the NRC's PDR Reference staff at 1–800–397–4209, extension 301–415–4737, or by e-mail to *pdr@nrc.gov*.

A copy of the license renewal application for the Pilgrim Nuclear Power Station is also available to local residents near the Pilgrim Nuclear Power Station at the Plymouth Public Library, 132 South Street, Plymouth, MA 02360.

Dated at Rockville, Maryland, this 31st day of January, 2006.

For the Nuclear Regulatory Commission.

Frank P. Gillespie,

Director, Division of License Renewal, Office of Nuclear Reactor Regulation.

[FR Doc. E6–1566 Filed 2–3–06; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–271]

Entergy Nuclear Operations, Inc. Notice of Receipt and Availability of Application for Renewal of Vermont Yankee Nuclear Power Station Facility Operating License No. Dpr–28 for an Additional 20-Year Period

The U.S. Nuclear Regulatory Commission (NRC or Commission) has received an application, dated January 25, 2006, from Entergy Nuclear Operations, Inc., filed pursuant to Section 104b (DPR–28) of the Atomic Energy Act of 1954, as amended, and 10 CFR part 54, to renew the operating license for the Vermont Yankee Nuclear Power Station. Renewal of the license would authorize the applicant to operate the facility for an additional 20-year period beyond the period specified in the current operating license. The current operating license for the Vermont Yankee Nuclear Power Station (DPR–28) expires on March 21, 2012. The Vermont Yankee Nuclear Power Station is a Boiling Water Reactor designed by General Electric. The unit is located in Vernon, VT. The acceptability of the tendered application for docketing, and other matters including an opportunity to request a hearing, will be the subject of subsequent **Federal Register** notices.

Copies of the application are available for public inspection at the Commission's Public Document Room (PDR), located at One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland, 20582 or electronically from the NRC's Agencywide Documents Access and Management System (ADAMS) Public Electronic Reading Room under accession number ML060300078. The ADAMS Public Electronic Reading Room is accessible from the NRC's Web site at *http://www.nrc.gov/reading-rm/adams.html*. In addition, the application is available at *http://www.nrc.gov/reactors/operating/licensing/renewal/applications.html*, on the NRC's Web page, while the application is under review. Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS should contact the NRC's PDR Reference staff at 1–800–397–4209, extension 301–415–4737, or by e-mail to *pdr@nrc.gov*.

A copy of the license renewal application for the Vermont Yankee Nuclear Power Station is also available to local residents near the Vermont Yankee Nuclear Power Station at the following four public libraries: Vernon Free Library, 567 Governor Hunt Rd, Vernon, VT 05354; Brooks Memorial Library, 224 Main Street, Brattleboro, VT 05301; Hinsdale Public Library, 122 Brattleboro Rd, Hinsdale, NH 03451; and Dickinson Memorial Library, 115 Main St, Northfield, MA 01360.

Dated at Rockville, Maryland, this 31st day of January, 2006.

For the Nuclear Regulatory Commission.

Frank P. Gillespie,

Director, Division of License Renewal, Office of Nuclear Reactor Regulation.

[FR Doc. E6–1567 Filed 2–3–06; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 030–11789]

Notice of Environmental Assessment Related to the Issuance of a License Amendment to Byproduct Material License No. 24–00196–07, for Unrestricted Release of a Facility for Saint Louis University, St. Louis, MO

AGENCY: Nuclear Regulatory Commission.

ACTION: Issuance of environmental assessment and Finding of No Significant Impact for license amendment.

FOR FURTHER INFORMATION CONTACT: George M. McCann, Senior Health Physicist, Decommissioning Branch, Division of Nuclear Materials Safety, Region III, U.S. Nuclear Regulatory Commission, 2443 Warrenville Road, Lisle, Illinois 60532–4352; telephone: (630) 829–9856; or by e-mail at *gmm@nrc.gov*.

SUPPLEMENTARY INFORMATION: The U.S. Nuclear Regulatory Commission (NRC) is considering the issuance of an amendment to NRC Byproduct Materials License No. 24–00196–07, which is held by Saint Louis University (licensee). The amendment would authorize the unrestricted release of the licensee's former Radioactive Waste Storage Facility, located at 1008 South Spring Avenue, St. Louis, Missouri. The NRC has prepared an Environmental Assessment in support of this action in accordance with the requirements of 10 CFR part 51. Based on the Environmental Assessment, the NRC has determined that a Finding of No Significant Impact is appropriate. The amendment to Saint Louis University's license will be issued following the publication of this Environmental Assessment and Finding of No Significant Impact.

I. Environmental Assessment

Identification of Proposed Action

The proposed action would approve St. Louis University's request to amend its license and release the licensee's former waste storage facility for unrestricted use in accordance with 10 CFR part 20, subpart E. The proposed action is in accordance with the Saint Louis University's request to the U.S. Nuclear Regulatory Commission (NRC) to amend its NRC Byproduct Material License by letters dated October 31, 2005 (ADAMS Accession No. ML060180319), and January 13, 2006 (ADAMS Accession No. ML060170694). Saint Louis University is licensed as an

NRC broad scope licensee and was first licensed to use byproduct materials for broad scope uses on January 19, 1976. The licensee is authorized to use byproduct materials for broad scope activities involving medical research, diagnostic and therapeutic medical procedures, laboratory studies and educational programs. The licensee is authorized to possess and use curie quantities of byproduct materials atomic number 1 through 83, inclusive.

The licensee's Radioactive Waste Storage Facility located at 1008 South Spring Avenue, St. Louis, Missouri, was designed to receive and process the licensee's research and laboratory wastes for disposal to authorized recipients. The use of the Radioactive Waste Storage Facility for waste processing activities was first authorized for use by the NRC in License No. 24–00196–07, Amendment No. 25, dated March 19, 1999. According to the licensee, use and storage of radioactive material in the Radioactive Waste Storage Facility ceased on August 12, 2005.

The licensee conducted surveys of the facility and provided this information to the NRC to demonstrate that the radiological conditions of former waste processing and storage areas, and offices located in the Radioactive Waste Storage Facility are consistent with radiological criteria for unrestricted use in 10 CFR part 20, subpart E. No radiological remediation activities are required to complete the proposed action. The NRC completed a closeout inspection and survey of the licensee's activities, which are the subject of this license amendment, on January 18, 2006 (NRC Inspection Report No. 030–11789/05–002 (DNMS) (ADAMS Accession No. ML060200576)), to conduct independent radiological surveys and to verify the licensee's survey findings.

Need for the Proposed Action

The licensee is requesting this license amendment because it no longer plans to use the Radioactive Waste Storage Facility for NRC-licensed activities at Saint Louis University. The NRC is fulfilling its responsibilities under the Atomic Energy Act to make a decision on the proposed action for decommissioning that ensures that residual radioactivity is reduced to a level that is protective of the public health and safety and the environment, and allows the Radioactive Waste Storage Facility to be released for unrestricted use.

Environmental Impacts of the Proposed Action

The NRC staff reviewed the information provided and surveys performed by the licensee to demonstrate that the release of the Radioactive Waste Storage Facility located at 1008 South Spring Avenue, St. Louis, Missouri, are consistent with the radiological criteria for unrestricted use specified in 10 CFR 20.1402. The NRC performed a closeout inspection and survey to confirm the licensee's findings. Based on its review, the staff determined that there were no radiological impacts associated with the proposed action because no radiological remediation activities were required to complete the proposed action, and that the radiological criteria for unrestricted use in § 20.1402 have been met.

Based on its review, the staff determined that the radiological environmental impacts from the proposed action for the former Radioactive Waste Storage Facility are bounded by the "Generic Environmental Impact Statement in Support of Rulemaking on Radiological Criteria for License Termination of NRC-Licensed Nuclear Facilities" (NUREG–1496). Additionally, no non-radiological or cumulative impacts were identified. Therefore, the NRC has determined that the proposed action will not have a significant effect on the quality of the human environment.

Alternatives to the Proposed Action

The only alternative to the proposed action of releasing the licensee's former Radioactive Waste Storage Facility for unrestricted use is to take no action. Under the no-action alternative, the licensee's facility would remain under an NRC license and would not be released for unrestricted use. Denial of the license amendment request would result in no change to current conditions at the University. The no-action alternative is not acceptable because it is inconsistent with 10 CFR 30.36, which requires licensees who have ceased licensed activities to request termination of their radioactive material license. This alternative would impose an unnecessary regulatory burden in controlling access to the facility, and limit potential benefits from the future use of the facility.

Conclusion

The NRC staff concluded that the proposed action is consistent with the NRC's unrestricted release criteria specified in 10 CFR 20.1402. Because the proposed action will not significantly impact the quality of the human environment, the NRC staff concludes that the proposed action is the preferred alternative.

Agencies and Persons Consulted

The NRC staff has determined that the proposed action will not affect listed species or critical habitats. Therefore, no further consultation is required under Section 7 of the Endangered Species Act. Likewise, the NRC staff has determined that the proposed action is not a type of activity that has potential to cause effect on historic properties. Therefore, consultation under Section 106 of the National Historic Preservation Act is not required.

The NRC consulted with the Missouri Department of Health and Senior Services. The Missouri Department of Health and Senior Services, Division of Community and Public Health, Office of Emergency Coordination was provided the draft EA for comment on January 19, 2006. Mr. Keith Henke, Planner III, with the Missouri Office of Emergency Coordination, responded to the NRC by telephone on January 19, 2006, indicating that the State had no comments regarding the NRC Environmental Assessment for the release of the Saint Louis University facility.

II. Finding of No Significant Impact

On the basis of the EA in support of the proposed license amendment to release the site for unrestricted use, the NRC has determined that the proposed action will not have a significant effect on the quality of the human environment. Thus, the NRC has not prepared an environmental impact statement for the proposed action.

III. Further Information

Documents related to this action, including the application for amendment and supporting documentation, are available electronically at the NRC's Electronic Reading Room at *http://www.nrc.gov/reading-rm/adams.html*. From this site, you can access the NRC's Agencywide Documents Access and Management System (ADAMS), which provides text and image files of NRC's public documents. If you do not have access to ADAMS, or if there are problems in accessing the documents located in ADAMS, contact the NRC Public Document Room (PDR) Reference staff at 1–800–397–4209, 301–415–4737, or by e-mail to *pdr@nrc.gov*. The documents and ADAMS accession numbers related to this notice are:

1. Haenchen, Mark, M.S., J.D., Director and Radiation Safety Officer, Office of Environmental Safety & Services,

Saint Louis University, October 31, 2005 letter to the NRC requesting a license amendment for the release of the former Radioactive Waste Storage Facility (ML060180319).
2. Bachmann, Kenneth, M.S., Health Physicist, Saint Louis University consultant, letter dated January 13, 2006, to the NRC (ML060170694).
3. NRC Inspection Report No. 030–11789/05–002 (DNMS) dated January 20, 2006 (ML060200576).
4. U.S. Nuclear Regulatory Commission, "Environmental Review Guidance for Licensing Actions Associated with NMSS Programs," NUREG–1748, August 2003.
5. U.S. Nuclear Regulatory Commission, "Environmental Review Guidance for Licensing Actions Associated with NMSS Programs," NUREG–1748, August 2003.
6. U.S. Nuclear Regulatory Commission, "Generic Environmental Impact Statement in Support of Rulemaking on Radiological Criteria for License Termination of NRC-Licensed Nuclear Facilities," NUREG–1496, August 1994.
7. NRC, NUREG–1757, "Consolidated NMSS Decommissioning Guidance," Volumes 1–3, September 2003.

Documents may also be viewed electronically on the public computers located at the NRC's PDR, O 1 F21, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852. The PDR reproduction contractor will copy documents for a fee.

Dated at Lisle, Illinois, this 27th day of January 2006.

For the Nuclear Regulatory Commission,

Jamnes L. Cameron,

Chief, Decommissioning Branch, Division of Nuclear Materials Safety, Region III.

[FR Doc. 06–1043 Filed 2–3–06; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–02]

University of Michigan; University of Michigan Ford Nuclear Reactor; Environmental Assessment and Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission (the Commission) is considering the issuance of a license amendment to Facility Operating License No. R–28, issued to the University of Michigan (UM or the licensee), that would allow decommissioning of the UM Ford Nuclear Reactor (FNR) located at the North Campus in Ann Arbor, Washtenaw County, Michigan.

Environmental Assessment

Identification of the Proposed Action

By letter dated June 18, 2004, the licensee submitted a decommissioning plan in accordance with Title 10 of the Code of Federal Regulation Part 50.82(b)(5) (10 CFR 50.82(b)(5)) in order to dismantle the 2 megawatts thermal (MWt) FNR, to dispose of its component parts and radioactive material, and to decontaminate the facility in accordance with the proposed dismantling plan to meet the Commission's unrestricted release criteria. After the Commission verifies that the release criteria have been met, Facility Operating License No. R–28 would be terminated. The licensee submitted an Environmental Report on June 18, 2004, that addressed the estimated environmental impacts resulting from decommissioning the UM FNR.

A "Notice and Solicitation of Comments Pursuant to 10 CFR 20.1405 and 10 CFR 50.82(b)(5) Concerning Proposed Action to Decommission the University of Michigan Ford Nuclear Reactor (FNR)" was published in the **Federal Register** on September 8, 2004 (69 FR 54326). No comments were received during the comment period.

Need for the Proposed Action

The proposed action is necessary to permanently cease operations of UM FNR. The licensee needs this license change because it no longer plans to conduct licensed activities at the UM FNR. As specified in 10 CFR 50.82, any licensee may apply to the Nuclear Regulatory Commission for authority to surrender a license voluntarily and to decommission the affected facility. Additionally, 10 CFR 51.53(d) stipulates that each applicant for a license amendment to authorize decommissioning of a production or utilization facility shall submit with its application an environmental report that reflects any new information or significant environmental change associated with the proposed decommissioning activities. Upon completion of the decommissioning activities, UM is planning to use the area that would be released for other academic purposes.

Environmental Impact of the Proposed Action

Residual radioactive contamination resulting from past reactor operations is contained in the FNR facility. All decontamination will be performed by trained personnel in accordance with previously reviewed procedures, and will be overseen by experienced health physics staff. Solid and liquid waste will be removed from the facility and managed in accordance with NRC regulations. The operations are calculated to result in a total occupational radiation exposure of about 4.8 person-rem. Radiation exposure to the general public during decommissioning is expected to be negligible. This will be accomplished by keeping the public at a safe distance and by meeting NRC requirements for effluent releases during decommissioning.

Occupational and public exposure may result from offsite disposal of the low-level residual radioactive material from the FNR. The handling, storage, and shipment of this radioactive material are to meet the requirements of 10 CFR 20.2006, "Transfer for Disposal and Manifest," and 49 CFR Parts 100–177, "Transportation of Hazardous Materials." It is anticipated that about 112 ft^3 of irradiated hardware will be shipped during one truck shipment in Type B shipping casks to a waste processor. A volume of 11,000 ft^3 of other waste in strong tight containers will be shipped during 27 truck shipments to the Envirocare of Utah facility. Included in the other waste shipment is mixed waste consisting primarily of activated and/or contaminated lead with a volume of 43 ft^3 and cadmium with a volume of 1 ft^3. Radiation exposure to the general public during waste shipments is expected to be negligible. In addition, Liquid waste that is generated during the decommissioning activities will be released to the environment in accordance with the regulations in 10 CFR Part 20, Subpart K, "Waste Disposal," or will be solidified and disposed of as solid waste in accordance with state and Federal guidelines.

The licensee analyzed accidents applicable to decommissioning activities. These accidents involve inhalation of hazardous or radioactive materials, confined space issues, heavy equipment movement, external radiation exposure, and dermal contact with radioactive and hazardous materials. To minimize the risk from identified hazards, procedures and conformance with FNR license and regulatory requirements will be used.

Based on the review of the specific proposed activities associated with the dismantling and decontamination of the UM FNR facility, the staff has determined that the proposed action will not increase the probability or consequences of accidents, change any effluents that may be released off site,

and cause any significant increase in occupational or public radiation exposure. Therefore, the staff concludes that there are no significant radiological environmental impacts associated with the proposed action.

With regard to potential non-radiological impacts, the proposed action does not involve any historic sites. In addition to the lead and cadmium discussed above, asbestos is present at the UM FNR facility. Asbestos will be removed by a licensed asbestos abatement contractor. Decommissioning activities will not affect non-radiological facility effluents and have no other environmental impact. The licensee states that there are no significant plant communities and no wetlands within the site.

There are three species listed as threatened or endangered under the Federal ESA within Washtenaw County. These are Indiana bat (*Myotis sodalis*), the Mitchell's satyr butterfly (*Neonympha mitchellii mitchellii*), and the Eastern prairie fringed orchid (*Platanthera leucophaea*). There are no records of any of these three species on the UM FNR site. Therefore, the staff concludes that there are no significant non-radiological environmental impacts associated with the proposed action. Accordingly, the NRC staff concludes that there are no significant environmental impacts associated with the proposed action.

Alternatives to the Proposed Action

The licensee has proposed to use the DECON alternative for the UM FNR facility. The DECON alternative is where the equipment, structures, and portions of the facility containing radioactive contaminants are removed or decontaminated to a level that permits the property to be released for unrestricted use. As a first alternative to the proposed DECON method, SAFSTOR will be used. In SAFSTOR, the nuclear facility is placed and maintained in a condition that allows the nuclear facility to be safely stored and subsequently decontaminated (deferred decontamination) to levels that permit release for unrestricted use. As a second alternative, the ENTOMB alternative is where radioactive contaminants are encased in a structurally long-lived material, such as concrete; the entombed structure is appropriately maintained; and continued surveillance is carried out until the radioactivity decays to a level permitting release of the property for unrestricted use.

The SAFSTOR, ENTOMB, and no-action alternatives would entail continued surveillance and physical security measures to be in place and continued monitoring by licensee personnel. The SAFSTOR and no-action alternatives would also require continued maintenance of the facility. The radiological impacts of SAFSTOR would be less than the DECON option because of radioactive decay prior to the start of decommissioning activities. However, this option involves the continued use of resources during the SAFSTOR period. The ENTOMB option would also result in lower radiological exposure than the DECON option but would involve the continued use of resources. UM FNR has determined that the proposed action (DECON) is the most efficient use of the existing facility, since it proposes to use the space that will become available for other academic purposes. These alternatives would have no significant environmental impact. In addition, the regulations in 10 CFR 50.82(b)(4)(i) only allow an alternative if it provides for completion of decommissioning without significant delay.

Alternative Use of Resources

This action does not involve the use of any resources not previously considered in the Environmental Report submitted on June 18, 2004, for the UM FNR facility.

Agencies and Persons Contacted

In accordance with the NRC staff's stated policy, on November 22, 2005, the NRC staff consulted with the Michigan State official, Chris Antieau, Department of Environmental Quality, Land and Water Management Division, regarding the environmental impact of the proposed action on the Coastal Zone Management Act. The state official stated that he concurred with the environmental assessment and had no comments. In addition, the staff contacted U.S. Fish and Wildlife Service (FWS) regarding the environmental impact of the proposed action to threatened or endangered species. The FWS provided the NRC staff with a list of threatened and endangered species to assist the NRC staff to determine if the UM FNR proposed action would cause any environmental impact in reference to the Endangered Species Act. On December 2, 2005, the NRC staff also consulted with the Michigan State Official, Robert D. Skowronek, Department of Environmental Quality, Waste and Hazardous Materials Division. Mr. Skowronek had no comments.

Finding of No Significant Impact

On the basis of the environmental assessment, the Commission concludes that the proposed action will not have a significant effect on the quality of the human environment. Accordingly, the NRC has determined not to prepare an environmental impact statement for the proposed action.

For further details with respect to the proposed action, see the licensee's letter dated June 18, 2004, which is available for public inspection, and can be copied for a fee, at the U.S. Nuclear Regulatory Commission's Public Document Room (PDR), located at One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland. The NRC maintains an Agencywide Documents Access and Management System (ADAMS), which provides text and image files of NRC's public documents. These documents may be accessed through the NRC's Public Electronic Reading Room on the internet at *http://www.nrc.gov*. Persons who do not have access to ADAMS or who have problems in accessing the documents located in ADAMS may contact the PDR reference staff at 1–800–397–4209, 301–415–4737 or by e-mail at *pdr@nrc.gov*.

Dated at Rockville, Maryland, this 25th day of January 2006.

For the Nuclear Regulatory Commission.

Brian E. Thomas,

Branch Chief, Research and Test Reactors Branch, Division of Policy and Rulemaking, Office of Nuclear Reactor Regulation.

[FR Doc. E6–1571 Filed 2–3–06; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Steam Generator Tube Integrity and Associated Technical Specifications

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has issued Generic Letter (GL) 2006–01 to all holders of operating licenses for pressurized water reactors, except those who have permanently ceased operation and have certified that fuel has been removed from the reactor vessel. A response to this GL is not needed for the following units since they have revised their technical specifications (TS) to be conceptually similar to the TS discussed in this GL: Arkansas Nuclear One Unit 1, Callaway, Catawba Units 1 and 2, Farley Units 1 and 2, Salem Unit 1, and South Texas Project Units 1 and 2. The NRC is issuing this generic letter to:

1. Request that addressees either submit a description of their program for ensuring steam generator (SG) tube

integrity for the interval between inspections or adopt alternative TS requirements for ensuring SG tube integrity, and

2. Require addressees to provide a written response to the NRC in accordance with Title 10 of the Code of Federal Regulations, Section 50.54(f).

This **Federal Register** notice is available through the NRC's Agencywide Documents Access and Management System (ADAMS) under accession number ML060240020.

DATES: The GL was issued on January 20, 2006.

ADDRESSES: Not applicable.

FOR FURTHER INFORMATION CONTACT: Kenneth Karwoski at 301–415–2752 or by e-mail kjk1@nrc.gov or David Beaulieu at 301–415–3243 or e-mail dpb@nrc.gov.

SUPPLEMENTARY INFORMATION: NRC GL 2006–01 may be examined, and/or copied for a fee, at the NRC's Public Document Room at One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible electronically from the Agencywide Documents Access and Management System (ADAMS) Public Electronic Reading Room on the Internet at the NRC Web site, *http://www.nrc.gov/NRC/ADAMS/index.html*. The ADAMS number for the generic letter is ML060200385.

If you do not have access to ADAMS or if you have problems in accessing the documents in ADAMS, contact the NRC Public Document Room (PDR) reference staff at 1–800–397–4209 or 301–415–4737 or by e-mail to *pdr@nrc.gov*.

Dated at Rockville, Maryland, this 27th day of January, 2006.

For The Nuclear Regulatory Commission.

Christopher I. Grimes,

Director, Division of Policy and Rulemaking, Office of Nuclear Reactor Regulation.

[FR Doc. E6–1569 Filed 2–3–06; 8:45 am]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 27220; 812–12818]

American Capital Strategies, Ltd.; Notice of Application

January 31, 2006.

AGENCY: Securities and Exchange Commission (the "Commission").

ACTION: Notice of an application for an order under section 61(a)(3)(B) of the Investment Company Act of 1940 (the "Act").

Summary of Application: Applicant, American Capital Strategies, Ltd., requests an order approving its 2000 Disinterested Director Stock Option Plan (the "Plan") and the grant of certain stock options under the Plan.

Filing Dates: The application was filed on April 24, 2002 and amended on January 24, 2006.

Hearing or Notification of Hearing: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicant with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on February 27, 2006, and should be accompanied by proof of service on applicant, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Secretary, U.S. Securities and Commission, 100 F Street, NE., Washington, DC 20549–1090; Applicant, 2 Bethseda Metro Center, 14th Floor, Bethesda, Maryland 20814.

FOR FURTHER INFORMATION CONTACT: Laura J. Riegel, Senior Counsel, at (202) 551–6873, or Nadya B. Roytblat, Assistant Director, at (202) 551–6821 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application is available for a fee at the Public Reference Desk, U.S. Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–0102 (tel. 202–551–5850).

Applicant's Representations

1. Applicant, a Delaware corporation, is a business development company ("BDC") within the meaning of section 2(a)(48) of the Act.[1] Applicant's primary business objectives are to increase its net operating income and net asset value by investing its assets in senior debt, subordinated debt with detachable warrants and equity of small to medium sized businesses with attractive current yields and potential for equity appreciation. Applicant's investment decisions are either made by its board of directors (the "Board"), based on recommendations of an investment committee comprised of senior officers of applicant, or, for investments that meet certain objective criteria established by the Board, by the investment committee, under authority delegated by the Board. Applicant does not have an external investment adviser within the meaning of section 2(a)(20) of the Act.

2. Applicant requests an order under section 61(a)(3)(B) of the Act approving the Plan, which provides for the grant of options to purchase shares of applicant's common stock to directors who are neither officers nor employees of applicant ("Non-employee Directors").[2] Applicant has a nine member Board. Six of the seven current members of the Board are not "interested persons" (as defined in section 2(a)(19) of the Act) of the applicant ("Disinterested Directors").[3] The Board initially approved the Plan at a meeting held on March 30, 2000 and amended the Plan on October 30, 2003 and July 28, 2005. Applicant's stockholders approved the Plan at the annual meeting of stockholders held on May 3, 2000. The Plan would become effective on the date that the Commission issues an order on the application (the "Order Date").

3. The Plan provides that on the Order Date, options for 25,000 shares of applicant's common stock will be granted to each of the six Non-employee Directors serving on the Board as of October 20, 2003 (the "Initial Grants"). Two-thirds of the options granted under the Initial Grants will vest on the Order Date and the remaining one-third of such options will vest on the third anniversary of October 20, 2003. In the event that any of the six Non-employee Directors are not directors on the Order Date or leave the Board before their options vest fully, persons who join the Board as Non-employee Directors will be eligible to receive options for 15,000 shares of applicant's common stock (the "Other Grants"). The options granted under the Other Grants will vest in three equal installments of 5,000 shares on each of the three anniversaries of the date of the grant. The Plan provides that

[1] Section 2(a)(48) defines a BDC to be any closed-end investment company that operates for the purpose of making investments in securities described in sections 55(a)(1) through 55(a)(3) of the Act and makes available significant managerial assistance with respect to the issuers of such securities.

[2] The Non-employee Directors receive a $50,000 per year retainer payment and $1,500 for each Board or committee meeting attended, and reimbursement of related expenses. Prior to July 1, 2005, the retainer payment was set at a rate of $25,000 per year.

[3] The Board presently has two vacancies. All of the Non-employee Directors are Disinterested Directors.

a maximum of 150,000 shares of applicant's common stock may be issued to Non-employee Directors as a group. Under the Plan, no single Non-employee Director may receive options to purchase more than 25,000 shares of applicant's common stock.

4. Under the terms of the Plan, the exercise price of an option will not be less than 100% of the current market value of, or if no such market value exists, the current net asset value per share of, applicant's common stock on the date of the issuance of the option.[4] Options granted under the Plan will expire ten years from the date of grant and may not be assigned or transferred other than by will or the laws of descent and distribution. In the event of the death or disability of a Non-employee Director during such director's service, all such director's unexercised options will immediately become exercisable and may be exercised for a period of three years following the date of death (by such director's personal representative) or one year following the date of disability, but in no event after the respective expiration dates of such options. In the event of the termination of a Non-employee Director for cause, any unexercised options will terminate immediately. If a Non-employee Director's service is terminated for any reason other than by death, disability, or for cause, the options may be exercised within one year immediately following the date of termination, but in no event later than the expiration date of such options.

5. Applicant's officers and employees, including employee directors are eligible or have been eligible to receive options under applicant's six other stock option plans under which Non-employee Directors are not entitled to participate (the "Employee Plans"). Non-employee Directors have participated in applicant's prior Disinterested Director stock option plan under which options for all available shares have been granted (such plan together with the Employee Plans, the "Other Plans"). The maximum number of applicant's voting securities that would result from the exercise of all outstanding options issued or options issuable to the directors, officers, and employees under the Other Plans and the Plan would be 12,240,580 shares, or approximately 10.3% of the 118,913,029 shares of applicant's common stock outstanding as of December 30, 2005.

[4] Under the Plan, "current market value" (defined as "fair market value") is generally the closing sales price of applicant's shares as quoted on the Nasdaq National Market, or alternatively, on the exchange where applicant's shares are traded, on the day the option is granted.

Applicant has no outstanding warrants, options, or rights to purchase its voting securities, other than the options granted or to be granted to its directors, officers, and employees under the Other Plans and the Plan.

Applicant's Legal Analysis

1. Section 63(3) of the Act permits a BDC to sell its common stock at a price below current net asset value upon the exercise of any option issued in accordance with section 61(a)(3) of the Act. Section 61(a)(3)(B) of the Act provides, in pertinent part, that a BDC may issue to its non-employee directors options to purchase its voting securities pursuant to an executive compensation plan, provided that: (a) The options expire by their terms within ten years; (b) the exercise price of the options is not less than the current market value of the underlying securities at the date of the issuance of the options, or if no market exists, the current net asset value of the voting securities; (c) the proposal to issue the options is authorized by the BDC's shareholders, and is approved by order of the Commission upon application; (d) the options are not transferable except for disposition by gift, will or intestacy; (e) no investment adviser of the BDC receives any compensation described in section 205(a)(1) of the Investment Advisers Act of 1940, except to the extent permitted by clause (b)(1) or (b)(2) of that section; and (f) the BDC does not have a profit-sharing plan as described in section 57(n) of the Act.

2. In addition, section 61(a)(3) of the Act provides that the amount of the BDC's voting securities that would result from the exercise of all outstanding warrants, options, and rights at the time of issuance may not exceed 25% of the BDC's outstanding voting securities, except that if the amount of voting securities that would result from the exercise of all outstanding warrants, options, and rights issued to the BDC's directors, officers, and employees pursuant to an executive compensation plan would exceed 15% of the BDC's outstanding voting securities, then the total amount of voting securities that would result from the exercise of all outstanding warrants, options, and rights at the time of issuance will not exceed 20% of the outstanding voting securities of the BDC.

3. Applicant represents that the terms of the Plan meet all the requirements of section 61(a)(3)(B) of the Act. Applicant states that the Board is actively involved in the oversight of applicant's affairs and that it relies extensively on the judgment and experience of its Board. In addition to their duties as Board members generally, applicant states that the Non-employee Directors provide guidance and advice on operational issues, underwriting policies, credit policies, asset valuation and strategic direction, as well as serving on committees. Applicant believes that the Plan will provide significant at-risk incentives to Non-employee Directors to remain on the Board and devote their best efforts to ensure applicant's success. Applicant states that the options will provide a means for the Non-employee Directors to increase their ownership interests in applicant, thereby ensuring close identification of their interests with those of applicant and its stockholders. Applicant asserts that by providing incentives such as options, applicant will be better able to maintain continuity in the Board's membership and to attract and retain the highly experienced, successful and dedicated business and professional people who are critical to applicant's success as a BDC.

4. Applicant states that the maximum number of voting securities that would result from the exercise of all outstanding options issued or options issuable to the directors, officers, and employees under the Other Plans and the Plan would be 12,240,580 shares, or approximately 10.3% of applicant's common stock outstanding as of December 30, 2005, which is below the percentage limitations in the Act. Applicant asserts that, given the relatively small amount of common stock issuable upon the exercise of the options under the Plan, the exercise of options would not, absent extraordinary circumstances, have a substantial dilutive effect on the net asset value of applicant's common stock.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Jill M. Peterson,

Assistant Secretary.

[FR Doc. E6–1542 Filed 2–3–06; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. IC–27221]

Notice of Applications for Deregistration Under Section 8(f) of the Investment Company Act of 1940

January 31, 2006.

The following is a notice of applications for deregistration under section 8(f) of the Investment Company Act of 1940 for the month of January,

2006. A copy of each application may be obtained for a fee at the SEC's Public Reference Branch (tel. 202–551–5850). An order granting each application will be issued unless the SEC orders a hearing. Interested persons may request a hearing on any application by writing to the SEC's Secretary at the address below and serving the relevant applicant with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on February 27, 2006, and should be accompanied by proof of service on the applicant, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Secretary, U.S. Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090. For Further Information Contact: Diane L. Titus at (202) 551–6810, SEC, Division of Investment Management, Office of Investment Company Regulation, 100 F Street, NE., Washington, DC 20549–0504.

WPG Large Cap Growth Fund [File No. 811–1447]; WPG Tudor Fund [File No. 811–1745]; Weiss Peck & Greer Funds Trust [File No. 811–4404]

Summary: Each applicant seeks an order declaring that it has ceased to be an investment company. On April 29, 2005, each applicant transferred its assets to a corresponding series of the RBB Fund, Inc., based on net asset value. Total expenses of $667,090 incurred in connection with the reorganizations were paid by Robeco USA, L.L.C., applicants' investment adviser.

Filing Date: The applications were filed on December 16, 2005.

Applicants' Address: 909 Third Ave., 31st Floor, New York, NY 10022.

Security Municipal Bond Fund [File No. 811–3225]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. On October 14, 2005, applicant made a liquidating distribution to its shareholders, based on net asset value. Expenses of $14,017 incurred in connection with the liquidation were paid by Security Management Company, LLC, applicant's investment adviser.

Filing Date: The application was filed on November 30, 2005.

Applicant's Address: One Security Benefit Place, Topeka, KS 66636–0001.

Aquila Fund [File No. 811–4083]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. On December 31, 2004, applicant made a liquidating distribution to its shareholders, based on net asset value. Expenses of $1,113 incurred in connection with the liquidation were paid by Aquila Investment Management LLC, applicant's investment adviser.

Filing Date: The application was filed on December 19, 2005.

Applicant's Address: 380 Madison Ave., New York, NY 10017.

Forward Funds, Inc. [File No. 811–8419]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. On June 30, 2005, each series of applicant transferred its assets to corresponding series of Forward Funds, based on net asset value. Expenses of $580,000 incurred in connection with the reorganization were paid by Forward Management, LLC, applicant's investment adviser.

Filing Date: The application was filed on December 12, 2005.

Applicant's Address: 433 California St., Suite 1100, San Francisco, CA 94104.

Oppenheimer Multi-Sector Income Trust [File No. 811–5473]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. On July 22, 2005, applicant transferred its assets to Oppenheimer Strategic Income Fund, based on net asset value. Expenses of $88,313 incurred in connection with the reorganization were paid by applicant.

Filing Date: The application was filed on December 13, 2005.

Applicant's Address: 6803 S. Tucson Way, Centennial, CO 80112.

Oppenheimer Capital Preservation Fund [File No. 811–8799]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. On February 10, 2005, applicant transferred its assets to Oppenheimer Cash Reserves, based on net asset value. Expenses of $55,563 incurred in connection with the reorganization were paid by applicant.

Filing Date: The application was filed on December 20, 2005.

Applicant's Address: 6803 S. Tucson Way, Centennial, CO 80112.

Quadrant Fund, Inc. [File No. 811–21704]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. On November 3, 2005, applicant made a liquidating distribution to its shareholders, based on net asset value. Expenses of $75,000 incurred in connection with the liquidation were paid by applicant and GMAC Institutional Advisors LLC, applicant's investment adviser. Applicant has retained approximately $123,000 to pay additional accrued expenses for which it has not yet been billed.

Filing Date: The application was filed on December 21, 2005.

Applicant's Address: 116 Welsh Rd., Horsham, PA 19044.

Columbia National Municipal Bond Fund, Inc. [File No. 811–7832]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. On June 17, 2005, applicant made liquidating distribution to its shareholders, based on net asset value. Applicant paid approximately $27,510 in expenses incurred in connection with the liquidation.

Filing Dates: The application was filed on October 21, 2005 and amended on January 11, 2006.

Applicant's Address: One Financial Center, Boston, MA 02110.

Tax-Free Income Trust [File No. 811–7397]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. By October 18, 2005, applicant's two shareholders had redeemed all their shares at net asset value. Expenses of $4,890 incurred in connection with the liquidation were paid by Ameriprise Financial, Inc., applicant's investment adviser.

Filing Dates: The application was filed on November 18, 2005, and amended on January 18, 2006.

Applicant's Address: 901 Marquette Avenue South, Suite 2810, Minneapolis, MN 55402–3268.

BQT Subsidiary Inc. [File No. 811–10451]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. On December 13, 2004, applicant made a liquidating distribution to its shareholders based on net asset value. Applicant incurred no expenses in connection with the liquidation.

Filing Date: The application was filed on December 30, 2005.

Applicant's Address: 100 Bellevue Parkway, Wilmington, DE 19809.

Sterling Capital Corporation [File No. 811–1537]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. On September 13, 2005, applicant transferred its assets to The Gabelli Equity Trust Inc. ("Gabelli"). Applicant's shareholders received .7914 newly issued shares of Gabelli common stock for each share of applicant, which represented a 1.4% premium to applicant's net asset value. Expenses of $121,000 incurred in connection with the reorganization were paid by applicant. Applicant has transferred $250,000 in cash to a liquidating trust to pay applicant's remaining liabilities. Any cash remaining after applicant's liabilities are paid will be distributed pro rata to applicant's former shareholders.

Filing Date: The application was filed on December 15, 2005.

Applicant's Address: 100 Wall St., 11th Floor, New York, NY 10005.

Lorent Investment Company [File No. 811–2935]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. Applicant has never made a public offering of its securities and does not propose to make a public offering. Applicant has fewer than one hundred beneficial owners and will continue to operate as private investment vehicle in reliance on section 3(c)(1) of the Act.

Filing Dates: The application was filed on July 1, 2005, and amended on August 16, 2005 and January 13, 2006.

Applicant's Address: 500 West Harbor Dr., Suite 1213, San Diego, CA 92101.

Pilgrim Government Securities Income Fund, Inc. [File No. 811–4031]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. On February 23, 2001, applicant transferred its assets to ING GNMA Income Fund, Inc. (formerly Pilgrim GNMA Income Fund, Inc.), based on net asset value. Expenses of $106,385 incurred in connection with the reorganization were paid by applicant, the acquiring fund, and applicant's investment adviser, ING Investments, LLC.

Filing Dates: The application was filed on October 19, 2001, and amended on September 9, 2005 and January 24, 2006.

Applicant's Address: 7337 East Doubletree Ranch Rd., Scottsdale, AZ 85258.

Pilgrim Silver Fund, Inc. [File No. 811–4111]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. On March 23, 2001, applicant transferred its assets to ING Precious Metals Fund, Inc. (formerly Pilgrim Precious Metals Fund, Inc.), based on net asset value. Expenses of $28,135 incurred in connection with the reorganization were paid by applicant, the acquiring fund, and applicant's investment adviser, ING Investments, LLC.

Filing Dates: The application was filed on October 19, 2001, and amended on September 9, 2005 and January 24, 2006.

Applicant's Address: 7337 East Doubletree Ranch Rd., Scottsdale, AZ 85258.

Pilgrim SmallCap Asia Growth Fund, Inc. [File No. 811–7287]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. On March 23, 2001, applicant transferred its assets to ING Asia-Pacific Equity Fund, a series of ING Advisory Funds, Inc. (formerly Pilgrim Advisory Funds. Inc.), based on net asset value. Expenses of $19,892 incurred in connection with the reorganization were paid by applicant, the acquiring fund, and applicant's investment adviser, ING Investments, LLC.

Filing Dates: The application was filed on October 19, 2001, and amended on September 9, 2005, and January 24, 2006.

Applicant's Address: 7337 East Doubletree Ranch Rd., Scottsdale, AZ 85258.

Pilgrim Global Technology Fund, Inc. [File No. 811–9649]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. On March 23, 2001, applicant transferred its assets to ING Global Information Technology Fund, a series of ING Funds Trust (formerly Pilgrim Funds Trust), based on net asset value. Expenses of $20,972 incurred in connection with the reorganization were paid by applicant, the acquiring fund, and applicant's investment adviser, ING Investments, LLC.

Filing Dates: The application was filed on October 19, 2001, and amended on September 9, 2005 and January 24, 2006.

Applicant's Address: 7337 East Doubletree Ranch Rd., Scottsdale, AZ 85258.

Pilgrim High Yield Fund III [File No. 811–5496]; Pilgrim Global Income Fund, Inc. [File No. 811–4675]; Pilgrim Global Corporate Leaders Fund, Inc. [File No. 811–5113]; Pilgrim Worldwide Emerging Markets Fund, Inc. [File No. 811–1838]

Summary: Each applicant seeks an order declaring that it has ceased to be an investment company. On March 31, 2000, February 23, 2001, February 23, 2001 and April 27, 2001, respectively, each applicant transferred its assets to a corresponding series of ING Mutual Funds (formerly Pilgrim Mutual Funds), based on net asset value. Expenses incurred in connection with the reorganizations were paid by applicants, the acquiring funds, and applicants' investment adviser, ING Investments, LLC.

Filing Dates: The applications were filed on October 19, 2001, and amended on September 9, 2005 and January 24, 2006.

Applicants' Address: 7337 East Doubletree Ranch Rd., Scottsdale, AZ 85258.

Acacia Variable Annuity Separate Account (formerly Acacia National Variable Annuity Separate Account II) [File No. 811–07627]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. Substantially all the assets of Applicant were transferred by Acacia National Life Insurance Company (Acacia National) to Ameritas Variable Life Insurance Company (Ameritas) under an assumption and reinsurance agreement transaction approved by the Securities and Exchange Commission in Release No. IC–25763, dated October 4, 2002. The Board of Directors of the parent of Acacia National approved the transfer of assets to Ameritas on December 3, 2001, and Applicant completed the transfer of its assets effective November 1, 2004. Shareholder approval of the transfer was not required. The fund surviving the transfer is Ameritas Variable Separate Account VA. Ameritas paid all the expenses incurred in connection with the transfer.

Filing Date: The application was filed on November 29, 2005, as amended.

Applicant's Address: 7315 Wisconsin Avenue, Bethesda, MD 20814.

Acacia Variable Life Separate Account (formerly Acacia National Variable Life Separate Account 1) [File No. 811–08998]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. Substantially all

the assets of Applicant were transferred by Acacia National Life Insurance Company (Acacia National) to Ameritas Variable Life Insurance Company (Ameritas) under an assumption and reinsurance agreement transaction approved by the Securities and Exchange Commission in Release No. IC–25763, dated October 4, 2002. The Board of Directors of the parent of Acacia National approved the transfer of assets to Ameritas on December 3, 2001, and Applicant completed the transfer of its assets effective November 1, 2004. Shareholder approval of the transfer was not required. The fund surviving the transfer is Ameritas Variable Separate Account VL. Ameritas paid the expenses incurred in connection with the transfer.

Filing Date: The application was filed on November 29, 2005, as amended.

Applicant's Address: 7315 Wisconsin Avenue, Bethesda, MD 20814.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Nancy M. Morris,

Secretary.

[FR Doc. E6–1575 Filed 2–3–06; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. PA–35; File No. S7–04–06]

Privacy Act of 1974: Establishment of a New System of Records: Automated Emergency Notification System (SEC–53)

AGENCY: Securities and Exchange Commission.

ACTION: Notice of the establishment of a new system of records.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, as amended, 5 U.S.C. 552a, the Securities and Exchange Commission gives notice of a proposed Privacy Act system of records: "Automated Emergency Notification System (SEC–53)." This system will contain emergency contact information for current members, employees, and selected contractors of the Commission.

DATES: The new system will become effective March 20, 2006 unless further notice is given. The Commission will publish a new notice if the effective date is delayed to review comments or if changes are made based on comment received. To be assured of consideration, comments should be received on or before March 8, 2006.

ADDRESSES: Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/other.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File Number S7–04–06 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–9303.

All submissions should refer to File Number S7–04–06. This file number should be included on the subject line if e-mail is used. To help us process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/other.shtml*). Comments are also available for public inspection and copying in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549. All comments received will be posted without change; we do not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly.

FOR FURTHER INFORMATION CONTACT: Barbara A. Stance, Chief Privacy Officer, U.S. Securities and Exchange Commission, Operations Center, 6432 General Green Way, Mail Stop 0–7, Alexandria, VA 22312–2413, (202) 551–7209.

SUPPLEMENTARY INFORMATION: The Commission gives notice of the proposed establishment of a new system of records, entitled "Automated Emergency Notification System (SEC–53)." The new system will contain emergency contact information for current members, employees, and selected contractors of the Commission.

The Commission has submitted a report of the new system of records to the Senate Committee on Homeland Security and Governmental Affairs, the House Committee on Government Reform, and the Office of Management and Budget, pursuant to 5 U.S.C. 552a(r) of the Privacy Act of 1974, as amended, and Appendix I to OMB Circular A–130, "Federal Agency Responsibilities for Maintaining Records About Individuals," as amended on February 20, 1996 (61 FR 6435).

Accordingly, the Commission is adding a new system of records to read as follows:

SEC–53

SYSTEM NAME:

Automated Emergency Notification System.

SYSTEM LOCATION:

Securities and Exchange Commission, 100 F Street, NE, Washington, DC 20549.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Members and employees of the Commission, and selected contractors.

CATEGORIES OF RECORDS IN THE SYSTEM:

Name, Commission division or office, home zip code, work and personal electronic mail addresses, work, home and cellular telephone numbers, and Blackberry PIN numbers.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301 and Executive Order 12656 of Nov. 18, 1988 on Assignment of Emergency Preparedness Responsibilities.

PURPOSE(S):

The purpose of this system of records is to maintain emergency contact information for current members, employees and selected contractors of the Commission. The system provides for high-speed message delivery that reaches all Commission personnel in response to threat alerts issued by the Department of Homeland Security, weather related emergencies or other critical situations that disrupt the operations and accessibility of a worksite. The system also provides for personnel accountability during an emergency, through personnel sign-in and rapid alert and notification.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSE OF SUCH USES:

In addition to the conditions of disclosure under 5 U.S.C. 552a(b), Commission staff may provide these records to any Federal government authority for the purpose of coordinating and reviewing agency continuity of operations plans or emergency contingency plans developed for responding to Department of Homeland Security threat alerts, weather related emergencies or other critical situations.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained in a computerized database and on paper. Paper documents are kept in filing cabinets in secured facilities.

RETRIEVABILITY:

Records may be retrieved by the individual's name or by the categories listed above under "Categories of Records in the System."

SAFEGUARDS:

Records are safeguarded by restricted computer passwords, locked file cabinets, and safes. Access to the records is restricted to those who require the records in the performance of official duties related to the purposes for which the system is maintained.

RETENTION AND DISPOSAL:

Periodic purging and disposal of those records concerning individuals no longer members, employees or contractors of the Commission. Otherwise, records are retained and disposed of in accordance with the appropriate National Archives and Records Administration General Records Schedules.

SYSTEM MANAGER(S) AND ADDRESS:

Executive Director, Office of the Executive Director, U.S. Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1627.

NOTIFICATION PROCEDURES:

All requests to determine whether this system of records contains a record pertaining to the requesting individual may be directed to the Privacy Act Officer, U.S. Securities and Exchange Commission, Operations Center, 6432 General Green Way, Mail Stop 0–7, Alexandria, VA 22312–2413.

RECORD ACCESS PROCEDURES:

Persons wishing to obtain information on the procedures for gaining access to or contesting the contents of this record may contact the Privacy Act Officer, U.S. Securities and Exchange Commission, Operations Center, 6432 General Green Way, Mail Stop 0–7, Alexandria, VA 22312–2413.

CONTESTING RECORDS PROCEDURES:

See record access procedures above.

RECORD SOURCE CATEGORIES:

Information is provided by current members and employees of the Commission and selected contractors.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

Dated: January 31, 2006.

By the Commission.

Nancy M. Morris,

Secretary.

[FR Doc. E6–1574 Filed 2–3–06; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–53191; File No. SR–Amex–2005–061]

Self-Regulatory Organizations; American Stock Exchange LLC; Notice of Filing and Order Granting Accelerated Approval to Proposed Rule Change and Amendment No. 1 Thereto Relating to the Listing and Trading of Options on Certain Russell Indexes

January 30, 2006.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 ("Act") and Rule 19b–4 thereunder,[2] notice is hereby given that on June 3, 2005, the American Stock Exchange LLC ("Amex" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange.[3] On July 14, 2005, Amex submitted Amendment No. 1 to the proposed rule change.[4] The Commission is publishing this notice and order to solicit comments on the proposed rule change, as amended, from interested persons and to approve the proposal on an accelerated basis.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to list and trade on the Exchange the following cash-settled, European-style index options on the full value of the following Russell Indexes: (1) Russell 1000® Index; (2) Russell 1000® Growth Index; (3) Russell 1000® Value Index; (4) Russell 2000® Index; (5) Russell 2000® Growth Index; (6) Russell 2000® Value Index; (7) Russell 3000® Index; (8) Russell 3000® Growth Index; (9) Russell 3000® Value Index; (10) Russell Midcap® Index; (11) Russell Midcap® Growth Index; (12) Russell Midcap® Value Index and (13) Russell Top 50® Index (each an "Index," and collectively, the "Russell Indexes" or "Indexes"). Additionally, the Exchange is also proposing to be able to list and trade long-term options on each of the full value Russell Indexes noted above.[5]

The text of the proposed rule change is available on Amex's Web site at *http://www.amex.com*, at Amex's principal office and at the Commission's Public Reference Room.

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 Exchange 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 III below. The Exchange 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

(1) Purpose

The purpose of the proposed rule change is to permit the Exchange to list and trade cash-settled, European-style, stock index options on the Russell Indexes. Each Russell Index is a capitalization-weighted index containing various groups of stocks drawn from the largest 3,000 companies incorporated in the U.S. and its territories. All component securities of the Russell Indexes are traded on the Amex, New York Stock Exchange, Inc. ("NYSE"), or The Nasdaq Stock Market, Inc. ("Nasdaq"). Options contracts on the Russell Indexes (except for the Russell Top 50) are currently listed and traded on the Chicago Board Options Exchange, Incorporated ("CBOE") and the International Securities Exchange, Inc. ("ISE").[6]

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Commission has made technical and clarifying changes to this notice with Amex's consent. Telephone conversation between Florence Harmon, Special Counsel, Division of Market Regulation ("Division"), Commission, Angela Muehr, Attorney, Division, Commission, Kristie Diemer, Attorney, Division, Commission and Jeffrey P. Burns, Associate General Counsel, Amex on June 29, 2005.

[4] In Amendment No. 1, Amex made clarifying changes to the contract specifications.

[5] Under Amex Rule 903C(a)(iii), "Long-term Options Series," the Exchange may list long-term options that expire twelve to sixty months from the date of issuance.

[6] *See* Securities Exchange Act Release Nos. 51619 (April 27, 2005), 70 FR 22947 (May 3, 2005) (approving the listing and trading of ISE options on 21 Russell Indexes); 49388 (March 10, 2004), 69 FR 12720 (March 17, 2004) (approving listing and trading on CBOE of options, including LEAPS, on the Russell Top 200 Index, Russell Top 200 Growth Index, and the Russell Top 200 Value Index); 48591 (October 2, 2003), 68 FR 58728 (October 10, 2003) (approving listing and trading on CBOE of options, including LEAPS, on the Russell 3000 Index, Russell 3000 Value Index, Russell 3000 Growth Index, Russell 2000 Value Index, Russell 2000 Growth Index, Russell 1000 Index, Russell 1000 Value Index, Russell 1000 Growth Index, Russell MidCap Index, Russell MidCap Value Index, and

Continued

Index Design and Composition

The Russell Indexes are designed to be a comprehensive representation of the investable U.S. equity market. These Indexes are capitalization-weighted and include only those common stocks of corporations domiciled in the U.S. and its territories and that are traded on Amex, NYSE, or Nasdaq. The component securities are weighted by their "available" market capitalization (also called "float-adjusted" market capitalization), which is calculated by multiplying the primary market price by the "available" shares.[7]

The following is a brief description of each Index:[8]

Russell 3000—Measures the performance of the 3,000 largest U.S. companies based on total market capitalization, which represents approximately 98% of the investable U.S. equity market.

Russell 3000 Growth—Measures the performance of those Russell 3000 Index companies with higher price-to-book ratios and higher forecasted growth values. The stocks in this index are also members of either the Russell 1000 Growth or the Russell 2000 Growth indexes.

Russell 3000 Value—Measures the performance of those Russell 3000 Index companies with lower price-to-book ratios and lower forecasted growth values. The stocks in this index are also members of either the Russell 1000 Value or the Russell 2000 Value.

Russell 2000—Measures the performance of the 2,000 smallest companies in the Russell 3000 Index, representing approximately 8% of the total market capitalization of the Russell 3000 Index.

Russell 2000 Growth—Measures the performance of those Russell 2000 Companies with higher price-to-book ratios and higher forecasted growth values.

Russell 2000 Value—Measures the performance of those Russell 2000 Companies with lower price-to-book ratios and lower forecasted growth values.

Russell 1000—Measures the performance of the 1,000 largest companies in the Russell 3000 Index, which represents approximately 92% of the total market capitalization of the Russell 3000 Index.

Russell 1000 Growth—Measures the performance of those Russell 1000 Companies with higher price-to-book ratios and higher forecasted growth values.

Russell 1000 Value—Measures the performance of those Russell 1000 Companies with lower price-to-book ratios and lower forecasted growth values.

Russell Midcap—Measures the performance of the 800 smallest companies in the Russell 1000 Index, which represent approximately 26% of the total market capitalization of the Russell 1000 Index.

Russell Midcap Growth—Measures the performance of those Russell Midcap companies with higher price-to-book ratios and higher forecasted growth values. The stocks are also members of the Russell 1000 Growth index.

Russell Midcap Value—Measures the performance of those Russell Midcap companies with lower price-to-book ratios and lower forecasted growth values. The stocks are also members of the Russell 1000 Value index.

Russell Top 50—Measures the performance of the 50 largest companies in the Russell 3000 Index, representing approximately 41% of the total market capitalization of the Russell 3000.

All equity securities listed on Amex, NYSE, or Nasdaq are considered for inclusion in the universe of stocks that comprise the Russell Indexes, with the following exceptions: (1) Stocks trading less than $1.00 per share on May 31 each year; (2) non-U.S. incorporated companies; and (3) preferred and convertible preferred stock, redeemable shares, participating preferred stock, warrants and rights, trust receipts, royalty trusts, limited liability companies, Bulletin Board and Pink Sheet stocks, closed-end investment companies, limited partnerships, and foreign stocks. As a special exception, Berkshire Hathaway is also excluded. The Russell 3000 Index is comprised of the top 3,000 eligible stocks ranked by available market capitalization. All of these stocks are "reported securities," as defined in Rule 11Aa3–1(a)(4) under the Act.[9]

All of the Russell Indexes described above are subsets of the Russell 3000 Index. The Growth and Value versions of each of the Russell 1000, Russell 2000, Russell 3000 and Russell Midcap may contain common components, but the capitalization of those components is apportioned so that the sum of the total capitalization of the Growth and Value indexes equals the total capitalization of the respective primary index.

As of May 5, 2005, the stocks comprising the Russell 3000 Index (and the other Russell Indexes) had an average market capitalization of $4.519 billion ranging from a high of $380.007 billion (General Electric Co.) to a low of $22.2 million (ITC Deltacom, Inc.). The number of available shares outstanding ranged from a high of 10.8 billion (Microsoft Corp.) to a low of 1.26 million (Seaboard Co.), and averaged 144.5 million shares. The six-month average daily trading volume for Russell 3000 Index components was 1.072 million shares per day, ranging from a high of 83.2 million shares per day (Sirus Satellite Radio) to a low of 1,500 shares per day (Wesco Financial Corp.). Component securities that averaged less than 50,000 shares per day for the previous six months accounted for 0.75% of the index weight. Over 66.18% of the Russell 3000 Index components satisfied Amex's listing criteria for equity options as set forth in Amex Rule 915, representing over 94.82% of the index weight.

The Russell Indexes themselves range in capitalization from a high of $13.6 trillion (Russell 3000) to a low of $866.2 billion (Russell 2000 Growth). The number of index components range from a high of 3,019 (Russell 3000) to a low of 49 (Russell Top 50). The Russell 1000 Growth Index has the highest percentage of options-eligible components with 100% by weight and 100% by number. The Russell 2000 Value Index has the lowest percentage of options-eligible components with 54.70% by weight and 44.97% by number.

Index Calculation and Index Maintenance

The values of each Index are currently calculated by Reuters on behalf of the Frank Russell Company and would be disseminated at 15-second intervals during regular Amex trading hours to market information vendors via the

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Russell MidCap Growth Index); and 31382 (October 30, 1992), 57 FR 52802 (November 5, 1992) (approving listing and trading on CBOE of options, including LEAPS, on the Russell 2000 Index). Amex recently listed the Rydex Russell Top 50 ETF and options on the Rydex Russell Top 50 ETF. *See http://www.amex.com.*

[7] "Available shares" are the total shares outstanding less corporate cross-owned shares, ESOP and LESOP-owned shares comprising 10% or more of shares outstanding, unlisted share classes and shares held by an individual, a group of individuals acting together, a corporation not in the index that owns 10% or more of the shares outstanding or shares subject to IPO lock-ups. ESOP and LESOP-owned shares represent, generally, those shares of a corporation that are owned through employee stock ownership plans.

[8] Additional information about the Russell Indexes can be found at *http://russell.com/us/indexes/us/definitions.asp.*

[9] 17 CFR 240.11Aa3–1(a)(4), n/k/a Rule 600(47) of Regulation NMS under the Act, 17 CFR 242.600(47).

Telephone conversation between Florence Harmon, Special Counsel, Division, Commission and Jeffrey P. Burns, Associate General Counsel, Amex on January 29, 2006.

Options Price Reporting Authority ("OPRA").

The methodology used to calculate the value of the Russell Indexes is similar to the methodology used to calculate the value of other well-known market-capitalization weighted indexes. The level of each Index reflects the total market value of the component stocks relative to a particular base period and is computed by dividing the total market value of the companies in each Index by its respective index divisor. The divisor is adjusted periodically to maintain consistent measurement of each Index. The following is a table of base dates and the respective Index levels as of May 5, 2005:

Index	Base date/ Base index value	05/05/2005 Index value
Russell 3000	12/31/86 = 140.00	670.29
Russell 3000 Growth	3/16/00 = 700.00	379.95
Russell 3000 Value	3/16/00 = 700.00	848.58
Russell 2000	12/31/86 = 135.00	595.64
Russell 2000 Growth	3/16/00 = 500.00	303.72
Russell 2000 Value	3/16/00 = 500.00	892.40
Russell 1000	12/31/86 = 130.00	632.33
Russell 1000 Growth	8/31/92 = 200.00	470.62
Russell 1000 Value	8/31/92 = 200.00	648.51
Russell Midcap	12/31/86 = 200.00	768.48
Russell Midcap Growth	3/16/00 = 500.00	321.56
Russell Midcap Value	3/16/00 = 500.00	859.76
Russell Top 50	12/31/01 = 1,000	973.11

Options on the Russell Indexes would expire on the Saturday following the third Friday of the expiration month. Trading in options on the Russell Indexes would normally cease at 4:15 p.m. Eastern time ("ET") on the Thursday preceding an expiration Saturday. The exercise settlement value at expiration of each Russell Index option would be calculated by Reuters on behalf of the Frank Russell Company, based on the opening prices of the Index's component securities on the last business day prior to expiration ("Settlement Day").[10] The Settlement Day would normally be the Friday preceding "Expiration Saturday." If a component security in a Russell Index does not trade on Settlement Day, the last reported sales price in the primary market from the previous trading day would be used to calculate the settlement value. Settlement values for the Russell Indexes would be disseminated by OPRA.

The Russell Indexes are monitored and maintained by the Frank Russell Company. The Frank Russell Company is responsible for making all necessary adjustments to the Indexes to reflect component deletions, share changes, stock splits, stock dividends (other than an ordinary cash dividend), and stock price adjustments due to restructuring, mergers, or spin-offs involving the underlying components. Some corporate actions, such as stock splits and stock dividends, require simple changes to the available shares outstanding and the stock prices of the component securities. Other corporate actions, such as share issuances, change the market value of the Indexes and would require the use of an index divisor to effect adjustments.

The Russell Indexes are re-constituted annually on June 30th, based on prices and available shares outstanding as of the preceding May 31st. New index components are added only as part of the annual re-constitution and, after which, should a component security be removed from an index for any reason, it cannot be replaced until the next re-constitution.

Although not involved in the maintenance of any of the Russell Indexes, the Exchange would monitor each Russell Index on a quarterly basis and notify the Commission's Division by filing a proposed rule change pursuant to Rule 19b–4 of the Act[11] if: (i) The number of securities in any Index drops by one-third or more; (ii) 10% or more of the weight of any Index is represented by component securities having a market value of less than $75 million; (iii) less than 80% of the weight of any Index is represented by component securities that are eligible for options trading pursuant to Amex Rule 915; (iv) 10% or more of the weight of any Index is represented by component securities trading less than 20,000 shares per day; or (v) the largest component security in any Index accounts for more than 15% of the weight of the Index, or the largest five components in the aggregate account for more than 50% of the weight of the Index.

The Exchange would also notify the Division immediately if the Frank Russell Company ceases to maintain or calculate any of the Russell Indexes on which Amex is proposing to list and trade options, or if the value of any of these Russell Indexes is not disseminated every 15 seconds by a widely available source. If a Russell Index ceases to be maintained or calculated, or its values are not

[10] The aggregate exercise value of the option contract is calculated by multiplying the Index value by the Index multiplier, which is 100.

[11] 17 CFR 240.19b–4.

disseminated every 15 seconds by a widely available source, the Exchange would not list any additional series for trading and would limit all transactions in options on that Index to closing transactions only for the purpose of maintaining a fair and orderly market and protecting investors.

Contract Specifications

The proposed contract specifications for the options on the Russell Indexes are based on the contract specifications of similar options currently listed on CBOE and ISE.[12] The Russell Indexes are broad-based indexes, as defined in Amex Rule 900C(b)(1). Options on the Russell Indexes would be European-style and a.m. cash-settled. The Exchange's standard trading hours for broad-based index options (9:30 a.m. to 4:15 p.m. ET), as set forth in Commentary .02 to Amex Rule 1, would apply to options on the Russell Indexes. Exchange rules that apply to the trading of options on broad-based indexes would also apply to options on the Russell Indexes.[13] The trading of these options would also be subject to, among others, Exchange rules governing margin requirements and trading halt procedures for index options.

For options on the Russell Indexes, the Exchange proposes to establish in Amex Rule 904C(b) an aggregate position limit of 50,000 contracts on the same side of the market, provided that no more than 30,000 of such contracts are in the nearest expiration month series.[14] These limits are identical to the limits applicable to options based on the Russell Indexes that currently trade on CBOE and ISE.[15]

However, neither CBOE nor ISE currently list and trade options on the Russell Top 50. The Exchange believes that the proposed position and exercise limits for the Russell Top 50 is appropriate because it measures the performance of the 50 largest companies in the Russell 3000 Index, representing approximately 41% of the total market capitalization of the Russell 3000. Russell Midcap options traded on both CBOE and ISE have the same position and exercise limits as are proposed for the Russell Top 50 options. The Russell Midcap measures the performance of the 800 smallest companies in the Russell 1000 Index, representing approximately 26% of the total market capitalization of the Russell 1000 Index. Since the Russell Top 50 represents 41% of the Russell 3000 as compared to the Russell Midcap representing 26% of the Russell 1000, the Exchange believes that the same position and exercise limits are appropriate. Accordingly, the Exchange submits that the Russell Top 50 should have position and exercise limits of 50,000 contracts with no more than 30,000 for the near term.

Commentary .01(c) to Amex Rule 904C provides that position limits for hedged index options may not exceed twice the established position limits for broad stock index groups. The Exchange proposes that a hedge exemption of 75,000 be available for the Russell Indexes.

Furthermore, pursuant to Commentary .02 to Amex Rule 904C, proprietary accounts of member organizations could receive an exemption of up to three times the established position limit for the purpose of facilitating public customer orders, to the extent they comply with the procedures and criteria listed in Commentary .02 to Amex Rules 950(d) and 950(d)—ANTE.

The Exchange proposes to apply broad-based index margin requirements for the purchase and sale of options on the Russell Indexes. Accordingly, purchases of put or call options with nine months or less until expiration would have to be paid for in full. Writers of uncovered put or call options would have to deposit/maintain 100% of the option proceeds, plus 15% of the aggregate contract value (current index level × $100), less any out-of-the-money amount, subject to a minimum of the option proceeds plus 10% of the aggregate contract value for call options and a minimum of the option proceeds plus 10% of the aggregate exercise price amount for put options.

The Exchange proposes to set a strike price interval of at least 2½ points for a near-the-money series in a near-term expiration month when the level of a Russell Index is below 200, a 5-point strike price interval for any options series with an expiration up to one year, and at least a 10-point strike price interval for any longer-term option. The minimum tick size for series trading below $3 would be $0.05, and for series trading at or above $3 would be $0.10.

The Exchange proposes to list options on the Russell Indexes in the three consecutive near-term expiration months, plus up to three successive expiration months in the March cycle. For example, consecutive expirations of January, February, March, plus June, September, and December expirations would be listed.[16] In addition, long-term option series having up to 60 months to expiration may be traded.[17] The trading of long-term options on the Russell Indexes would be subject to the same rules that govern all the Exchange's index options, including sales practice rules, margin requirements, and trading rules.

Surveillance and Capacity

The Exchange represents that it has an adequate surveillance program in place for options on the Russell Indexes and intends to apply those same procedures that it applies to the Exchange's other index options. In addition, the Exchange is a member of the Intermarket Surveillance Group ("ISG"). The members of the ISG include all of the national securities exchanges, plus the National Association of Securities Dealers, Inc. The ISG members work together to coordinate surveillance and share information regarding the stock and options markets. In addition, the major futures exchanges are affiliated members of the ISG, which allows for the sharing of surveillance information for potential intermarket trading abuses.

The Exchange also represents that it has the necessary systems capacity to support the new options series that would result from the introduction of options on the Russell Indexes, including long-term options. The Exchange has provided the Commission with system capacity information to support this representation.

(2) Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6 of the Act,[18] in general, and furthers the objectives of Section 6(b)(5) of the Act,[19] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market and a national market system.

B. Self-Regulatory Organization's Statement on Burden on Competition*

The Exchange believes that the proposed rule change does not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

[12] *See supra* note 6.

[13] *See* Amex Rules 900C through 980C.

[14] 14 The same limits that apply to position limits would apply to exercise limits for these products.

[15] *See* CBOE Rule 24.4(e) and ISE Rule 2004.

[16] *See* Amex Rule 903C(a).

[17] *See* Amex Rule 903C(a)(iii).

[18] 15 U.S.C. 78f.

[19] 15 U.S.C. 78f(b)(5).

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change, as amended, is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File Number SR–Amex–2005–061 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–Amex–2005–061. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). 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, 100 F Street, NE, Washington, DC 20549. Copies of such filing also will be available for inspection and copying at the principal office of Amex. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–Amex–2005–061 and should be submitted on or before February 27, 2006.

IV. Commission's Findings and Order Granting Accelerated Approval of Proposed Rule Change

The Commission finds that the proposed rule change, as amended, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[20] In particular, the Commission believes that the proposal is consistent with Section 6(b)(5) of the Act,[21] which requires that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and in general to protect investors and the public interest.

The Commission notes that it previously has found that the listing and trading on CBOE and ISE of options on most of the Russell Indexes described above, and CBOE's position and ISE's position and exercise limits associated with those options, are consistent with the Act. Amex has proposed substantially the same contract specifications for these options, as well as identical position and exercise limits for these options. The Commission presently is not aware of any issue that would cause it to revisit those earlier findings or preclude the listing and trading of these options on Amex.

Amex also has proposed to list and trade new options on the Russell Top 50 Index—options that have not previously been approved by the Commission for listing and trading on any national securities exchange. The Commission believes that the composition of this Index and the characteristics of Amex's proposed options on this Index will minimize the potential for manipulation, and that listing and trading them on Amex is reasonable and consistent with the Act.

As noted above, the Russell Indexes are designed to represent broad segments of the U.S. equity securities markets. Furthermore, Amex has represented that it would notify the Commission if: (i) The number of securities in any Index drops by one-third or more; (ii) 10% or more of the weight of any Index is represented by component securities having a market value of less than $75 million; (iii) less than 80% of the weight of any Index is represented by component securities that are eligible for options trading pursuant to Amex Rule 915; (iv) 10% or more of the weight of any Index is represented by component securities trading less than 20,000 shares per day; or (v) the largest component security accounts for more than 15% of the weight of any Index or the largest five components in the aggregate account for more than 50% of the weight of any Index.

The Commission also believes that the position and exercise limits for the new Russell Index options, including the index hedge exemption from such position limits, are reasonable and consistent with the Act. These limits are modeled on existing position and exercise limits for options on very similar Russell Indexes that previously have been approved by the Commission.

In approving this proposal, the Commission has specifically relied on the following representations made by the Exchange:

1. The Exchange will notify the Division immediately if the Frank Russell Company ceases to maintain or calculate any Russell Index on which an Amex option is based, or if the value of any such Russell Index is not disseminated every 15 seconds by a widely available source. If a Russell Index ceases to be maintained or calculated, or its values are not disseminated every 15 seconds by a widely available source, the Exchange will not list any additional series on that Index and will limit all transactions in such options to closing transactions only for the purpose of maintaining a fair and orderly market and protecting investors.

2. The Exchange has an adequate surveillance program in place for the proposed options on the Russell Indexes.

3. The additional quote and message traffic that will be generated by listing and trading the proposed options on the Russell Indexes will not exceed the Exchange's current message capacity allocated by the Independent System Capacity Advisor.

The Commission further notes that, in approving this proposal, it relied on the Exchange's discussion of how the Frank Russell Company currently calculates the Russell Indexes. If the manner in which any Russell Index is calculated were to change substantially, this approval order, with respect to any Amex options on that Index, might no longer be effective.

The Commission finds good cause for approving this proposal before the thirtieth day after the publication of notice thereof in the **Federal Register**. Most of the proposed options on the Russell Indexes already have been

[20] In approving this proposal, the Commission has considered its impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[21] 15 U.S.C. 78f(b)(5).

approved for listing and trading on another exchange and are governed by contract specifications that are substantially the same as those proposed by Amex. The new options proposed by Amex will be governed by contract specifications that are substantially the same as those that govern the similar existing products. Therefore, accelerating approval of Amex's proposal should benefit investors by creating, without undue delay, additional competition in the market for the existing options, as well as an additional investment opportunity with regard to the new options.

V. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[22] that the proposed rule change, as amended (SR–Amex–2005–061), is hereby approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[23]

Nancy M. Morris,

Secretary.

[FR Doc. E6–1536 Filed 2–3–06; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–53187; File No. SR–NASD–2006–006]

Self-Regulatory Organizations; National Association of Securities Dealers, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change and Amendment No. 1 Thereto To Modify the Hours of Operation of Nasdaq's Brut System

January 30, 2006.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on January 20, 2006, the National Association of Securities Dealers, Inc.("NASD"), through its subsidiary, The Nasdaq Stock Market, Inc. ("Nasdaq"), submitted to the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by Nasdaq. Nasdaq filed the proposed rule change pursuant to section 19(b)(3)(A) of the Act[3] which renders it effective upon filing with the Commission. On January 25, 2006, the Amex filed Amendment No. 1 to the proposed rule change.[4] 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

Nasdaq proposes to amend NASD Rule 4912. The text of the proposed rule change is below. Additions are *italicized;* deletions are [bracketed].[5]

* * * * *

4912. Normal Business Hours

The Brut System operates from [6:30] 7:30 a.m. to 8:00 p.m. Eastern Time on each business day.

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, Nasdaq 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. Nasdaq 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 Statutory Basis for, the Proposed Rule Change

1. Purpose

Nasdaq proposes to modify the starting time for the Brut ECN hours of operation, order acceptance time, from 6:30 a.m. to 7:30 a.m. (Eastern Time). This change will standardize the system start times of the Nasdaq Market Center and Nasdaq's Brut Facility.

The current configuration allows connectivity and order entry from the time the System is brought online beginning at 6:30 a.m., which allows orders and executions to begin at 6:30 a.m.[6]

The proposed amendment would:

(1) Allow client connection from System up time, scheduled to begin at 6:30 a.m. (this process takes 10–15 minutes);

(2) Reject orders entered prior to 7:30 a.m.;

(3) Allow orders and executions beginning at 7:30 a.m.

2. Statutory Basis

Nasdaq believes that the proposed rule change is consistent with section 15A of the Act,[7] in general, and furthers the objectives of section 15A(b)(6) of the Act,[8] in particular, in that it is designed to protect investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

Nasdaq does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written 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

Nasdaq has filed the proposed rule change pursuant to section 19(b)(3)(A) of the Act[9] and subparagraph (f)(6) of Rule 19b–4 thereunder.[10] Because the foregoing proposed rule change: (1) Does not significantly affect the protection of investors or the public interest; (2) does not impose any significant burden on competition; and (3) does not become operative for 30 days from the date of filing, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6) thereunder. As required under Rule 19b–4(f)(6)(iii), Nasdaq provided the Commission with written notice of its intent to file the proposed rule change at least five business days prior to filing the proposal with the Commission or such shorter period as designated by the Commission.

At any time within 60 days of the filing of such proposed rule change, the

[22] 15 U.S.C. 78s(b)(2).

[23] 17 CFR 200.30–3(a)12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] Amendment No. 1 clarified that the filing was made pursuant to section 19(b)(3)(A)(iii) of the Act and Rule 19b–4(f)(6) thereunder.

[5] Changes are marked to the rule text that appears in the electronic NASD Manual found at *http://www.nasd.com*. Prior to the date when The NASDAQ Stock Market LLC ("NASDAQ LLC") commences operations, NASDAQ LLC will file a conforming change to the rules of NASDAQ LLC approved in Securities Exchange Act Release No. 53128 (January 13, 2006).

[6] Phone call from Jonathan Cayne, Associate General Counsel, Nasdaq, to Angela R. Muehr, Attorney, Commission, on January 27, 2006.

[7] 7 15 U.S.C. 78o–3.

[8] 8 15 U.S.C. 78o–3(6).

[9] 9 15 U.S.C. 78s(b)(3)(A).

[10] 10 17 CFR 240.19b–4(f)(6).

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 Act.[11]

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/ sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File Number SR–NASD–2006–006 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASD–2006–006. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). 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 Room. Copies of such filing also will be available for inspection and copying at the principal office of Nasdaq. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASD–2006–006 and should be submitted on or before February 27, 2006.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[12]

Nancy M. Morris,

Secretary.

[FR Doc. E6–1537 Filed 2–3–06; 8:45 am]

BILLING CODE 8010–01–P

[11] The effective date of the original proposed rule change is January 20, 2006 and the effective date of Amendment No. 1 is January 25, 2006. The proposed rule change does not become operative for 30 days from the date of filing. For purposes of calculating the 60-day period within which the Commission may summarily abrogate the proposed rule change, as amended, under section 19(b)(3)(C) of the Act, the Commission considers the period to commence on January 25, 2006, the date on which Nasdaq submitted Amendment No. 1. *See* 15 U.S.C. 78s(b)(3)(C).

[12] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–53189; File No. SR–NASD–2006–007]

Self-Regulatory Organizations; National Association of Securities Dealers, Inc; Notice of Filing of Proposed Rule Change Relating to Position Limits and Position Reporting Obligations for Conventional Index and Equity Options

January 30, 2006.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Exchange Act")[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on January 23, 2006, the National Association of Securities Dealers, Inc. ("NASD") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by NASD. 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

NASD is proposing to amend NASD Rule 2860 to: (a) Revise the definition of the term "underlying index" to include indexes underlying standardized index options and other indexes that meet certain specified criteria; and (b) allow members to calculate the position limits, in accordance with volume and float criteria specified by the options exchanges, for conventional equity options overlying securities that are part of the FTSE All-World Index Series.[3] The text of the proposed rule change is available on the NASD's Web site (*http://www.nasd.com*), at the NASD's principal office, and at the Commission's Public Reference Room.

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 NASD 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 Exchange 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 Statutory Basis for, the Proposed Rule Change

1. Purpose

Amendment to Definition of "Underlying Index": NASD Rule 2860 governs the activities of members in standardized and conventional options contracts. Paragraph (b)(5) of Rule 2860 imposes a position-reporting obligation on members when they or their customers establish options positions that exceed certain thresholds. Specifically, members are required to file, or cause to be filed, a report with NASD with respect to each account that establishes an aggregate position of 200 or more contracts on the same side of the market covering the same underlying security or index. The current definition of "underlying index" is limited to an index upon which a Nasdaq index option is based.[4] Since Nasdaq no longer trades any index options, this definition fails to require members to report positions in conventional index options. The proposed rule change would require members to report positions in conventional[5] index options and would require access firms to report position limits in standardized index options.[6] In

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Financial Times and the London Stock Exchange operate the FTSE All-World Index Series, which covers approximately 30 different countries and over 1900 stocks.

[4] Nasdaq briefly traded stock index options in the mid-1980s.

[5] A "conventional option" is an option contract not issued or subject to issuance by the Options Clearing Corporation. *See* Rule 2860(b)(2)(N).

[6] As noted in *Notice to Members* 01–01, the options position reporting requirements are applicable to all standardized options positions established by "access" firms or their customers and all conventional options positions established by members or their customers. Access firms, in this context, are understood to be NASD members.

Continued

a separate filing, in connection with NASD's proposed rule changes to reflect Nasdaq's separation from NASD following the Commission's approval of Nasdaq as a national securities exchange,[7] NASD has proposed to amend Rule 2860 to remove all references to Nasdaq.[8]

To require members to report members' and customers' positions in conventional index options, NASD proposes amending the definition of "underlying index" to mean an index underlying a "standardized index option" or "conventional index option." In addition, the proposed rule change would define the terms "standardized index option" and "conventional index option." Under the proposed rule change, the definition of "underlying index" would include indexes such as the S&P 500, Dow Jones Industrial Average, and the Nasdaq 100, because these indexes underlie standardized index options that are issued, or subject to issuance, by the Options Clearing Corporation.

The proposed rule change also would amend the definition of "underlying index" to include certain indexes that do not underlie standardized index options but that meet specified criteria. The proposed criteria for customized indexes are based upon the standards in place at the options exchanges for listing narrow-based index options.[9] The purpose of these criteria is to exclude from the definition of "underlying index" indexes that are so narrowly constructed that they are the economic equivalent of, or have attributes of, an equity option on common stock. These criteria also serve to prevent the creation of an index so narrow as to subvert position limit requirements, which do not apply to conventional index options.[10]

Under the proposed rule change, a member would have the burden of demonstrating that an index meets the specified criteria before it would be considered a "conventional index option." Thus, members should maintain detailed records to be able to demonstrate promptly, upon a request from NASD, that a particular "conventional index option" meets the necessary criteria. Members also should be aware that options based on a security that do not meet the definition of "conventional index option" would continue to be subject to position limits and position reporting requirements as if the non-conforming index were deconstructed into its equity security components.

Position Limits for Conventional Equity Options Overlying Certain Foreign Securities: The proposed rule change also addresses the need for members to identify position limits for conventional equity options on securities that do not underlie a standardized equity option. Under Rule 2860(b)(3)(viii), the position limits for conventional equity options are the same as the limits for the standardized equity options overlying the same security. For example, if standardized equity options on ABC have a position limit of 75,000 contracts, then conventional equity options on ABC also have a position limit of 75,000 contracts. On the other hand, for an option on an equally liquid foreign security such as DEF, for which there are no standardized equity options, a member must obtain prior approval from NASD staff for any position limit in excess of 13,500 contracts (the base limit in the absence of a pilot program [11]). Obtaining prior approval could place a significant burden on a member's ability to execute transactions with customers given the time difference between the foreign market and the U.S. market and the time frame in which customers typically desire to trade.

The proposed rule change would allow members to calculate on their own the position limits for conventional equity options overlying securities that are part of the FTSE All-World Index Series using the volume and float criteria (as measured during the most recent six-month period) established by the option exchanges' rules.[12] The position limit levels are described in the chart below:

Options position limit	Criteria
22,500 (or 50,000 during the pilot period)	Trading volume of 20,000,000 shares; or trading volume of 15,000,000 shares, *and* 40,000,000 shares currently outstanding.
31,500 (or 75,000 during the pilot period)	Trading volume of 40,000,000 shares; or trading volume of 30,000,000 shares, *and* 120,000,000 shares currently outstanding.
60,000 (or 200,000 during the pilot period)	Trading volume of 80,000,000 shares; or trading volume of 60,000,000 shares, *and* 240,000,000 shares currently outstanding.
75,000 (or 250,000 during the pilot period)	Trading volume of 100,000,000 shares; or trading volume of 75,000,000 shares, *and* 300,000,000 shares currently outstanding.

NASD has chosen the FTSE All-World Index Series [13] in part because the Commission staff has deemed securities in the predecessor to this index of foreign securities to receive comparable treatment to U.S. equity securities under the securities haircut provisions of the Commission's net capital rule as set forth in Rule 15c3–1 under the Exchange Act,[14] and the Federal Reserve Board recognizes this index for determining whether stocks are eligible for margin treatment.[15] Under the proposed rule change, a member would make a post-trade notice filing-within

that conduct a business in standardized options but are not themselves members of the options exchange upon which such options are listed and traded.

[7] *See* In the Matter of the Application of the Nasdaq Stock Market LLC, Securities Exchange Act Release No. 53128 (January 13, 2006), 71 FR 3550 (January 23, 2006) (File No. 10–131).

[8] *See* Securities Exchange Act Release No. 52049 (July 15, 2005), 70 FR 42398 (July 22, 2005) (SR–NASD–2005–087).

[9] *See, e.g.*, Chicago Board Options Exchange ("CBOE") Rule 24.2(b).

[10] *See* NASD *Notice to Members* 94–46 (June 1994).

[11] The six national securities exchanges that list and trade options have adopted pilot rules establishing higher position limits for standardized options. These pilots expire between February 23, 2006 and March 3, 2006. *See infra* note 12.

[12] *See* Commentary .07 to American Stock Exchange Rule 904, section 7(c) of Chapter III of the Boston Options Exchange Rules, Interpretation .02 to CBOE Rule 4.11; International Securities Exchange Rule 412(d); Commentary .06 to Pacific Exchange Rule 6.8; Commentary .05 to Philadelphia Stock Exchange Rule 1001.

[13] In the event NASD designates another index in addition to or instead of the FTSE All-World Index Series, NASD will publish the designation of the new applicable index in a *Notice to Members* and provide members at least 30 days written notice of the change.

[14] Letter to Dominic A. Carone, Capital Committee Chairman, Securities Industry Association from Michael Macchiaroli, Assistant Director, Division of Market Regulation, Commission, dated August 13, 1993. *See* 1993 SEC No-Act LEXIS 967 (Aug. 13, 1993).

[15] *See* section 220.11(c) and (d) of Regulation T, 12 CFR part 220.11(c) and (d). *See also* 69 FR 10601 (March 8, 2004) (removing certain foreign securities from the list of securities that meet the financial requirements of section 220.11(c) and (d) of Regulation T).

one business day—to NASD staff providing the necessary trade data and/or current float data to support the member's position limit calculation. Thus, in the example above, a conventional equity option on DEF would be subject to a position limit of 75,000 contracts rather than 13,500 contracts because the underlying securities' characteristics meet the volume and float thresholds established by the options exchanges necessary to raise the position limits from 13,500 contracts to 75,000 contracts, provided the member makes the necessary filing within the prescribed time.

Under the proposed rule change, NASD staff would review the member's notice filing, and, if the staff determined that a member incorrectly assigned a position limit, it would notify the firm and instruct the firm to reduce its position promptly to fall below the appropriate limits determined by the NASD staff.

NASD would announce the effective date of the proposed rule change in a *Notice to Members* to be published no later than 60 days following Commission approval, if the Commission approves this proposal. The effective date would be 30 days following publication of the *Notice to Members* announcing any Commission approval.

2. Statutory Basis

NASD believes that the proposed rule change is consistent with the provisions of section 15A(b)(6) of the Exchange Act,[16] which requires, among other things, that NASD's rules must be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest. NASD believes that amending the definition of "underlying index" would ensure more complete reporting of options positions. NASD also believes that permitting members to calculate position limits for certain foreign securities would enable members to effect options transaction in such securities without unnecessary delay.

B. Self-Regulatory Organization's Statement on Burden on Competition

NASD does not believe that the proposed rule change would result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Exchange Act.

[16] 15 U.S.C. 78*o*–3(b)(6).

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written 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 NASD 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, including whether the proposed rule change is consistent with the Exchange Act. Comments may be submitted by any of the following methods.

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File No. SR–NASD–2006–007 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File No. SR–NASD–2006–007. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). 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 Room. Copies of such filing will also be available for inspection and copying at the principal office of the NASD. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR–NASD–2006–007 and should be submitted on or before February 27, 2006.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[17]

Nancy M. Morris,

Secretary.

[FR Doc. E6–1541 Filed 2–3–06; 8:45 am]

BILLING CODE 8010–01–P

[17] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–53190; File No. SR–NFA–2005–02]

Self-Regulatory Organization; National Futures Association; Notice of Filing and Immediate Effectiveness of a Proposed Amendment to NFA Compliance Rule 2–10 Regarding Recordkeeping

January 30, 2006.

Pursuant to section 19(b)(7) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b–7 under the Act,[2] notice is hereby given that on December 6, 2005, National Futures Association ("NFA") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change described in Items I, II, and III below, which Items have been prepared by NFA. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons. NFA also has filed the proposed rule change with the Commodity Futures Trading Commission ("CFTC").

NFA, on December 6, 2005, submitted the proposed rule change to the CFTC for approval. The CFTC approved the proposed rule change on January 5, 2006.[3]

[1] 15 U.S.C. 78s(b)(7).

[2] 17 CFR 240.19b–7.

[3] *See* Letter from Thomas W. Sexton, Vice President and General Counsel, NFA, to Elizabeth King, Associate Director, Division of Market Regulation, Commission, dated January 26, 2006 (enclosing letter from Jean A. Webb, Secretary,

Continued

I. Self-Regulatory Organization's Description of the Proposed Rule Change

The proposed rule change amends NFA Compliance Rule 2–10 to ensure that NFA has effective access to books and records maintained by foreign firms or in a foreign language. Section 15A(k) of the Act[4] makes NFA a national securities association for the limited purpose of regulating the activities of Members who are registered as brokers or dealers in security futures products under section 15(b)(11) of the Act.[5] This rule change will apply to all NFA Members, including Members registered under section 15(b)(11).

The text of the proposed rule change is below. Proposed new language is italicized.

Text of Proposed Rule Changes

COMPLIANCE RULES

* * * * *

RULE 2–10. RECORDKEEPING

(a) Each member shall maintain adequate books and records necessary and appropriate to conduct its business including, without limitation, the records required to be kept under CFTC Regulations 1.18 and 1.32 through 1.37 for the period required under CFTC Regulation 1.31.

(b) Each FCM Member must either:

(1) Maintain an office in the continental United States, Alaska, Hawaii, or Puerto Rico responsible for preparing and maintaining financial and other records and reports required by CFTC and/or NFA rules; or

(2) Maintain an office in a jurisdiction that the CFTC has found to have a comparable regulatory scheme for purposes of Part 30 of the CFTC's rules and be subject to that regulatory scheme. This foreign office must be responsible for preparing and maintaining financial and other records and reports required by CFTC and/or NFA rules, and the Member must agree to reimburse NFA for any travel, translation, telephone, and similar expenses incurred in connection with inquiries, examinations and investigations of the Member that exceed the normal expenses incurred by NFA in examining an FCM Member located at the closest point in the continental United States, Alaska, Hawaii, or Puerto Rico.

(c) Each Member subject to minimum capital requirements must:

(1) Prepare financial reports required to be filed with the CFTC and/or NFA in English, using U.S. dollars, and according to U.S. accounting standards; and

(2) Maintain a general ledger in English using U.S. dollars.

(d) Each Member must:

(1) File reports, requests for extensions, and other documents required to be filed with the CFTC and/or NFA in English;

(2) Maintain English translations of all foreign-language promotional material, including disclosure documents and Web sites, distributed to or intended for viewing by customers located in the United States, its territories, or possessions;

(3) Maintain written procedures required by CFTC or NFA rules in English (as well as in any other language if necessary for them to be understood by the Member's employees and agents);

(4) Provide English translations of other foreign-language documents and records and file financial information in U.S. dollars when requested by NFA; and

(5) Make available to NFA (during an examination or to respond to other inquiries) an individual who is authorized to act on the Member's behalf, is fluent in English, and is knowledgeable about the Member's business and about financial matters.

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, NFA has prepared statements concerning the purpose of, and basis for, the proposed rule change, burdens on competition, and comments received from members, participants, and others. The text of these statements may be examined at the places specified in Item IV below. NFA 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 Statutory Basis for, the Proposed Rule Change

1. Purpose

NFA has seen a marked increase in the number of foreign firms applying for Futures Commission Merchant ("FCM")[6] registration and NFA membership. NFA Compliance Rule 2–10 requires all Members to maintain books and records necessary to conduct their business, but that requirement is useless if NFA staff cannot audit or understand those books and records.

NFA is concerned about its ability to audit and obtain information from foreign FCMs located in countries without regulatory systems comparable to that in the U.S. Furthermore, there have been instances where promotional materials and other documents prepared by U.S. Members were in a foreign language and it fell on NFA to get them translated. Amending NFA Compliance Rule 2–10 ensures that NFA has effective access to books and records maintained by foreign firms or in a foreign language.

Although NFA has had foreign firms as Members since its inception, they have been concentrated in the Commodity Pool Operator ("CPO")[7] and Commodity Trading Advisor ("CTA")[8] categories, with a few Introducing Brokers ("IBs")[9] sprinkled in. Applications from foreign FCMs were rare, and those firms all had a U.S. office by the time they became Members. This has changed recently, primarily due to membership applications from foreign firms that want to offer retail forex to U.S. customers.

As of October 3, 2005, NFA had six foreign FCM Members. Four of the foreign FCMs are located in London and the other two are located in Ontario, Canada, so they are all subject to established regulatory schemes in their home countries. As of that same date, there were three firms with pending applications for FCM registration and NFA membership and one firm with a pending application for registration only. The four pending firms are located in Columbia (two firms), Cyprus, and Israel. Within the past few years, NFA has also received applications from firms located in Argentina, Jordan, Pakistan, Romania, Russia, and Singapore, although those firms

CFTC, to Thomas W. Sexton, Vice President and General Counsel, NFA, dated January 5, 2006, confirming approval of the proposal) ("Confirmation of CFTC Approval").

[4] 4 15 U.S.C. 78*o*–3(k).

[5] 5 15 U.S.C. 78*o*(b)(11).

[6] "Futures Commission Merchant" means a person who is required to register or is registered as a futures commission merchant under the Commodities Exchange Act ("CEA") and CFTC rules. NFA Compliance Rule 1–1(o).

[7] "Commodity Pool Operator" means a person who is required to register or is registered as a commodity pool operator under the CEA and CFTC rules. NFA Compliance Rule 1–1(g).

[8] "Commodity Trading Advisor" means a person who is required to register or is registered as a commodity trading advisor under the CEA and CFTC rules. NFA Compliance Rule 1–1(h).

[9] "Introducing Broker" means a person who is required to register or is registered as an introducing broker under the CEA and CFTC rules. NFA Compliance Rule 1–1(q).

withdrew their applications before they completed the registration process.

Since December 1987, NFA has required foreign firms to certify that they can and will produce their books and records in the U.S. within 72 hours and that they are not subject to any blocking, privacy, or secrecy laws that would interfere with this inspection. NFA shortened the response time for FCMs to 24 hours in 2003, after more foreign firms started applying for FCM registration.

NFA audits most foreign firms by asking them to provide copies of their books and records, and this procedure has proven workable for auditing CPOs, CTAs, and IBs. For the foreign FCMs, NFA sent auditors to Canada, and each of the London firms either maintains a U.S. office to prepare and maintain the books relating to its U.S.-regulated business or provides those books and records through a U.S. agent. As the number of foreign FCM applicants grows, however, concerns about NFA's ability to conduct efficient and effective audits of these firms increase.

Finally, U.S. firms occasionally provide NFA with documents written in foreign languages without also providing a translation. NFA has taken at least two disciplinary actions involving foreign-language solicitations made to a targeted group within the U.S. In the most recent case, a Forex Dealer Member located in California solicited Chinese-speaking individuals to trade OTC forex. In the other case, a CTA Member located in New York solicited Chinese-speaking individuals to trade products on U.S. exchanges. In both cases, NFA bore the onus of translating the materials into English. We believe this onus should be on the Member rather than on NFA, although NFA would check the accuracy of the translations in appropriate circumstances.

The amendments to NFA Compliance Rule 2–10 add three new sections, with the current text becoming section (a).[10] Section (b) requires FCMs to maintain their books and records in an office located in the U.S. or a part 30 jurisdiction (*e.g.*, Great Britain, Canada).[11] Section (b) also requires FCMs that do not maintain their books and records in the U.S. to reimburse NFA for travel and related expenses if travel to a foreign jurisdiction is necessary.

Section (c) applies to all Members subject to minimum capital requirements (*i.e.*, FCMs and independent IBs). It requires them to prepare financial and other required reports in English, using U.S. dollars and U.S. accounting standards, and to maintain a general ledger in English using U.S. dollars. Section (d) applies to all Members. That section requires them to:

- File documents with NFA in English;
- Maintain English translations of foreign-language promotional material;
- Maintain required procedures in English;
- Provide English translations of other documents when requested by NFA; and
- Ensure that an English-speaking individual who is knowledgeable about the firm's business is available to assist NFA during an audit.

2. Statutory Basis

The rule change is authorized by, and consistent with, section 15A(k) of the Act.[12]

B. Self-Regulatory Organization's Statement on Burden on Competition

The rule change will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act and the CEA.[13]

C. Self-Regulatory Organization's Statement of Comments on the Proposed Rule Change Received from Members, Participants, or Others

NFA did not publish the rule change to the membership for comment. NFA did not receive comment letters concerning the rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The proposed rule change became effective on January 5, 2006, upon approval by the CFTC.[14] Within 60 days of the date of effectiveness of the proposed rule change, the Commission, after consultation with the CFTC, may summarily abrogate the proposed rule change and require that the proposed rule change be refiled in accordance with the provisions of section 19(b)(1) of the Act.[15]

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File No. SR–NFA–2005–02 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File No. SR–NFA–2005–02. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). 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 Room. Copies of such filing will also be available for inspection and copying at the principal office of the NFA. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR–NFA–2005–02 and should be submitted on or before February 27, 2006.

[10] Many of these requirements are taken from NASD Rule 1090 or CBOE Rule 3.4 regarding foreign members.

[11] *See* CFTC Rule 30.10 (17 CFR 30.10) and Appendix C to that rule. A list of the Part 30 jurisdictions can be found on the CFTC's Web site at *http://www.cftc.gov*.

[12] 15 U.S.C. 78*o*–3(k).

[13] 7 U.S.C. 1.

[14] *See* Confirmation of CFTC Approval, *supra* note 3.

[15] 15 U.S.C. 78s(b)(1).

[16] 17 CFR 200.30–3(a)(73).

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[16]

Nancy M. Morris,

Secretary.

[FR Doc. E6–1540 Filed 2–3–06; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–53188; File No. SR–Phlx–2005–70]

Self-Regulatory Organizations; Philadelphia Stock Exchange, Inc.; Notice of Filing of Proposed Rule Change Relating to the Deletion of Phlx Rule 454, "Limitations on Members" Trading Because of Options, etc."

January 30, 2006.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 9, 2005, the Philadelphia Stock Exchange, Inc. ("Phlx" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Phlx. 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 Phlx proposes to delete Phlx Rule 454, "Limitations on Members" Trading Because of Options, etc." The text of Phlx Rule 454 is set forth below, with [brackets] indicating its proposed deletion.

[Rule 454. Limitations on Members' Trading Because of Options, etc.

No member, while on the floor, shall initiate the purchase or sale on the Exchange for his own account or for any account in which he, or the organization of which he is a partner or officer, or any partner or officer of such organization, is directly or indirectly interested, of any security in which he holds or has granted any put, call, straddle or option, or in which he has knowledge that the organization of which he is a partner or officer, or any partner or officer of such organization holds or has granted any put, call, straddle or option, unless such put, call, straddle or option position is in an exchange-traded option issued by the Options Clearing Corporation and is immediately reported to the Exchange.

* * * Supplementary Material: * * *

.01 A member who issues a commitment to trade from the Exchange through ITS or any other Application of the System shall, as a consequence thereof, be deemed to be initiating a purchase or a sale of a security on the Exchange as referred to in this Rule.]

* * * * *

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 Phlx 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 Phlx 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 Statutory Basis for, the Proposed Rule Change

1. Purpose

Phlx Rule 454 prohibits a member on the floor from initiating the purchase or sale of stock on the Exchange for his own or a related account if he or a related account holds or has granted an option on it. According to a 1976 Commission approval order, Phlx Rule 454 was originally adopted at the urging of the Commission in 1935 for the purpose of deterring options-related manipulation of underlying stocks by specialists, odd-lot dealers, and floor traders.[3] The rule change approved by this 1976 approval order carved out Options Clearing Corporation ("OCC")-issued options from the coverage of the rule. The approval order stated that because the Phlx's share of the total market volume in securities for which options trading would be permitted by the proposed rule change averaged less than 1.7 percent, the manipulative potential inherent in changing the restrictions appeared insignificant.[4]

The Exchange is now proposing to delete Phlx Rule 454 in its entirety because the Phlx believes that the likelihood that any options-related manipulation of an underlying stock could occur through an equities trade initiated on the Phlx floor is extremely remote. The Exchange believes that the costs of manipulating the price of a security to produce a gain in a pre-established options position would outweigh the benefits due to the capital that would be required to manipulate the price of a security in the National Market System today. The Exchange notes that it is required to take into account the consolidated national best bid and offer quotations of the National Market System. As such, any attempt to manipulate the price of a security would involve moving the price not only on the Phlx but on other exchanges as well. The Phlx believes that even in less liquid securities this seems unlikely, and there are other rules and mechanisms to capture such activity. As with the 1976 proposed rule change, the Phlx believes that the manipulative potential inherent in eliminating Phlx Rule 454's restrictions appears insignificant. The Exchange notes that it has found no comparable rule for Nasdaq market makers, who can have over-the-counter or "OTC" (non-OCC-issued. non-exchange traded) options on either Nasdaq or listed stocks. Furthermore, Phlx Rule 454 does not in any event prohibit the Phlx member from buying stock first, prior to obtaining an OTC option on it. Thus, the Exchange believes that the rule is of little real usefulness and therefore unnecessarily restricts its floor members from engaging in productive business on the floor of the Exchange.[5]

2. Statutory Basis

The Exchange believes that its proposal is consistent with section 6(b) of the Act,[6] in general, and furthers the objectives of section 6(b)(5) of the Act,[7] in particular, in that it eliminates an outdated prohibition which imposes an unnecessary burden on floor members and serves no real useful purpose. The Phlx believes that lifting the prohibition should result in enhanced market depth and liquidity, which should benefit investors.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 13016 (November 29, 1976), 41 FR 53383 (December 6, 1976) (order approving File No. SR–Phlx–76–15).

[4] *Id.*

[5] Note that Phlx Rule 213, "Puts and Calls," will continue to apply to Phlx specialists. Phlx Rule 213 provides that "[n]o specialist, no organization of which he is a partner or officer and no partner or officer of such organization shall acquire, hold or grant, directly or indirectly, any interest in any put, call, straddle, or option in any security in which such specialist is registered by the Exchange, unless such put, call, straddle or option position is in any exchange-traded option issued by the Options Clearing Corporation and is immediately reported to the Exchange."

[6] 15 U.S.C. 78f(b).

[7] 15 U.S.C. 78f(b)(5).

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others

No written comments were either solicited or 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 Phlx 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, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File Number SR–Phlx–2005–70 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR—Phlx–2005–70. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). 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 Room. Copies of such filing also will be available for inspection and copying at the principal office of the Phlx. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–Phlx–2005–70 and should be submitted on or before February 27, 2006.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[8]

Nancy M. Morris,

Secretary.

[FR Doc. E6–1538 Filed 2–3–06; 8:45 am]

BILLING CODE 8010–01–P

DEPARTMENT OF STATE

[Public Notice 5298]

Bureau of Educational and Cultural Affairs; U.S. Summer Institutes for Pakistani Undergraduate Students

Announcement Type: New Cooperative Agreement.

Funding Opportunity Number: ECA/A/E/NEA–SA–06–001SIP.

Catalog of Federal Domestic Assistance Number: 00.0000.

Key Dates: Application Deadline: March 31, 2006.

Executive Summary: The Near East/South Asia Branch, Office of Academic Exchange Programs, Bureau of Educational and Cultural Affairs, announces an open competition for public and private non-profit organizations to develop and implement the U.S. Summer Institutes for Pakistani Undergraduate Students, to take place in the U.S. during the summer of 2006. The Bureau anticipates awarding two separate assistance awards to support two institutes for Pakistani undergraduate students. Each institute is intended to provide a minimum of 15–20 highly motivated second- and third-year undergraduate students from Pakistan with a six-week academic seminar, including a two-week U.S. travel component that will give the participants a deeper understanding of the program themes.

I. Funding Opportunity Description

Authority: Overall grant making authority for this program is contained in the Mutual Educational and Cultural Exchange Act of 1961, Public Law 87–256, as amended, also known as the Fulbright-Hays Act. The purpose of the Act is "to enable the Government of the United States to increase mutual understanding between the people of the United States and the people of other countries * * *; to strengthen the ties which unite us with other nations by demonstrating the educational and cultural interests, developments, and achievements of the people of the United States and other nations * * * and thus to assist in the development of friendly, sympathetic and peaceful relations between the United States and the other countries of the world." The funding above is provided through legislation.

Purpose: The Bureau is seeking detailed proposals for the U.S. Summer Institutes for Pakistani Undergraduate Students from U.S. colleges, universities, consortia of colleges and universities, and other not-for-profit academic organizations that have an established reputation in one or more of the following fields: Political science, international relations, law, history, sociology, American studies, and/or other disciplines or sub-disciplines related to the study of the United States.

"The United States Today: Politics, Society and Culture" Summer Institutes are intended to provide two groups of 15–20 undergraduate students from Pakistan with an introduction to the main contours of contemporary American life and institutions. The Summer Institutes should be designed in such a way that the central institutions of the American experience political, economic, social, religious and cultural are explored through a series of lectures, debates, roundtable discussions, and site visits. While the general focus should be on the United States today, the program should be structured to provide an introductory overview on the evolution of American institutions throughout U.S. history. The program should therefore seek to introduce participants to the core values of the people of the United States in the 21st century as those values have evolved over time.

Among the many themes and topics that might be explored are: American constitutionalism; the American federal system; civil liberties and the rule of law; freedom of speech and the role of media, particularly broadcast media, in American society; the U.S. political economy and market economics;

[8] 17 CFR 200.30–3(a)(12).

American foreign policy; the role of women; multiculturalism; ethnic pluralism; the demography of American religion; individualism and equality; national unity and diversity; and the role of popular culture, literature, music and the arts. The program may be organized in a variety of ways—historically, thematically, or topically, or through a combination thereof.

The grantee institution for each institute should take into account that the participants may have little or no prior knowledge of the U.S. and varying degrees of experience in expressing their opinions, and should tailor the curriculum and classroom activities accordingly. The grantee institution will be required to develop a program that provides ample time and opportunity for discussion, training and interaction, rather than standard lectures or broad survey reading assignments.

It is critical that the participants gain a more informed and coherent understanding of the United States and share their own culture and way of life. To accomplish this, each institute should include opportunities for participants to meet American citizens from a variety of backgrounds, to interact with peers, and to speak to appropriate student and civic groups about their experiences and life in their home countries.

Additionally, as grassroots ambassadors to the communities in which they will be studying, an important objective of the institutes is to develop the participants' leadership skills. In this context, the programs should include lectures, community service activities, group discussions, training, and exercises focusing on such topics as the essential attributes of leadership; teambuilding; effective communication and problem-solving skills; and management skills for diverse organizational settings.

The host institution for each institute will also be expected to provide participants post-program opportunities for further investigation and research on the topics and issues examined and discussed during each institute.

Each institute should be six weeks in length including a domestic travel component of not more than fourteen (14) days, of which 3–4 days should be spent in Washington, DC, at the end of the program. This travel component should directly complement the academic residency segment. It should include visits to cities and other sites of interest in the region of the host institution.

The project director or one of the key program staff responsible for the academic program must have an advanced degree in one of the following fields: Political science, history, art, sociology, American studies, and/or other disciplines or sub-disciplines related to the study of the United States. If the project director or key program staff does not have an advanced degree, the proposal will be considered technically ineligible.

Programs must conform with Bureau requirements and guidelines outlined in the Solicitation Package. Bureau programs are subject to the availability of funds.

Applicants are encouraged to design thematically coherent programs in ways that draw upon the particular strengths, faculty and resources of their institutions as well as upon the expertise of nationally recognized scholars and other experts throughout the United States. Within the limits of their thematic focus and organizing framework, institutes should also be designed to:

1. Bring an interdisciplinary or multi-disciplinary focus to bear on the program content;

2. Give participants a multi-dimensional view of U.S. society and institutions that includes a broad and balanced range of perspectives. Where possible, programs should therefore include the views not only of scholars, cultural critics and public intellectuals, but also those of other professionals such as government officials, journalists and others who can substantively contribute to the topics at issue; and,

3. Ensure access to library and material resources that will enable grantees to continue their research and studies upon returning to their home institutions.

Participants: As specified in the Project Objectives, Goals and Implementation (POGI) guidelines in the solicitation package, each program should be designed for highly motivated second- and third-year undergraduates from colleges, universities, and teacher training institutions in Pakistan who have demonstrated leadership through academic achievements, community involvement, and extracurricular activities. Their major fields will be varied, including the arts and humanities, social sciences, education, business, and other professional fields. All participants will be conversant in English.

Please note: The level of English among the students may vary. The host institution will be required to prepare lectures and discussions meeting the highest academic standards while using language appropriate for students with English as their second or third language.

The U.S. Embassy will make a particular effort to recruit participants from non-elite or underprivileged backgrounds and from both rural and urban sectors of Pakistan. All participants will be 22 years of age or younger; have completed their first or second year of undergraduate studies; be committed to returning to their home universities in the fall of 2006 following completion of their institute program; have had little or no prior study or travel experience in the United States or elsewhere outside of their home countries; and be willing and able to fully participate in an intensive academic program, community service, and active educational travel program. As participants will be selected in large part on the basis of their demonstrated leadership capacity, it is expected they will utilize the experience derived from the program in positions of leadership upon return to their home countries.

Please note: Special attention will be required on the part of the host institution to the students' limited knowledge of the U.S. and their varying levels of academic sophistication. Special sensitivity on the part of the host institution also will be required to the cultural traditions and religious practices of the participating students, who will represent a variety of Muslim or other religious traditions. Special requirements and restrictions regarding diet, daily worship, housing and medical care should be considered. The Bureau will provide guidance and assistance, as needed.

Program Dates: Ideally, the program should be 44 days in length (including participant arrival and departure days) and is anticipated to begin mid July 2006.

Program Guidelines: While the conception and structure of each institute program is the responsibility of the organizers, it is critically important that proposals provide a full, detailed and comprehensive narrative describing the objectives of the institute; the title, scope and content of each session; and how each session relates to the overall institute theme. A syllabus must be included that indicates the subject matter for each lecture, panel discussion or other activity (e.g., group exercises), confirms or provisionally identifies proposed lecturers, trainers and session leaders, and clearly shows how assigned readings will support each session. A calendar of all program activities must also be included. Additionally, applicant institutions should describe their plans for public and media outreach in connection with the program.

Note: In a cooperative agreement, the Bureau is substantially involved in program activities above and beyond routine grant monitoring. ECA activities and responsibilities for this program are as follows: ECA will participate in the selection of participants, exercise oversight with one or

more site visits, debrief participants while they are in Washington and also engage in follow-up communications with the participants upon their return home. ECA may require changes in the content of the program as well as the activities proposed after the grant is awarded. The recipient will be required to obtain review and approval of significant agenda/syllabus changes in advance of their implementation.

II. Award Information

Type of Award: Cooperative Agreement. ECA's level of involvement in this program is listed under "Note" above. The numbers below reflect figures for each institute.

Fiscal Year Funds: FY–06.

Approximate Total Funding for each institute: $250,000.

Approximate Number of Awards: 2.

Approximate Average Award for each institute: $250,000.

Floor of Award Range for each institute: $225,000.

Ceiling of Award Range for each institute: $250,000.

Anticipated Award Date for each institute: Pending availability of funds, May 18, 2006.

Anticipated Project Completion Date for each institute: September 30, 2006.

III. Eligibility Information

III.1. Eligible applicants

Applications may be submitted by public and private non-profit organizations meeting the provisions described in Internal Revenue Code section 26 U.S.C. 501(c)(3).

III.2. Cost Sharing or Matching Funds

There is no minimum or maximum percentage required for this competition. However, the Bureau encourages applicants to provide maximum levels of cost sharing and funding in support of its programs.

When cost sharing is offered, it is understood and agreed that the applicant must provide the amount of cost sharing as stipulated in its proposal and later included in an approved cooperative agreement. Cost sharing may be in the form of allowable direct or indirect costs. For accountability, you must maintain written records to support all costs which are claimed as your contribution, as well as costs to be paid by the federal government. Such records are subject to audit. The basis for determining the value of cash and in-kind contributions must be in accordance with OMB Circular A–110, (Revised), Subpart C.23—Cost Sharing and Matching. In the event you do not provide the minimum amount of cost sharing as stipulated in the approved budget, ECA's contribution will be reduced in like proportion.

III.3 Other Eligibility Requirements

(a.) Bureau grant and cooperative agreement guidelines require that organizations with less than four years experience in conducting international exchanges be limited to $60,000 in Bureau funding. ECA anticipates awarding one cooperative agreement in an amount up to $250,000 for each institute to support program and administrative costs required to implement these exchange programs. Therefore, organizations with less than four years experience in conducting international exchanges are ineligible to apply under this competition.

(b.) Technical Eligibility: All proposals must comply with the following: The project director or one of the key program staff responsible for the academic program must have an advanced degree in one of the following fields: political science, international relations, law, history, art, sociology, literature, American studies, and/or other disciplines or sub-disciplines related to the program themes. Failure to meet this criterion will result in your proposal being declared technically ineligible and given no further consideration in the review process.

IV. Application and Submission Information

Note: Please read the complete announcement before sending inquiries or submitting proposals. ECA staff will be available to consult with prospective applicant institutions about program design and content up until the proposal submission deadline. Once the RFGP deadline has passed, Bureau staff may not discuss this competition with applicants until the proposal review process has been completed.

IV.1 Contact Information to Request an Application Package

Please contact the Near East/South Asia Branch ECA/A/E/NEA–SA, Room Number 252, U.S. Department of State, SA–44, 301 4th Street, SW., Washington, DC 20547, telephone number (202) 453–8096 and fax number (202) 453–8095, e-mail *KreiserJD@state.gov* to request a Solicitation Package. Please refer to the Funding Opportunity Number ECA/A/E/NEA-SA–06–001SIP located at the top of this announcement when making your request.

Alternatively, an electronic application package may be obtained from grants.gov. Please see section IV.3f for further information.

The Solicitation Package contains the Proposal Submission Instruction (PSI) document which consists of required application forms, and standard guidelines for proposal preparation.

It also contains the Project Objectives, Goals and Implementation (POGI) document, which provides specific information, award criteria and budget instructions tailored to this competition.

Please specify Program Officer Joshua Kreiser and refer to the Funding Opportunity Number ECA/A/E/NEA–SA–06–001SIP located at the top of this announcement on all other inquiries and correspondence.

IV.2. To Download A Solicitation Package Via Internet

The entire Solicitation Package may be downloaded from the Bureau's Web site at *http://exchanges.state.gov/education/rfgps/menu.htm*, or from the grants.gov Web site at *http://www.grants.gov*. Please read all information before downloading.

IV.3. Content and Form of Submission

Applicants must follow all instructions in the Solicitation Package. The original and ten (10) copies of the application should be sent per the instructions under IV.3f. "Submission Dates and Times section" below.

IV.3a. You are required to have a Dun and Bradstreet Data Universal Numbering System (DUNS) number to apply for a grant or cooperative agreement from the U.S. Government. This number is a nine-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, access *http://www.dunandbradstreet.com* or call 1–866–705–5711. Please ensure that your DUNS number is included in the appropriate box of the SF—424 which is part of the formal application package.

IV.3b. All proposals must contain an executive summary, proposal narrative and budget. Please Refer to the Solicitation Package. It contains the mandatory Proposal Submission Instructions (PSI) document and the Project Objectives, Goals and Implementation (POGI) document for additional formatting and technical requirements.

IV.3c. You must have nonprofit status with the IRS at the time of application. If your organization is a private nonprofit which has not received a grant or cooperative agreement from ECA in the past three years, or if your organization received nonprofit status from the IRS within the past four years, you must submit the necessary documentation to verify nonprofit status as directed in the PSI document. Failure to do so will cause your proposal to be declared technically ineligible.

IV.3d. Please take into consideration the following information when preparing your proposal narrative:

IV.3d.1 Adherence to All Regulations Governing the J Visa.

The Bureau of Educational and Cultural Affairs is placing renewed emphasis on the secure and proper administration of Exchange Visitor (J visa) Programs and adherence by grantees and sponsors to all regulations governing the J visa. Therefore, proposals should demonstrate the applicant's capacity to meet all requirements governing the administration of the Exchange Visitor Programs as set forth in 22 CFR part 62, including the oversight of Responsible Officers and Alternate Responsible Officers, screening and selection of program participants, provision of pre-arrival information and orientation to participants, monitoring of participants, proper maintenance and security of forms, record-keeping, reporting and other requirements. ECA will be responsible for issuing DS–2019 forms to participants in this program.

A copy of the complete regulations governing the administration of Exchange Visitor (J) programs is available at *http://exchanges.state.gov* or from: United States Department of State, Office of Exchange Coordination and Designation, ECA/EC/ECD—SA–44, Room 734, 301 4th Street, SW., Washington, DC 20547, Telephone: (202) 203–5029, Fax: (202) 453–8640.

Please refer to Solicitation Package for further information.

IV.3d.2 Diversity, Freedom and Democracy Guidelines. Pursuant to the Bureau's authorizing legislation, programs must maintain a non-political character and should be balanced and representative of the diversity of American political, social, and cultural life. "Diversity" should be interpreted in the broadest sense and encompass differences including, but not limited to ethnicity, race, gender, religion, geographic location, socio-economic status, and physical challenges. Applicants are strongly encouraged to adhere to the advancement of this principle both in program administration and in program content. Please refer to the review criteria under the 'Support for Diversity' section for specific suggestions on incorporating diversity into your proposal. Public Law 104–319 provides that "in carrying out programs of educational and cultural exchange in countries whose people do not fully enjoy freedom and democracy," the Bureau "shall take appropriate steps to provide opportunities for participation in such programs to human rights and democracy leaders of such countries." Public Law 106–113 requires that the governments of the countries described above do not have inappropriate influence in the selection process. Proposals should reflect advancement of these goals in their program contents, to the full extent deemed feasible.

IV.3d.3. Program Monitoring and Evaluation. Proposals must include a plan to monitor and evaluate the project's success, both as the activities unfold and at the end of the program. The Bureau recommends that your proposal include a draft survey questionnaire or other technique plus a description of a methodology to use to link outcomes to original project objectives. The Bureau expects that the grantee will track participants or partners and be able to respond to key evaluation questions, including satisfaction with the program, learning as a result of the program, changes in behavior as a result of the program, and effects of the program on institutions (institutions in which participants work or partner institutions). The evaluation plan should include indicators that measure gains in mutual understanding as well as substantive knowledge.

Successful monitoring and evaluation depend heavily on setting clear goals and outcomes at the outset of a program. Your evaluation plan should include a description of your project's objectives, your anticipated project outcomes, and how and when you intend to measure these outcomes (performance indicators). The more that outcomes are "smart" (specific, measurable, attainable, results-oriented, and placed in a reasonable time frame), the easier it will be to conduct the evaluation. You should also show how your project objectives link to the goals of the program described in this RFGP.

Your monitoring and evaluation plan should clearly distinguish between program *outputs* and *outcomes*. *Outputs* are products and services delivered, often stated as an amount. Output information is important to show the scope or size of project activities, but it cannot substitute for information about progress towards outcomes or the results achieved. Examples of outputs include the number of people trained or the number of seminars conducted. *Outcomes,* in contrast, represent specific results a project is intended to achieve and is usually measured as an extent of change. Findings on outputs and outcomes should both be reported, but the focus should be on outcomes.

We encourage you to assess the following four levels of outcomes, as they relate to the program goals set out in the RFGP (listed here in increasing order of importance):

1. Participant satisfaction with the program and exchange experience.

2. Participant learning, such as increased knowledge, aptitude, skills, and changed understanding and attitude. Learning includes both substantive (subject-specific) learning and mutual understanding.

3. Participant behavior, concrete actions to apply knowledge in work or community; greater participation and responsibility in civic organizations; interpretation and explanation of experiences and new knowledge gained; continued contacts between participants, community members, and others.

4. Institutional changes, such as increased collaboration and partnerships, policy reforms, new programming, and organizational improvements.

Please note: Consideration should be given to the appropriate timing of data collection for each level of outcome. For example, satisfaction is usually captured as a short-term outcome, whereas behavior and institutional changes are normally considered longer-term outcomes.

Overall, the quality of your monitoring and evaluation plan will be judged on how well it (1) specifies intended outcomes; (2) gives clear descriptions of how each outcome will be measured; (3) identifies when particular outcomes will be measured; and (4) provides a clear description of the data collection strategies for each outcome (i.e., surveys, interviews, or focus groups).

Please note: Because the cooperative agreements to be awarded under the terms of this RFGP are likely to be of less than one year's duration, prospective host institutions will not be expected to be able to demonstrate significant specific results in terms of participant behavior or institutional changes during the agreement period. Applicant institutions monitoring and evaluation plans should, therefore, focus primarily on the first and more particularly the second level of outcomes (learning). ECA will assume principal responsibility for developing performance indicators and conducting post-institute evaluations to measure changes in participant behavior as a result of the program, and effect of the program on institutions, over time.

Grantees will be required to provide reports analyzing their evaluation findings to the Bureau in their regular program reports. All data collected, including survey responses and contact information, must be maintained for a minimum of three years and provided to the Bureau upon request.

IV.3d.4. Describe your plans for overall program management, staffing, and coordination with ECA. ECA considers program management, staffing and coordination with the Department of State essential elements of your program. Please be sure to give sufficient attention to these elements in your proposal. Please refer to the Technical Eligibility Requirements and the POGI in the Solicitation package for specific guidelines.

IV.3e. Please take the following information into consideration when preparing your budget:

IV.3e.1. Applicants must submit a comprehensive budget for the entire program. Awards for each institute may not exceed $250,000. There must be a summary budget as well as breakdowns reflecting both administrative and program budgets. Applicants may provide separate sub-budgets for each program component, phase, location, or activity to provide clarification. Separate budgets must be submitted if applicants intend to submit proposals for each institute.

Based on a group of 15–20 participants, the total Bureau-funded budget (program and administrative) for each program should not exceed $250,000, with Bureau-funded administrative costs as defined in the budget details section of the solicitation package accounting for no more than $85,000 of the total amount.

Justifications for any costs above these amounts must be clearly indicated in the proposal submission. Proposals should try to maximize cost sharing in all facets of the program and to stimulate U.S. private sector, including foundation and corporate, support. Applicants must submit a comprehensive budget for the entire program. The Bureau reserves the right to reduce, revise, or increase proposal budgets in accordance with the needs of the program, and availability of U.S. government funding.

Please refer to the "POGI" in the Solicitation Package for complete institute budget guidelines and formatting instructions.

IV.3e.2. Allowable costs for the program include the following:

(1) Institute staff salary and benefits;
(2) Honoraria for Guest speakers;
(3) Participant per diem.

Please refer to the Solicitation Package for complete budget guidelines and formatting instructions.

IV.3f. Application Deadline and Methods of Submission:

Application Deadline Date: Friday, March 31, 2006.

Reference Number: ECA/A/E/NEA–SA–06–001SIP.

Methods of Submission:

Applications may be submitted in one of two ways:

(1.) In hard-copy, via a nationally recognized overnight delivery service (i.e., DHL, Federal Express, UPS, Airborne Express, or U.S. Postal Service Express Overnight Mail, etc.), or

(2.) Electronically through *http://www.grants.gov.*

Along with the Project Title, all applicants must enter the above Reference Number in Box 11 on the SF–424 contained in the mandatory Proposal Submission Instructions (PSI) of the solicitation document.

IV.3f.1 Submitting Printed Applications. Applications must be shipped no later than the above deadline. Delivery services used by applicants must have in-place, centralized shipping identification and tracking systems that may be accessed via the Internet and delivery people who are identifiable by commonly recognized uniforms and delivery vehicles. Proposals shipped on or before the above deadline but received at ECA more than seven days after the deadline will be ineligible for further consideration under this competition. Proposals shipped after the established deadlines are ineligible for consideration under this competition. ECA will not notify you upon receipt of application. It is each applicant's responsibility to ensure that each package is marked with a legible tracking number and to monitor/confirm delivery to ECA via the Internet. Delivery of proposal packages may not be made via local courier service or in person for this competition. Faxed documents will not be accepted at any time. Only proposals submitted as stated above will be considered.

Important note: When preparing your submission please make sure to include one extra copy of the completed SF–424 form and place it in an envelope addressed to "ECA/EX/PM".

The original and ten (10) copies of the application should be sent to: U.S. Department of State, SA–44, Bureau of Educational and Cultural Affairs, Ref.: ECA/A/E/NEA–SA/06–001SIP, Program Management, ECA/EX/PM, Room 534, 301 4th Street, SW., Washington, DC 20547.

IV.3f.2 Submitting Electronic Applications. Applicants have the option of submitting proposals electronically through Grants.gov (*http://www.grants.gov*). Complete solicitation packages are available at Grants.gov in the "Find" portion of the system. Please follow the instructions available in the "Get Started" portion of the site (*http://www.grants.gov/GetStarted*).

Applicants have until midnight (12 a.m.) of the closing date to ensure that their entire applications have been uploaded to the grants.gov site. Applications uploaded to the site after midnight of the application deadline date will be automatically rejected by the grants.gov system, and will be technically ineligible.

Applicants will receive a confirmation e-mail from grants.gov upon the successful submission of an application. ECA will not notify you upon receipt of electronic applications.

IV.3g. Intergovernmental Review of Applications: Executive Order 12372 does not apply to this program.

Applicants must also submit the "Executive Summary" and "Proposal Narrative" sections of the proposal in text (.txt) format on a PC-formatted disk. The Bureau will provide these files electronically to the Public Affairs Section at the U.S. embassy for its review.

V. Application Review Information

V.1. Review Process

The Bureau will review all proposals for technical eligibility. Proposals will be deemed ineligible if they do not fully adhere to the guidelines stated herein and in the Solicitation Package. All eligible proposals will be reviewed by the program office, as well as the Public Diplomacy section overseas, where appropriate. Eligible proposals will be subject to compliance with Federal and Bureau regulations and guidelines and forwarded to Bureau grant panels for advisory review. Proposals may also be reviewed by the Office of the Legal Adviser or by other Department elements. Final funding decisions are at the discretion of the Department of State's Assistant Secretary for Educational and Cultural Affairs. Final technical authority for cooperative agreements resides with the Bureau's Grants Officer.

Review Criteria

Technically eligible applications will be competitively reviewed according to the criteria stated below. These criteria are not rank ordered and all carry equal weight in the proposal evaluation:

1. *Overall Quality of Proposal, Program Planning and Administration, and Ability To Achieve Objectives:* Proposals should exhibit originality and substance, consonant with the highest standards of American teaching and scholarship, and be suitable for students with English as their second or third language. Program elements should be

tailored for students with limited knowledge of the U.S. and with varying degrees of academic sophistication. Lectures, panels, and other interactive classroom activities, readings, community service, and site visits, taken as a whole, should offer a balanced presentation of issues, reflecting both the continuity of the American experience as well its inherent diversity and dynamism. Proposals should demonstrate careful planning. The organization and structure of each institute should be clearly delineated and be fully responsive to all program objectives. A program syllabus (noting specific sessions and topical readings supporting each academic unit) should be included, as should a calendar of activities. The travel component should not simply be a tour, but should be an integral and substantive part of the program, reinforcing and complementing the academic segment. Proposals should provide evidence of continuous administrative and managerial capacity as well as the means by which program activities and logistical matters will be implemented. Objectives should be reasonable, feasible, and flexible. Proposals should clearly demonstrate how the institution will meet the program's objectives and plan.

2. *Institutional Capacity and Record/ Ability:* Proposed personnel, including faculty and administrative staff as well as outside presenters, should be fully qualified to achieve the project's goals. Library and meeting facilities, housing, meals, transportation and other logistical arrangements should fully meet the needs of participants. Proposals should demonstrate an institutional record of successful exchange program activities, indicating the experience that the organization and its professional staff have had working with foreign students. The Bureau will consider the past performance of prior recipients and the demonstrated potential of new applicants.

3. *Support of Diversity:* Proposals should demonstrate substantive support of the Bureau's policy on diversity. "Diversity" should be interpreted in the broadest sense and encompass differences including, but not limited to ethnicity, race, gender, religion, geographic location, socio-economic status, and disabilities. Applicants are strongly encouraged to adhere to the advancement of this principle both in program administration and in program content. Applicant should highlight instances of diversity in their proposal.

4. *Project Evaluation and Follow-up:* Proposals should include a plan to evaluate the activity's success, both as the activities unfold and at the end of the program. A draft survey questionnaire or other technique plus description of a methodology to link outcomes to original project objectives is strongly recommended. Proposals should discuss provisions for follow-up with returned grantees as a means of establishing longer-term individual and institutional linkages.

5. *Cost-effectiveness and cost sharing:* The overhead and administrative components of the proposal, including salaries and honoraria, should be kept as low as possible. All other items should be necessary and appropriate.

VI. Award Administration Information

VI.1. Award Notices

Final awards cannot be made until funds have been appropriated by Congress, allocated and committed through internal Bureau procedures. Successful applicants will receive an Assistance Award Document (AAD) from the Bureau's Grants Office. The AAD and the original grant proposal with subsequent modifications (if applicable) shall be the only binding authorizing document between the recipient and the U.S. Government. The AAD will be signed by an authorized Grants Officer, and mailed to the recipient's responsible officer identified in the application.

Unsuccessful applicants will receive notification of the results of the application review from the ECA program office coordinating this competition.

VI.2 Administrative and National Policy Requirements

Terms and Conditions for the Administration of ECA agreements include the following:

Office of Management and Budget Circular A–122, "Cost Principles for Nonprofit Organizations."

Office of Management and Budget Circular A–21, "Cost Principles for Educational Institutions."

OMB Circular A–87, "Cost Principles for State, Local and Indian Governments".

OMB Circular No. A–110 (Revised), Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and other Nonprofit Organizations.

OMB Circular No. A–102, Uniform Administrative Requirements for Grants-in-Aid to State and Local Governments.

OMB Circular No. A–133, Audits of States, Local Government, and Non-profit Organizations.

Please reference the following Web sites for additional information: *http://www.whitehouse.gov/omb/grants, http://exchanges.state.gov/education/grantsdiv/terms.htm#articleI.*

VI.3. Reporting Requirements

You must provide ECA with a hard copy original plus two (2) copies of a final program and financial report no more than 90 days after the conclusion of the program.

Grantees will be required to provide reports analyzing their evaluation findings to the Bureau in their regular program reports. (Please refer to IV. Application and Submission Instructions (IV.3d.3) above for Program Monitoring and Evaluation information.

All data collected, including survey responses and contact information, must be maintained for a minimum of three years and provided to the Bureau upon request.

All reports must be sent to the ECA Grants Officer and ECA Program Officer listed in the final assistance award document.

VI.4. Program Data Requirements

Organizations awarded grants will be required to maintain specific data on program participants and activities in an electronically accessible database format that can be shared with the Bureau as required. As a minimum, the data must include the following:

(1) Name, address, contact information and biographic sketch of all persons who travel internationally on funds provided by the grant or who benefit from the grant funding but do not travel.

(2) Itineraries of international and domestic travel, providing dates of travel and cities in which any exchange experiences take place. Final schedules for in-country and U.S. activities must be received by the ECA Program Officer at least three work days prior to the official opening of the activity.

VII. Agency Contacts

For questions about this announcement, contact: Joshua Kreiser, ECA/A/E/NEA–SA, Room Number 252, Ref. #: ECA/A/E/NEA–SA–06–001SIP, U.S. Department of State, SA–44, 301 4th Street, SW., Washington, DC 20547, telephone number (202) 453-8096 and fax number (202) 453–8095, e-mail *KreiserJD@state.gov.*

All correspondence with the Bureau concerning this RFGP should reference the above title and number ECA/A/E/NEA–SA–06–001SIP.

Please read the complete announcement before sending inquiries or submitting proposals. Once the RFGP

deadline has passed, Bureau staff may not discuss this competition with applicants until the proposal review process has been completed.

VIII. Other Information

Notice

The terms and conditions published in this RFGP are binding and may not be modified by any Bureau representative.

Explanatory information provided by the Bureau that contradicts published language will not be binding.

Issuance of the RFGP does not constitute an award commitment on the part of the Government. The Bureau reserves the right to reduce, revise, or increase proposal budgets in accordance with the needs of the program and the availability of funds. Awards made will be subject to periodic reporting and evaluation requirements per section VI.3 above.

Dated: January 31, 2006.

C. Miller Crouch,

Principal Deputy Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 06–1069 Filed 2–3–06; 8:45 am]

BILLING CODE 4710–05–U

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA 2005–23170; Notice 2]

Kumho Tire Co., Inc., Grant of Petition for Decision of Inconsequential Noncompliance

Kumho Tire Co., Inc. (Kumho) has determined that certain tires that it produced in 2005 do not comply with S4.3.4 of 49 CFR 571.109, Federal Motor Vehicle Safety Standard (FMVSS) No. 109, "New pneumatic tires." Pursuant to 49 U.S.C. 30118(d) and 30120(h), Kumho has petitioned for a determination that this noncompliance is inconsequential to motor vehicle safety and has filed an appropriate report pursuant to 49 CFR Part 573, "Defect and Noncompliance Reports." Notice of receipt of a petition was published, with a 30-day comment period, on December 9, 2005, in the **Federal Register** (70 FR 73325). NHTSA received one comment.

Affected are a total of approximately 197,147 temporary spare tires produced in February 2005. S4.3.4 of FMVSS No. 109 requires that each tire have permanently molded onto the sidewall the maximum inflation pressure in kPa followed in parentheses by the equivalent inflation pressure in psi, and the maximum load marking in kilograms followed in parentheses by the equivalent load rating in pounds. The affected tires have the maximum inflation pressure marking only in psi and not in kPa, and have reversed the maximum load markings so that the load rating in pounds is followed in parentheses by the equivalent load rating in kilograms. Kumho has corrected the problem that caused these errors so that they will not be repeated in future production.

Kumho believes that the noncompliance is inconsequential to motor vehicle safety and that no corrective action is warranted. Kumho states that the noncompliance "will have no impact on the operational performance or safety of vehicles on which the tires are used." Kumho says that the tires meet or exceed all FMVSS No. 109 performance requirements.

One comment was received from a private individual. The comment concerns the danger presented by not having maximum "load pressures" on a tire. As explained above, the affected tires do have correct information on maximum load markings (although the information on pounds and kilograms is in reverse order) and maximum inflation pressure (although expressed only in psi). Therefore, these tires do not present the danger referred to in the comment, and the comment provides no basis on which the petition should be denied.

NHTSA agrees with Kumho that the noncompliance is inconsequential to motor vehicle safety. The correct English unit information required by FMVSS No. 109 is provided and therefore is likely to achieve the safety purposes of the requirement. All other informational markings are present, and the tires meet or exceed all of the performance requirements of FMVSS No. 109.

In consideration of the foregoing, NHTSA has decided that the petitioner has met its burden of persuasion that the noncompliance described is inconsequential to motor vehicle safety. Accordingly, Kumho's petition is granted and the petitioner is exempted from the obligation of providing notification of, and a remedy for, the noncompliance.

Authority: (49 U.S.C. 30118, 30120; delegations of authority at CFR 1.50 and 501.8).

Issued on: January 31, 2006.

Daniel C. Smith,

Associate Administrator for Enforcement.

[FR Doc. E6–1539 Filed 2–3–06; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Finance Docket No. 34815]

Cassatt Management, LLC d/b/a/ Bay Coast Railroad—Operation Exemption—Shenandoah Valley Railroad Line

Cassatt Management, LLC d/b/a/ Bay Coast Railroad (BCR), a noncarrier, has filed a verified notice of exemption under 49 CFR 1150.31 to operate, pursuant to an agreement with the Shenandoah Valley Railroad, LLC (SVRR), SVRR's approximately 20.2-mile line of railroad extending from milepost 5.0 at Pleasant Valley to milepost 25.2 in Staunton, in Rockingham and Augusta Counties, VA.[1]

BCR certifies that its projected annual revenues as a result of the transaction will not exceed those that would qualify it as a Class III rail carrier and will not exceed $5 million.

The transaction was expected to be consummated on or after January 18, 2006.

If the verified notice contains false or misleading information, the exemption is void *ab initio*. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the transaction.

An original and 10 copies of all pleadings, referring to STB Finance Docket No. 34815, must be filed with the Surface Transportation Board, 1925 K Street, NW., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on John D. Heffner, John D. Heffner, PLLC, 1920 N Street, NW., Suite 800, Washington, DC 20036.

Board decisions and notices are available on our Web site at *http://www.stb.dot.gov*.

Decided: January 27, 2006.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 06–1015 Filed 2–3–06; 8:45 am]

BILLING CODE 4915–01–P

[1] SVRR retains the residual right to conduct rail operations itself or through an agent in the event of BCR's default of its obligation under the agreement.

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Finance Docket No. 34814]

Cassatt Management, LLC d/b/a Bay Coast Railroad-Lease and Operation Exemption—Canonie Atlantic Co. on Behalf of Accomack-Northampton Transportation District Commission

Cassatt Management, LLC d/b/a/ Bay Coast Railroad (BCR), a noncarrier, has filed a verified notice of exemption under 49 CFR 1150.31 to lease from Canonie Atlantic Co. (Canonie), acting on behalf of the Accomack-Northampton Transportation District Commission, and to operate approximately 68.3 miles of rail line as follows: (1) Between ESHR milepost 30.5 at Pocomoke City, MD (Norfolk Southern Railway Company (NS) interchange), and ESHR milepost 94.8 at Cape Charles, VA (float bridge); (2) between ESHR milepost 95.0 at Little Creek (Virginia Beach), VA, and ESHR milepost 97.6 at Camden Heights (Norfolk), VA; and (3) between ESHR milepost 100.7 at North Junction and ESHR milepost 102.1 at St. Julian, VA. As part of the transaction, BCR is being assigned to operate a 4.6-mile line of railroad leased by Canonie from NS extending (a) between ESHR milepost 97.6 at Camden Heights and ESHR milepost 100.7 at North Junction; and (b) on the Diamond Springs Line between NS milepost SN 5.2 and NS milepost SN 6.7. BCR also is being assigned to operate Canonie's trackage rights over a 4.0-mile line of railroad owned by NS, extending between Coleman Place and NS's Portlock Yard for interchange purposes. The Eastern Shore Railroad, Inc. currently operates these lines.

BCR certifies that its projected annual revenues as a result of the transaction will not exceed those that would qualify it as a Class III rail carrier and will not exceed $5 million.

The transaction was expected to be consummated on or after January 18, 2006.

If the verified notice contains false or misleading information, the exemption is void *ab initio*. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the transaction.

An original and 10 copies of all pleadings, referring to STB Finance Docket No. 34814, must be filed with the Surface Transportation Board, 1925 K Street, NW., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on John D. Heffner, John D. Heffner, PLLC, 1920 N Street, NW., Suite 800, Washington, DC 20036.

Board decisions and notices are available on our Web site at *http://www.stb.dot.gov*.

Decided: January 27, 2006.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. E6–1487 Filed 2–3–06; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Ex Parte No. 575]

Review of Rail Access and Competition Issues—Renewed Petition of the Western Coal Traffic League

AGENCY: Surface Transportation Board, DOT.

ACTION: Request for comments.

SUMMARY: The Surface Transportation Board is requesting comments on the renewed petition of the Western Coal Traffic League (WCTL) for a rulemaking to address agreements to sell or lease a rail line that restrict the ability of the purchaser or tenant to interchange traffic with competitors of the seller or landlord railroad.

DATES: Opening comments may be filed by any interested member of the public by March 8, 2006. Reply comments may be filed by March 28, 2006.

ADDRESSES: Any filing submitted in this proceeding must refer to STB Ex Parte No. 575 and may be submitted either via the Board's e-filing format or in the traditional paper format. Any person using e-filing must comply with the instructions found on the Board's *http://www.stb.dot.gov* Web site, at the "E-FILING" link. Any person submitting a filing in the traditional paper format must submit an original and 10 paper copies of the filing (and also an IBM-compatible floppy disk with any textual submission in any version of either Microsoft Word or WordPerfect) to: Surface Transportation Board, 1925 K Street, NW., Washington, DC 20423–0001. Because all comments will be posted to the Board's Web site, persons filing them with the Board need not serve them on other participants but must furnish a hard copy on request to any participant.

FOR FURTHER INFORMATION CONTACT: Joseph H. Dettmar, (202) 565–1609. [Federal Information Relay Service for the hearing impaired: 1–800–877–8339.]

SUPPLEMENTARY INFORMATION: Since enactment of the Staggers Rail Act of 1980, larger railroads have sold or leased many rail lines to small, newly created short line railroads. Some of the lease or sale agreements have had "paper barrier" provisions that limit the incentive or ability of the short line railroad to interchange traffic with connecting carriers that could compete with the lessor or vendor. Such paper barriers may result from credits for cars interchanged with the lessor or vendor, or they may involve a penalty for traffic interchanged with a competitor of the lessor or vendor, or a total ban on such interchange.

Concerns about such paper barriers were raised in STB Ex Parte No. 575, *Review of Rail Access and Competition Issues*, an ongoing umbrella proceeding to examine various issues concerning competition between railroads.[1] In response, on September 10, 1998, the Association of American Railroads (AAR) and the American Short Line and Regional Railroad Association (ASLRRA) executed a broad "Railroad Industry Agreement" ("RIA" or "agreement") that addressed paper barriers as well as various other issues.[2]

The provisions of the RIA specifically pertaining to paper barriers establish a few general principles,[3] applicable only

[1] In STB Ex Parte No. 575, the Board initiated a broad review of several railroad access and competition issues. *Review of Rail Access and Competition Issues*. 3 S.T.B. 92 (1998).

[2] The broader RIA was evaluated by the Board in STB Docket No. S5R 100. In that proceeding, the Board requested comments on, and granted interim approval for, the rate-related provisions of the broader agreement for which the parties requested approval. Assn. of American Railroads et al.—Agreement—49 U.S.C. 10706, 3 S.T.B. 673 (1998). The Board subsequently granted final approval of these rate-related provisions. Assn. of American Railroads et al.—Agreement—49 U.S.C. 10706, 3 S.T.B. 910 (1998). The Board made no findings as to the paper barrier and other non-rate provisions because approval for them was not sought. The original 1998 version of the RIA is included in Attachment 2 of the renewed petition of WCTL, filed on March 21, 2005, that is the subject of this notice. The agreement has been amended at least once: see the comments of the Rail Industry Working Group filed May 2, 2005.

[3] *See, e.g.*, the following provisions:

Paper Barriers:

Only legitimate paper barriers should be enforceable. Paper barriers are restrictions on interchange imposed by contract at the time of creation of the Short Line. Legitimate paper barriers are those that are designed as fair payment for the sale or rental value of the line that created the Short Line. Such barriers should not restrict the Short Line's ability to develop New Traffic with another carrier if the selling or leasing Large Railroad can not or will not participate in the New Traffic. Excessive per car charges or other penalties imposed if a car is interchanged to another Large Railroad (other than legitimate paper barriers) are unreasonable and should not be permitted.

3. Paper Barriers and New Routes (applies to participating Class I and III Railroads)

to new traffic (traffic that did not exist when a line was spun off), and illustrate their application by presenting the outcome (access/no access) under hypothetical situations with diagrams illustrating the relationships between the parties. The paper barrier provisions do not grant enforcement rights to shippers. Rather, the RIA provides for non-binding arbitration under Board auspices and creates a Rail Industry Working Group (RIWG) that can issue interpretations and provide a forum for discussion.

By petition filed on December 21, 1998, in STB Ex Parte No. 575, WCTL asked the Board to initiate a separate rulemaking to consider eliminating unreasonable paper barriers. WCTL argued that the agreement negotiated between AAR and ASLRRA did not adequately deal with the barriers. WCTL proposed rules that would restrict paper barriers. By decision served on March 2, 1999, the Board deferred action on WCTL's petition in order to gain experience under the AAR/ASLRRA agreement with respect to paper barriers.

By petition filed on March 21, 2005, WCTL renewed its 1998 request for rulemaking on the paper barrier issue. WCTL asserts that, since 1999, there have been significant changes in the Board's policies regarding competition, citing in particular the Board's revised merger guidelines for Class I railroads.[4] WCTL argues that, given the benefit of experience, unreasonable paper barriers should be subject to challenge by shippers as well as short lines and that any restrictions on these provisions should cover pre-existing traffic as well as new traffic. WCTL proposes specific rules that would establish a rebuttable presumption that a paper barrier is unreasonable and contrary to the public interest if the paper barrier (1) lasts longer than 5 years, (2) includes any financial penalty for interchanging traffic with another carrier, or (3) includes a credit for interchanging traffic with the seller or landlord railroad against a rental or sale price that reflects a return on the "fair market value" of the properties sold or leased that is greater than the railroad industry's cost of capital.

Replies in support of WCTL's petition were filed on April 29, 2005, by Entergy Services, Inc. (Entergy); and on May 2, 2005, by Albany & Eastern Railroad Company (AERC) and jointly by Arkansas Electric Cooperative Corporation and Entergy Arkansas, Inc. (Arkansas Electric/Entergy).

Replies in opposition to WCTL's petition were filed on May 2, 2005, by: ASLRRA; AAR; and RIWG. On May 5, 2005, the Union Pacific Railroad Company filed a statement rebutting statements in the replies of Arkansas Electric/Entergy and Entergy, to which Entergy responded on May 17, 2005. BNSF Railway Company responded to the AERC filing on May 20, 2005.

We are especially interested in comments that: (a) Discuss our statutory authority to address pre-existing paper barriers; (b) identify and describe existing paper barriers so that we can determine the extent of the problem alleged by WCTL; (c) identify and quantify any problems experienced by shippers as a result of paper barriers; (d) address the short and long term economic impacts of paper barriers; (e) address the effectiveness of the existing AAR/ASLRRA agreement on paper barriers; and (f) include information about the RIA, including the most recent version, amendment history, interpretations, proceedings, handbooks, etc.

Board filings, decisions, and notices are available on its Web site at *http://www.stb.dot.gov*.

This action will not significantly affect either the quality of the human environment or the conservation of energy resources.

Decided: January 30, 2006.

By the Board, Chairman Buttrey and Vice Chairman Mulvey.

Vernon A. Williams,

Secretary.

[FR Doc. E6–1558 Filed 2–3–06; 8:45 am]

BILLING CODE 4915–01–P

(a) General Premise: If the requested Access or routing helps the connecting Short Line and does not harm the Large railroad, then the request should be approved as it will improve shipper rail service while strengthening the rail industry.

[4] *See Major Rail Consolidation Procedures,* 5 S.T.B. 539 (2001). WCTL argues that these procedures require that the Board be proactive in taking steps to promote competition.

DEPARTMENT OF THE TREASURY

Financial Crimes Enforcement Network; Proposed Renewal Without Change; Comment Request; Anti-Money Laundering Programs for Various Financial Institutions.

AGENCY: Financial Crimes Enforcement Network, Department of the Treasury.

ACTION: Notice and request for comments.

SUMMARY: As part of our continuing effort to reduce paperwork and respondent burden, we invite comment on a proposed renewal, without change, to information collections found in existing regulations requiring money services businesses, mutual funds, operators of credit card systems, dealers in precious metals, stones, or jewels, and certain insurance companies to develop and implement written anti-money laundering programs reasonably designed to prevent those financial institutions from being used to facilitate money laundering and the financing of terrorist activities. Comment also is invited on an existing proposed regulation that would require unregistered investment companies to establish and maintain written anti-money laundering programs and to file a notice with us identifying themselves and providing related basic information. This request for comments is being made pursuant to the Paperwork Reduction Act of 1995, Public Law 104–13, 44 U.S.C. 3506(c)(2)(A).

DATES: Written comments are welcome and must be received on or before April 7, 2006.

ADDRESSES: Written comments should be submitted to: Financial Crimes Enforcement Network, P.O. Box 39, Vienna, VA 22183, Attention: Anti-Money Laundering Program Comments. Comments also may be submitted by electronic mail to the following Internet address: *regcomments@fincen.gov*, again with a caption, in the body of the text, "Attention: Anti-Money Laundering Program Comments."

Inspection of comments. Comments may be inspected, between 10 a.m. and 4 p.m., in our reading room in Washington, DC. Persons wishing to inspect the comments submitted must request an appointment by telephoning (202) 354–6400 (not a toll free number).

FOR FURTHER INFORMATION CONTACT: Financial Crimes Enforcement Network, Regulatory Policy and Programs Division at (800) 949–2732.

SUPPLEMENTARY INFORMATION:

Abstract: The Director of the Financial Crimes Enforcement Network is the delegated administrator of the Bank Secrecy Act. The Act authorizes the Director to issue regulations to require all financial institutions defined as such in the Act to maintain or file certain reports or records that have been determined to have a high degree of usefulness in criminal, tax, or regulatory investigations or proceedings, or in the conduct of intelligence or counter-intelligence activities, including analysis, to protect against international terrorism, and to implement anti-money laundering programs and compliance procedures.[1]

[1] Public Law 91–508, as amended and codified at 12 U.S.C. 1829b, 12 U.S.C. 1951–1959 and 31 U.S.C.

Continued

Regulations implementing section 5318(h)(1) of the Act are found in part at 31 CFR 103.125, 103.130, 103.132, 103.135, 103.137, and 103.140. In general, the regulations require financial institutions, as defined in 31 U.S.C. 5312(a)(2) and 31 CFR 103.11 to establish, document, and maintain anti-money laundering programs as an aid in protecting and securing the U.S. financial system.

1. *Titles:* Anti-money laundering programs for money services businesses (31 CFR 103.125), Anti-money laundering programs for mutual funds (31 CFR 103.130), Anti-money laundering programs for operators of credit card systems (31 CFR 103.135).

Office of Management and Budget Control Number: 1506–0020.

Abstract: Money services businesses, mutual funds, and operators of credit card systems are required to develop and implement written anti-money laundering programs. A copy of the written program must be maintained for five years.

Current Action: There is no change to existing regulations.

Type of Review: Extension of a currently approved information collection.

Affected Public: Business and other for-profit institutions.

Burden: Estimated Number of Respondents: 203,006.

31 CFR 103.125 = 200,000.
31 CFR 103.130 = 3,000.
31 CFR 103.135 = 6.

Estimated Number of Responses: 203,006.

31 CFR 103.125 = 200,000.
31 CFR 103.130 = 3,000.
31 CFR 103.135 = 6.

Estimated Number of Hours: 203,006. Estimated at one hour per respondent.

31 CFR 103.125 = 200,000.
31 CFR 103.130 = 3,000.
31 CFR 103.135 = 6.

2. *Title:* Anti-money laundering programs for unregistered investment companies (31 CFR 103.132).

Office of Management and Budget Control Number: 1506–0028.

Abstract: This proposed rule would require unregistered investment companies to establish and maintain written anti-money laundering programs. A copy of the written program would have to be maintained for five years. These companies would also be required to file notices with us, identifying themselves and providing related basic information.

Current Action: There is no change to the proposed regulation.

Type of Review: Extension of a currently approved information collection.

Affected Public: Business and other for-profit institutions

Description of Recordkeepers and Responders: Unregistered investment companies as defined in 31 CFR 103.132(a).

Estimated Number of Recordkeepers: 5,000.

Estimated Average Annual Burden per Recordkeeper: The estimated average burden associated with the recordkeeping requirement in this proposed rule is one hour per recordkeeper.

Estimated Total Annual Recordkeeping Burden: 5,000 hours.

Estimated Number of Respondents: 5,000.

Estimated Average Annual Burden Per Respondent: The estimated average burden associated with the notice requirement in this proposed rule is 30 minutes per respondent.

Estimated Total Annual Respondent Burden: 2,500 hours.

3. *Title:* Anti-money laundering programs for dealers in precious metals, precious stones, or jewels (31 CFR 103.140).

Office of Management and Budget Control Number: 1505–0030.

Abstract: Dealers in precious metals, stones, or jewels are required to establish and maintain written anti-money laundering programs. A copy of the written program must be maintained for five years.

Current Action: There is no change to existing regulations.

Type of Review: Extension of a currently approved information collection.

Affected Public: Business and other for-profit institutions.

Burden: Estimated Number of Respondents = 20,000.

Estimated Number of Responses = 20,000.

Estimated Number of Hours = 20,000.

4. *Title:* Anti-money laundering programs for insurance companies (31 CFR 103.137).

Office of Management and Budget Control Number: 1506–0035.

Abstract: Insurance companies are required to establish and maintain written anti-money laundering programs. A copy of the written program must be maintained for five years.

Current Action: There is no change to existing regulations.

Type of Review: Extension of a currently approved information collection.

Affected Public: Business and other for-profit institutions.

Burden: Estimated Number of Respondents = 1,200.

Estimated Number of Responses = 1,200.

Estimated Number of Hours = 1,200.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by the Office of Management and Budget. Records required to be retained under the Bank Secrecy Act must be retained for five years. Generally, information collected pursuant to the Bank Secrecy Act is confidential but may be shared as provided by law with regulatory and law enforcement authorities.

Request for Comments

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected: (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance and purchase of services to provide information.

Dated: January 30, 2006.

William D. Langford, Jr.,

Associate Director, Regulatory Policy and Programs Division, Financial Crimes Enforcement Network.

[FR Doc. E6–1524 Filed 2–3–06; 8:45 am]

BILLING CODE 4810–02–P

5311–5332. Language expanding the scope of the Bank Secrecy Act to intelligence or counter-intelligence activities to protect against international terrorism was added by section 358 of the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Ob struct Terrorism (USA PATRIOT) Act of 2001, Public Law 107–56.

DEPARTMENT OF VETERANS AFFAIRS

Veterans' Disability Benefits Commission

Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under Pub. L. 92–463 (Federal Advisory Committee Act) that the Veterans' Disability Benefits Commission has scheduled a town hall meeting for February 15, 2006, at the Hilton St. Petersburg Bayfront, 333 First Street South, St. Petersburg, Florida. The town hall meeting will begin at 7 p.m. and end at 9 p.m. A one half day business session of the Commission has been scheduled for February 16, 2006 at the same location. The half day meeting will begin at 8:30 a.m. and end at 11:30 a.m. Both meetings are open to the public.

The purpose of the Commission is to carry out a study of the benefits under the laws of the United States that are provided to compensate and assist veterans and their survivors for disabilities and deaths attributable to military service.

The Commission's visit to St. Petersburg will be the first of eight fact-finding, data-gathering site visits throughout the United States. The St. Petersburg/Tampa area was selected based upon criteria that included the concentration of veterans, active-duty service members and National Guard and Reserves, and the co-location of Veterans Benefits Administration, Veterans Health Administration, and Department of Defense (DoD) facilities, with particular interest in transition activities. The goal of this visit is to allow the commissioners the opportunity to tour local Department of Veterans Affairs (VA) and DoD facilities; examine the processes in place, which assist veterans in their efforts to obtain their benefits; and to present veterans, survivors and the general public with an opportunity to learn about the work of the Commission and to offer comments in a face-to-face forum.

The agenda for the half day meeting will include updates of the research work plans and work in progress by the Center for Naval Analyses (CNA) and the Institute of Medicine (IOM), an overview of the Tampa VA Polytrauma Rehabilitation Center, and an opportunity for public comments.

Interested persons may attend either or both meetings and present oral statements to the Commission. Oral presentations will be limited to five minutes or less, depending on the number of participants. Interested parties may provide written comments for review by the Commission prior to the meeting, by e-mail to *veterans@vetscommission.intranets.com* or by mail to Mr. Ray Wilburn, Executive Director, Veterans' Disability Benefits Commission, 1101 Pennsylvania Avenue, NW., 5th Floor, Washington, DC 20004.

Dated: January 26, 2006.

By Direction of the Secretary.

E. Philip Riggin,

Committee Management Officer.

[FR Doc. 06–1039 Filed 2–3–06; 8:45 am]

BILLING CODE 8320–01–M

DEPARTMENT OF VETERANS AFFAIRS

Privacy Act of 1974

AGENCY: Department of Veterans Affairs (VA).

ACTION: Notice of establishment of new system of records.

SUMMARY: The Privacy Act of 1974 (5 U.S.C. 552(e)(4)) requires that all agencies publish in the **Federal Register** a notice of the existence and character of their systems of records. Notice is hereby given that the Department of Veterans Affairs (VA) is establishing a new system of records entitled "Veteran Canteen Service (VCS) Payroll Deduction System-VA" (117VA103).

DATES: Comments on this new system of records must be received no later than March 8, 2006. If no public comment is received, the new system will become effective March 8, 2006.

ADDRESSES: Written comments concerning the proposed system of records may be submitted by: Mail or hand-delivery to Director, Regulations Management (00REG1), Department of Veterans Affairs, 810 Vermont Avenue, NW., Room 1068, Washington, DC 20420; fax to (202) 273–9026; or e-mail to *VAregulations@mail.va.gov*. All comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1063B, between the hours of 8 a.m. and 4:30 p.m., Monday through Friday (except holidays). Please call (202) 273–9515 for an appointment.

FOR FURTHER INFORMATION CONTACT: Chief Financial Officer, Veterans Canteen Service, Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420; telephone 314–845–1301.

SUPPLEMENTARY INFORMATION:

I. Description of Proposed Systems of Records

The VCS Payroll Deduction System allows VA employees, also known as customers, who participate in the program to pay for purchases in VCS canteens through deduction from their pay. It is used to track purchases, payments, refunds, balances, payment status, and other information for these customers.

II. Proposed Routine Use Disclosures of Data in the System

VA is proposing to establish the following Routine Use disclosures of information maintained in this system:

1. VA may disclose information from this system of records to a private debt collection agent for the purpose of collecting unpaid balances from customers who have left VA employment without making full payment for purchases made under the program.

2. VA may disclose information from this system of records to the U.S. Treasury Offset Program (TOPS) for the purpose of collecting unpaid balances from customers who have left VA employment without making full payment for purchases made under the program.

VA needs to be able to collect unpaid balances from customers who have left VA employment without making full payment to VCS for purchases made under the program.

3. Disclosure may be made to the Federal Labor Relations Authority, including its General Counsel, when requested in connection with investigation and resolution of allegations of unfair labor practices, in connection with the resolution of exceptions to arbitrator awards when a question of material fact is raised and matters before the Federal Service Impasses Panel.

The release of information to FLRA from this Privacy Act system of records is necessary to comply with the statutory mandate under which FLRA operates.

4. Disclosure may be made to officials of labor organizations recognized under 5 U.S.C. chapter 71 when relevant and necessary to their duties of exclusive representation concerning personnel policies, practices, and matters affecting working conditions.

5. Disclosure may be made to officials of the Merit Systems Protection Board, including the Office of the Special Counsel, when requested in connection with appeals, special studies of the civil service and other merit systems, review of rules and regulations, investigation of

alleged or possible prohibited personnel practices, and such other functions promulgated in 5 U.S.C. 1205 and 1206, or as may be authorized by law.

6. Disclosure may be made to the Equal Employment Opportunity Commission when requested in connection with investigations of alleged or possible discrimination practices, examination of Federal affirmative employment programs, compliance with the Uniform Guidelines of Employee Selection Procedures, or other functions vested in the Commission by the President's Reorganization Plan No. 1 of 1978.

7. Disclosure may be made to the National Archives and Record Administration (NARA) in records management inspections conducted under authority of Title 44 United States Code.

NARA is responsible for archiving old records no longer actively used but which may be appropriate for preservation; they are responsible in general for the physical maintenance of the Federal government's records. VA must be able to turn records over to these agencies in order to determine the proper disposition of such records.

8. Disclosure of relevant information may be made to individuals, organizations, private or public agencies, etc., with whom VA has a contract or agreement to perform such services as VA may deem practicable for the purposes of laws administered by VA, in order for the contractor or subcontractor to perform the services of the contract or agreement.

VA occasionally contracts out certain functions when this would contribute to effective and efficient operations. VA must be able to give a contractor whatever information is necessary for the contractor to fulfill its duties. In these situations, safeguards are provided in the contract prohibiting the contractor from using or disclosing the information for any purpose other than that described in the contract.

9. Disclosure may be made to a member of Congress or staff person acting for the member when the member or staff person requests the records on behalf of and at the request of that individual.

Individuals sometimes request the help of a member of Congress in resolving some issues relating to a matter before VA. The member of Congress then writes VA, and VA must be able to give sufficient information to be response to the inquiry.

10. Disclosure may be made to a Federal, State or local agency, upon its official request, to the extent that it is relevant and necessary to that agency's decision regarding: the hiring, retention or transfer of an employee, the issuance of a security clearance, the letting of a contract, or the issuance or continuance of a license, grant or other benefit given by that agency. However, in accordance with an agreement with the U.S. Postal Service, disclosures to the U.S. Postal Service for decisions concerning the employment of veterans will only be made with the veteran's prior written consent.

VA must be able to provide information to agencies conducting background checks on applicants for employment or licensure.

III. Compatibility of the Proposed Routine Uses

The Privacy Act permits VA to disclose information about individuals contained in a system of records without their consent for a routine use, when the information will be used for a purpose that is compatible with the purpose for which the information was collected. In all of the routine use disclosures described above, either the recipient of the information will use the information in connection with a matter relating to one of VA's programs or to provide a benefit to VA, or disclosure is required by law.

The notice of intent to publish and an advance copy of the system notice have been sent to the appropriate Congressional committees and to the Director of the Office of Management and Budget (OMB) as required by 5 U.S.C. 552a(r) (Privacy Act) and guidelines issued by OMB (65 FR 77677), December 12, 2000.

Approved: January 24, 2006.

Gordon H. Mansfield,

Deputy Secretary of Veterans Affairs.

117VA103

SYSTEM NAME:

Veteran Canteen Service (VCS) Payroll Deduction System—VA

SYSTEM LOCATION:

Individual purchase records are maintained in the Veterans Canteen Service office at each Department of Veterans Affairs (VA) health care facility. Addresses for VA facilities are listed in VA Appendix 1. In addition, information from these records or copies of records are maintained in a centralized electronic database at the Austin Automation Center (AAC), 1615 East Woodward Street, Austin TX, 78772.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The individuals covered by the system encompass permanent VA employees, also known as customers, who participate in the VCS Payroll Deduction System, which permits them to pay for purchases in VCS canteens through deduction from their pay.

CATEGORIES OF RECORDS IN THE SYSTEM:

These records include the following information:

—Customer identification information such as last name, first name, middle initial, social security number;
—Customer purchases made under the program;
—Payroll payments, cash payments, refunds for returned merchandise, and refunds for overpayments;
—Customer account balances and amounts written-off as uncollectible;
—Customer pay status when customer is in a "without pay" status;
—Identification of VCS employees creating customer transactions is by manual or electronic data capture. Manual transactions can be traced by a user ID within the payroll deduction system that identifies the individual entering the manual transaction. Electronic transactions can be traced via cashier code of the cashier ringing the transaction into the cash register; and
—Customer station number and canteen of purchase.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Title 38, United States Code, Part V, Chapter 78.

PURPOSE(S):

The records and information will be used to track customer purchases, payment and balances due to VCS. Records may also be used to identify and submit a customer for the purpose of debt collection. The records and information may be used for management and analysis reports of VCS programs.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. VA may disclose information from this system of records to a private debt collection agent for the purpose of collecting unpaid balances from customers who have left VA employment without making full payment for purchases made under the program.

2. VA may disclose information from this system of records to the U. S. Treasury Offset Program (TOPS) for the purpose of collecting unpaid balances from customers who have left VA employment without making full payment for purchases made under the program.

3. Disclosure may be made to the Federal Labor Relations Authority, including its General Counsel, when requested in connection with investigation and resolution of allegations of unfair labor practices, in connection with the resolution of exceptions to arbitrator awards when a question of material fact is raised and matters before the Federal Service Impasses Panel.

4. Disclosure may be made to officials of labor organizations recognized under 5 U.S.C. chapter 71 when relevant and necessary to their duties of exclusive representation concerning personnel policies, practices, and matters affecting working conditions.

5. Disclosure may be made to officials of the Merit Systems Protection Board, including the Office of the Special Counsel, when requested in connection with appeals, special studies of the civil service and other merit systems, review of rules and regulations, investigation of alleged or possible prohibited personnel practices, and such other functions promulgated in 5 U.S.C. 1205 and 1206, or as may be authorized by law.

6. Disclosure may be made to the Equal Employment Opportunity Commission when requested in connection with investigations of alleged or possible discrimination practices, examination of Federal affirmative employment programs, compliance with the Uniform Guidelines of Employee Selection Procedures, or other functions vested in the Commission by the President's Reorganization Plan No. 1 of 1978.

7. Disclosure may be made to the National Archives and Record Administration (NARA) in records management inspections conducted under authority of Title 44 United States Code.

8. Disclosure of relevant information may be made to individuals, organizations, private or public agencies, etc., with whom VA has a contract or agreement to perform such services as VA may deem practicable for the purposes of laws administered by VA, in order for the contractor or subcontractor to perform the services of the contract or agreement.

9. Disclosure may be made to a member of Congress or staff person acting for the member when the member or staff person requests the records on behalf of and at the request of that individual.

10. Disclosure may be made to a Federal, State or local agency, upon its official request, to the extent that it is relevant and necessary to that agency's decision regarding: The hiring, retention or transfer of an employee, the issuance of a security clearance, the letting of a contract, or the issuance or continuance of a license, grant or other benefit given by that agency. However, in accordance with an agreement with the U.S. Postal Service, disclosures to the U.S. Postal Service for decisions concerning the employment of veterans will only be made with the veteran's prior written consent.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

Pursuant to 5 U.S.C. 552a(b)(12), VA may disclose records from this system to consumer reporting agencies as defined in the Fair Credit Reporting Act (15 US.C. 168la(f) or the Federal Claims Collection Act of 1966 (31 US.C. 3701(a)(3)).

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained primarily on a computer disk in a centralized database system. Paper records of program Participation Agreements and individual customer records are maintained in canteen office files.

RETRIEVABILITY:

Records are retrieved by name and/or social security number of the participating VA employees or customers.

SAFEGUARDS:

1. Access to VA work and file areas is restricted to VA personnel with a legitimate need for the information in the performance of their official duties. Strict control measures are enforced to ensure that access by these individuals is appropriately limited. Information stored electronically may be accessed by authorized VCS employees at remote locations, including VA health care facilities. Access is controlled by individually unique passwords or codes, which must be changed periodically by the users.

2. Physical access to the Austin VA Data Processing Center is generally restricted to Center employees, custodial personnel, Federal Protective Service, and other security personnel. VA file areas are generally locked after normal duty hours, and the facilities are protected from outside access by the Federal Protective Service or other security personnel. Access to computer rooms is restricted to authorized operational personnel through electronic locking devices. All other persons gaining access to computer rooms are escorted.

3. All data transmissions are encrypted to prevent disclosure of protected Privacy Act information. Access to backup copies of data is restricted to authorized personnel in the same manner as the Austin VA Data Processing Center.

RETENTION AND DISPOSAL:

Records for active participants in the Payroll Deduction Program are maintained indefinitely. Records for participants who leave VA employment or voluntarily or involuntarily terminate their participation in the Payroll Deduction Program are retained for three years following the date the account attains a zero balance; or for three years following the date the account balance is written off following unsuccessful collection action.

SYSTEM MANAGER(S) AND ADDRESS:

Official responsible for policies and procedures: Office of the Chief Financial Officer, Veterans Canteen Service (103), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420. Officials maintaining the system: Chief of the Canteen Service at the facility where the individuals were associated. Addresses for VA facilities are listed in VA Appendix 1.

NOTIFICATION PROCEDURE:

Individuals who wish to determine whether this system of records contains records about them should contact the VCS Payroll Deduction Program Specialist at the Veterans Canteen Service Central Office (VCSCO–FC), St. Louis, Missouri 63125; telephone: (314) 845–1301. Inquiries should include the person's full name, social security number, date(s) of contact, and return address.

RECORD ACCESS PROCEDURE:

Individuals seeking information regarding access to and contesting of records in this system may write, call, or visit the VCS Payroll Deduction Program Specialist at the Veterans Canteen Service Central Office (VCSCO–FC), St. Louis, Missouri 63125; telephone: (314) 845–1301.

CONTESTING RECORD PROCEDURES:

(See Record Access Procedures above.)

RECORD SOURCE CATEGORIES:

Information in this system of records is provided by the customers who participate in the program, VA employees and various VA systems.

[FR Doc. 06–1078 Filed 2–3–06; 8:45 am]

BILLING CODE 8320–01–P

Corrections

Federal Register

Vol. 71, No. 24

Monday, February 6, 2006

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9, 141, and 142

[EPA–HQ–OW–2002–0039; FRL–8013–1]

RIN 2040–AD37

National Primary Drinking Water Regulations: Long Term 2 Enhanced Surface Water Treatment Rule

Correction

In rule document 06–4 beginning on page 654 in the issue of Thursday, January 5, 2006, make the following correction:

§141.719 [Corrected]

On page 781, in §141.719(b)(v), in the second column, the equation "LRV = $LOG_{10}(C_f) \times LOG_{10}(C_p)$" should read "LRV = $LOG_{10}(C_f) - LOG_{10}(C_p)$".

[FR Doc. C6–4 Filed 2–3–06; 8:45 am]

BILLING CODE 1505–01–D

Federal Register

Monday,
February 6, 2006

Part II

Environmental Protection Agency

40 CFR Parts 9 and 26
Protections for Subjects in Human Research; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 26

[EPA–HQ–OPP–2003–0132; FRL–7759–8]

RIN 2070–AD57

Protections for Subjects in Human Research

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: With this final rule, EPA bans research for pesticides involving intentional exposure of human subjects, when the subjects are pregnant women or children. The rule further strengthens existing protections for subjects in research conducted or supported by EPA, by prohibiting such research if it would involve intentional exposure of human subjects who are pregnant women or children. The rule also extends new protections to adult subjects in research for pesticides conducted by others who intend to submit the research to EPA, when it involves intentional exposure of human subjects who are non-pregnant adults, and creates a new, independent Human Studies Review Board to advise the Agency on the ethical and scientific issues arising in such research. This final rule focuses on third-party intentional dosing human studies for pesticides and sets the stage for further Agency actions. In addition, in order to display the OMB control number for the information collection requirements contained in this final rule, EPA is amending the table of OMB approval numbers for EPA regulations that appears in 40 CFR part 9.

DATES: This rule is effective on April 7, 2006.

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2003–0132. All documents in the docket are listed in the index for the docket. Although listed in the docket index, some information is not publicly available, i.e., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not available through the electronic docket and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically at *http://www.regulations.gov* or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: William L. Jordan, Mailcode 7501C, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–1049; fax number: (703) 308–4776; e-mail address: *jordan.william@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. What Does this Final Rule Do?

With this final rule EPA significantly strengthens and expands the protections for subjects of "third-party" human research (i.e., research that is not conducted or supported by EPA) by: (1) Prohibiting new research involving intentional exposure of pregnant women or children, intended for submission to EPA under the pesticide laws; (2) extending the provisions of the Federal Policy for the Protection of Human Subjects of Research (the "Common Rule") to other human research involving intentional exposure of non-pregnant adults, intended for submission to EPA under the pesticide laws; (3) requiring submission to EPA of protocols and related information about covered human research before it is initiated; and (4) establishing an independent Human Studies Review Board to review both proposals for new research and reports of covered human research on which EPA proposes to rely under the pesticide laws.

The final rule also: (1) Categorically prohibits any EPA research involving intentional exposure of human subjects who are pregnant women or children to pesticides or any substances; and (2) adapts regulations of the Department of Health and Human Services providing additional protections beyond those of the Common Rule to pregnant women and children as subjects in EPA observational research—i.e., research which does not involve intentional exposure to any substance. (Research conducted by EPA is referred to as "first-party" research, and "second-party" research refers to research supported by EPA but performed by others.)

Finally, this rule forbids EPA to rely, in its actions under the pesticide laws, on intentional-exposure human research that either involves pregnant women or children or is otherwise considered unethical, except in narrowly defined circumstances. For example, if children were at risk from unsafe exposure to a substance, the Agency would be permitted to rely on otherwise unacceptable research to justify setting a more restrictive standard to protect them.

B. Legal Authority

EPA is promulgating this final rule to effectuate the express mandate of the United States Congress as set forth in section 201 of the Department of the Interior, Environment, and Related Agencies Appropriations Act, 2006, Public Law No. 109–54 (Appropriations Act), which provides appropriated funds for EPA and other federal departments and agencies. In addition, today's final rule is authorized under provisions of the following statutes that EPA administers: Section 3(a) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), which authorizes the Administrator to regulate the distribution, sale, or use of any unregistered pesticide in any State "[t]o the extent necessary to prevent unreasonable adverse effects on the environment" (defined at FIFRA section 2(bb), in pertinent part, as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide"); section 25(a) of FIFRA, which authorizes the Administrator to "prescribe regulations to carry out the purposes of [FIFRA]," and section 408(e)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FFDCA), which authorizes the Administrator to issue a regulation establishing "general procedures and requirements to implement [Section 408]." In addition, EPA's expansion of its human subject protection regulations to include additional subparts supplementing EPA's codification of the Common Rule regarding first- and second-party research are authorized pursuant to 5 U.S.C. 301 and 42 U.S.C. 300v–1(b).

C. Does this Action Apply to Me?

You may be potentially affected by this action if you conduct human research on substances regulated by EPA. Potentially affected entities may include, but are not limited to, entities that conduct or sponsor research involving intentional exposure of human subjects that may be submitted to EPA under FIFRA or FFDCA. Although EPA has in the past received such third-party research from pesticide registrants, other entities could submit such information to EPA.

- Pesticide and other Agricultural Chemical Manufacturing (NAICS code 325320).

This listing is not intended to be exhaustive, but rather provides a guide regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) code has been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions of 40 CFR part 26. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

D. How Can I Access Electronic Copies of this Document and Other Related Information?

You may access an electronic copy of this **Federal Register** document and the associated electronic docket at *http://www.regulations.gov*, or you may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of the Code of Federal Regulations (CFR) is available at *http://www.gpoaccess.gov/ecfr/*.

II. Background

A. Summary of EPA Goals for this Final Rule

EPA's most important statutory responsibility is to protect public health and the environment by regulating air and water pollutants, pesticides, hazardous wastes, industrial chemicals, and other environmental substances. To meet this responsibility the Agency considers a wide range of information about each substance, including its potential to cause harm—i.e., its toxicity—and how and at what levels people may be exposed to it—i.e., their exposure. By linking information about toxicity with estimates of exposure, EPA can estimate the risk a substance poses to exposed populations, and then decide whether and how best to regulate releases of the substance into the environment.

EPA believes that in general it can best protect public health by considering all available, relevant, scientifically sound information, including information developed through research with human subjects. But at the same time, EPA wants to take action to ensure that research conducted by EPA or for EPA, submitted to EPA, and relied on by EPA—especially research with human subjects—has been conducted ethically.

B. The Role of Human Research in EPA Risk Assessments

The Agency's understanding of potential risks to people is usually based on many tests performed with laboratory animals. These tests differ in the kinds of animals used, the duration of exposure, the age of test animals, and the pathway of exposure–through food, air, or the skin. When they are considered together, the results of all these studies provide a good general understanding of a pesticide's potential effects.

Animal studies, however, are not the only source of relevant information for characterizing potential risks of a substance. Epidemiological studies, for example, provide valuable information about the relationship between chemical exposure and effects of concern. Monitoring studies that measure concentrations of a substance in air, water, food, or on surfaces also provide valuable insights into chemical exposures. Sometimes, however, the relationship between environmental concentrations of a substance and potential human exposure is unclear, and can be understood only through research involving human subjects. For example, a farmer's actual exposure to a pesticide he or she is applying will depend on his or her equipment, the kind and quantity of pesticide he or she uses, what protective clothing or equipment he or she uses, and how many hours he or she works each day. To be able to take these factors into account, workers will often wear monitors in the field to measure exposure levels in their routine work. Research like this provides critical data for defining protective standards for pesticide handlers and applicators. Without these and similar studies characterizing the exposures received by individuals in the normal course of their work and daily life, the Agency would not understand adequately either what types of application equipment and protective clothing to require for a pesticide, or how soon harvesters or other workers could safely enter pesticide-treated areas.

Some human research, however, involves intentional exposure of human subjects—defined in this rule as exposure they would not have experienced had they not participated in the research. One kind of research involves exposing subjects to low doses of a substance to measure how it is absorbed, distributed, metabolized, and excreted. Humans process some substances differently from animals, and studies of this kind can provide essential support for safety monitoring programs, such as those which measure the known metabolites of a substance in the blood or urine of workers to estimate their exposure to the substance.

Although EPA has not required or encouraged it, some third parties have occasionally conducted and submitted to EPA reports of research involving intentional exposure of human subjects to a substance to identify or measure its toxic effects. These studies occur in a controlled laboratory or clinical setting.

Animal data alone can sometimes provide an incomplete or misleading picture of a substance's safety or risks. Sometimes human research shows people to be more susceptible than animals to the effects of a chemical, and supports regulatory measures more protective than could be justified by animal data alone. This has been the case, for example, for arsenic, certain air pollutants, and the pesticide ingredients methyl isothiocyanate (MITC) and hexavalent chromium. Even when human research does not show people to be more sensitive than animals, scientifically sound human data developed under strict ethical standards can strengthen the basis for EPA regulatory actions.

C. Societal Concern over the Ethics of Human Research

Scientific experimentation with human beings has always been controversial. The history of human research contains well-known examples of unethical behavior in the name of science, which have led to reforms in the way the government and others carry out and oversee human research. Through these reforms, the standards for ethical human research have evolved to become progressively more stringent and protective of the subjects of the research. In the United States the "Common Rule," a regulation followed by EPA and 17 federal departments and agencies, contains a widely accepted set of standards for conducting ethical research with human subjects, together with a set of procedures designed to ensure that the standards are met. See Unit V.

For several years EPA has been at the center of an intense debate about the acceptability of intentional dosing human toxicity studies for pesticides, and about what to do with human studies that are ethically deficient. In this debate some have argued that all research involving intentional exposure of human subjects to pesticides is fundamentally unethical and should never be conducted or accepted. Others, while acknowledging the possibility of

ethical human research with pesticides, have argued that EPA should simply refuse to consider data from ethically problematic research in its regulatory decisions. Those who hold this view interpret Agency reliance on an ethically flawed study as an endorsement of the investigators' behavior, and as encouragement to others to engage in similarly unethical research. Some also argue that EPA's reliance on ethically deficient human data could directly benefit the wrongdoer. For example, if EPA based a regulatory decision on a human study that shows humans to be less sensitive than animals, the result might be a less stringent regulatory measure, advantageous to the company that conducted the study. If the key study was unethical, the company could benefit from its own misconduct.

On the other hand, human research has contributed enormously to scientific understanding of the risks posed by many substances in the environment, and to some of EPA's past regulatory actions. With this in mind, others argue that the Agency should consider all relevant and scientifically sound information—not excluding ethically deficient human data—because to do so will lead to better decisions, based on assessments that better reflect actual risks. Holders of this view argue that the ethical deficiencies of the research are the responsibility of the researchers, not of EPA. They further argue that EPA can do no additional harm to the subjects of the research by relying on scientifically valid and relevant data from an ethically deficient study, whereas EPA's refusal to rely on such data could do nothing to benefit the subjects of the research. Moreover, they assert that while the Agency cannot undo what has already happened, EPA can clearly express its disapproval of past unethical conduct. Holders of this view also stress the importance of strengthening protections for volunteers who participate in future studies, while taking advantage of all that past research can offer to benefit society.

D. EPA's Solicitation of Expert Advice

In response to public concerns over human research with pesticides, EPA convened an advisory committee under the joint auspices of the EPA Science Advisory Board (SAB) and the FIFRA Scientific Advisory Panel (SAP) to address issues of the scientific and ethical acceptability of such research. This committee, known as the Data from Testing of Human Subjects Subcommittee (DTHSS), met in December 1998 and November 1999, and completed its report in September 2000. Their report is available in the public docket for this rulemaking, and on the web at: *http://www.epa.gov/science1/pdf/ec0017.pdf.*

The DTHSS advisory committee agreed unanimously on several broad principles, including the following:

- Any policy adopted should reflect the highest standards, and special concern for the interests of vulnerable populations.
- The threshold of justification for intentional exposure of human subjects to toxic substances should be very high.
- The justification cannot be to facilitate commercial interests, but only to safeguard public health.
- Not only the nature and magnitude of risks and benefits but their distribution must be considered in assessing research protocols.
- Bad science is always unethical.

No clear consensus, however, emerged from the committee on many other points, including either the scientific merit or the ethical acceptability of studies to identify or measure toxic effects of pesticides in human subjects. A vigorous public debate continued about the extent to which EPA should accept, consider, or rely on third-party intentional dosing human studies for pesticides.

In December 2001, EPA asked the advice of the National Academy of Sciences (NAS) on the many difficult scientific and ethical issues concerning intentional human dosing studies. At EPA's request, the NAS convened a committee to provide the requested advice. The committee met publicly in December 2002, and again in January and March 2003. After long and thoughtful consideration of the full range of issues, the committee released its final report, "Intentional Human Dosing Studies for EPA Regulatory Purposes: Scientific and Ethical Issues," in February 2004. Their report is available at: *http://www.nap.edu/books/0309091721/html/.*

The NAS recommendations addressed what standards should guide the conduct of future human research and whether or not EPA should rely on the results of ethically deficient human studies. The NAS Report concluded that the answers to these questions should start from the existing standards for the ethical treatment of human research embodied in the Common Rule. The NAS Report then offered numerous recommendations, supported by detailed rationales, for how to apply the principles of the Common Rule to the particular issues confronting EPA. EPA has relied heavily on the advice of this committee in developing this rule. The NAS Report discusses the full range of types of human studies available to EPA and the full breadth of statutory programs under which they might be considered.

E. Balancing Conflicting Societal Goals

EPA's mission is to make the best possible regulatory decisions to protect public health and the environment. EPA does not want to ignore potentially important information that might benefit its assessments and decision-making. At the same time, the Agency's conduct should encourage high ethical standards in research with human subjects. If all research with human subjects always met the highest contemporary ethical standards, these goals could all be pursued together. But sometimes they conflict.

Two salient issues illustrate the difficulty in striking an appropriate balance between societal goals in conflict. First, the Agency must decide what standard to apply to assess the ethical acceptability of research performed before the new rule takes effect. The choices are: To apply today's standards of ethical conduct to research performed in the past, or to judge past research against the ethical norms prevailing when it was conducted.

Codes of ethical research conduct regulate the behavior of investigators before and during the research. It is reasonable to expect investigators to follow ethical codes that prevail when they do their work; but EPA believes it is unreasonable to expect them to anticipate and follow standards that may be developed after their work is done. EPA believes that scientifically meritorious research that adhered to accepted high ethical standards when it was conducted should not be set aside because ethical standards have subsequently changed. EPA also believes that ethical standards are likely to continue to change in the future and that if and when they do, such a change should not invalidate or make unacceptable otherwise meritorious research conducted now, in conformity with high ethical standards of today. Other parts of the U.S. government, and other countries, have arrived at a similar position.

In the final rule, EPA has implemented the applicable recommendation of the NAS, and will accept scientificatiated before the rule becomes effective unless there is clear and convincing evidence that it was fundamentally unethical or significantly deficient with respect to the ethical standards prevailing when the research was conducted.

The second salient issue concerns whether it is ever justified to rely on a

report of scientifically sound research judged to be unethical. To illustrate this problem, assume that EPA received a report of scientifically valid research involving intentional exposure of children, which is defined by this rule as unacceptable. But assume this study shows that the level of exposure to the tested substance safe for children is 5 parts per billion (ppb), whereas all other information available from animal studies and ethical human studies suggests that children would be safe if exposed at levels up to 90 ppb. A regulatory standard of 5 ppb based on the unacceptable study would adequately protect exposed children; a standard which did not rely on the unacceptable study would be set at 90 ppb, and would not adequately protect exposed children.

In such a situation, what should the Agency do? If EPA refused to rely on the unethical research in this example, it would set its standard at 90 ppb and would not adequately protect exposed children. Moreover, if the final rule always prohibited reliance on data from research involving intentional exposure of children, even in this exceptional case, using the data to justify a level at 5 ppb would be a plain violation of a regulation that could be subject to legal challenge.

The ethical and responsible course, EPA believes, would be to rely on the data to set a fully protective standard, while strongly condemning unethical research conduct and imposing appropriate administrative sanctions. Moreover, the number of people who would benefit from EPA's regulatory intervention could be far greater than the number of subjects involved in the research. Thus EPA has retained the proposed exception, to permit it to take legally defensible action to protect public health in this kind of exceptional situation.

EPA expects a circumstance like this example to arise only rarely, if at all. But however rarely it might occur, any decision to rely on unacceptable data, should only be made with great care, with full opportunity for public discussion, and in reliance on expert advice. As discussed further later, the final rule both provides for the essential public health protection exception, narrowly defined, and meets all these additional criteria.

III. EPA's Proposed Human Studies Rulemaking and General Public Comments

Summary: This unit reviews the general public comments on EPA's proposed rulemaking. The detailed comments are addressed in subsequent units of this preamble.

An extensive review of the historical development of ethical standards for the conduct of human research and the events leading up to the promulgation of this final rule appeared in the preamble to the proposed rule, available in the public docket for this action.

Today's final rule is the first to emerge from the process which began with publication of an Advance Notice of Proposed Rulemaking in the **Federal Register** on May 7, 2003 (68 FR 24410) (FRL–7302–8). On February 8, 2005 (70 FR 6661) (FRL–7695–4), EPA published and invited public comment on a **Federal Register** notice announcing its plan to establish a comprehensive framework for deciding whether to consider or rely on certain types of research with human subjects.

On September 12, 2005 (70 FR 53838) (FRL–7728–2), EPA published in the **Federal Register** a notice of proposed rulemaking to strengthen the protections for people who participate as subjects in human research. The Agency proposed to ban intentional dosing human testing for pesticides when the subjects are pregnant women or children, to formalize and further strengthen existing protections for subjects in human research conducted or supported by EPA, and to extend new protections to adult subjects in human research for pesticides, involving intentional exposure of human subjects and conducted by others who intend to submit the research to EPA. The proposal also contained provisions to establish an independent Human Studies Review Board responsible for reviewing proposals to conduct new, intentional-exposure human research under the pesticide laws and EPA decisions to rely on the results of certain types of completed human research in its actions under the pesticides laws.

EPA received approximately 50,000 comments during the 90–day public comment period. The vast majority of the comments were submitted by private individuals as part of e-mail and letter-writing campaigns. The remaining unique comments came from individuals and organizations representing a range of stakeholders including pesticide companies, farm groups and other pesticide users, and environmental and public health advocacy groups. EPA has reviewed, summarized, and responded to these comments in the Response to Comments document available in the docket for this rule. In addition, this unit summarizes the major themes raised by the comments on the proposal, and explains how EPA has addressed them in the final rule.

Comment: All human research with pesticides is fundamentally unethical.

Response: EPA agrees with the advice it has received, as discussed in Unit II., from its advisory committees. The SAB/SAP Data from Testing of Human Subjects Subcommittee agreed that although ethical human research with pesticides was possible, the threshold of justification should be set very high. The NAS Committee likewise counseled care, recommending many specific conditions which should be satisfied, but nonetheless acknowledged the possibility of ethical research when those conditions were met. On that basis EPA has gone forward with this final rule.

Comment: Comments objected to the Agency's rulemaking on the ground that it would promote unethical research on human subjects by pesticide companies.

Response: EPA expects its tougher new rules will eliminate all unethical research and will decrease the overall number of future intentional dosing studies conducted for pesticides. The additional science and ethics reviews by EPA and the Human Studies Review Board should eliminate any proposed unethical research.

Over the period 1996 to 2001, EPA received approximately 33 intentional dosing studies of all types annually. These included studies measuring worker exposure; the efficacy of insect repellents; studies of absorption, distribution and excretion that help EPA assess exposure; and studies of systemic toxicity. Of these 33, only 4 a year, on average, involved intentional exposure of human subjects to measure minor, reversible systemic toxic effects. (Systemic effects are those that occur within the body, such as trembling, nausea, or headaches resulting from chemical changes in the nervous system.) See the Economic Analysis, Appendix B.

Since 1996 we have received about 26 intentional dosing, systemic toxicity studies on humans. After this rule is finalized, we expect that number to decrease from an average of 3 a year to as few as 0 or 1 per year. We expect that number of non-toxicity intentional dosing studies to remain about the same.

Comment: The proposal was unclear.

Response: Many comments on the proposed rule reflected confusion about which provisions applied to EPA and which to regulated third parties, and about how the standards applying to the conduct of new research by EPA or third parties differed from the standards applying to EPA decisions to consider

completed research. These different elements were mingled in some subparts of the proposed rule, contributing to this confusion. A concerted effort has been made in the final rule to eliminate these potential causes of confusion, by sharpening the focus of each subpart and grouping subparts in three broad groups:

- Rules applying to EPA's conduct and support of new research with human subjects.
- Rules applying to certain types of new third-party research for pesticides with human subjects.
- Rules applying to EPA in its regulatory capacity.

Comment: Ethical standards can be evaded simply by denying intent to submit the results of the research to EPA.

Response: The final rule, like the proposal, extends the Common Rule requirements only to third-party research intended for submission to EPA under the pesticide laws, FIFRA and FFDCA. EPA believes this is appropriate because there has not been adequate consideration of the policy consequences of extending the provisions of the final rule to investigators who have no intent to provide their research results to EPA and would otherwise have no reason to be aware of these requirements.

EPA also disagrees that the approach used in the final rule makes it easy to evade ethical standards for research by denying the intent to submit. Several elements in the final rule interact to ensure the application of appropriate standards. First is the explicit presumption in the rule that all research submitted by a pesticide registrant was intended for submission to EPA. Specific, credible documentation would have to be provided to rebut this presumption; a denial of intent, standing alone, could not serve as a rebuttal.

Second, if a submitter successfully rebutted the presumption of intent, it would make little practical difference, and would certainly not compel the Agency to accept unethically conducted research. Under the final rule, whether or not it was intended for submission to EPA when research was initiated, and whether or not it was otherwise subject to the requirements of subpart K: (1) After the effective date of the rule, all reports of human research submitted to EPA under the pesticide laws are required by subpart M to be accompanied by documentation of ethical conduct of the research, (2) all completed post-rule intentional-exposure research, on which the Agency intends to rely in actions under the pesticide laws, is required by subpart P to be reviewed by the Human Studies Review Board, and (3) all post-rule intentional-exposure research considered under the pesticide laws is subject under subpart Q to the Common Rule as the ethical standard of acceptability.

Consequently, the likelihood that unethical research will be used by EPA in actions under its pesticide laws is very small—only when it is determined that the data are crucial to support more protective public health actions would the Agency consider such data.

Comment: Limitation to research involving intentional exposure of human subjects excludes many kinds of studies.

Response: Most third-party human research for pesticides conducted by or for EPA, or intended for submission to EPA, meets the rule's definition of research involving intentional exposure, and thus will be subject to the requirements of subpart K. But whether or not research is subject to subpart K, all reports of all post-rule human research submitted to EPA are required by subpart M to be accompanied by documentation of ethical conduct.

Comment: Prohibitions of new research involving intentional exposure of pregnant women, fetuses, and children are subject to exceptions.

Response: The rule provides for no exceptions under any circumstances to the bans on the conduct of new research involving intentional exposure of pregnant women, fetuses, and children as subjects. The final rule has been revised for clarity; the prohibitions have been moved to subparts B (applying to EPA) and L (applying to third parties,) where they stand alone, and they have been reworded to emphasize that they apply notwithstanding any other provisions anywhere in 40 CFR part 26.

Comment: The prohibition on considering human subjects research involving intentional exposure of pregnant women, fetuses, and children applies only to regulatory decisions, and not to such non-regulatory agency actions as risk assessments.

Response: The final rule has been changed from the proposal to make this prohibition applicable to all Agency actions taken under the pesticide laws.

Comment: The proposed exception permitting EPA to consider unethically obtained data when to do so would be "crucial to protection of public health" undermines all other provisions of the rule. Anything from a more accurate risk assessment to increased agricultural production could be interpreted as "crucial to protection of public health," and used to justify reliance on unethical data.

Response: Such a broad interpretation was never intended by the Agency, but EPA acknowledges that its intentions were not perfectly clear from the language of the proposal. The final rule retains a "public health exception," but it is reworded to make it very clear that it could never be invoked to support a less stringent regulatory outcome than could be justified without consideration of the unethical research.

Comment: Many provisions of the Common Rule allow for exceptions to its requirements at the discretion of the Administrator or Institutional Review Boards (IRBs); these exceptions should not be allowed for third-party research.

Response: EPA agrees that some exceptions in the Common Rule are not appropriate for the kinds of third-party human research covered by this rule. In mirroring the core protections of the Common Rule as they apply to third parties in subpart K of the final rule, EPA has eliminated or narrowed many of these exceptions, as discussed in detail in Unit VII.

IV. Reorganization of the Rule Structure

Summary: To clarify the various requirements in the proposal and how they apply to first, second, and third parties, the Agency has extensively reorganized the final rule. The new organization regroups the provisions of the proposal into several new subparts.

In this final rule, EPA's codification of the Common Rule remains in force with no changes except to designate it as subpart A of part 26. Following today's action, the text of 40 CFR 26.101 through 26.124 remains identical to the codifications of the Common Rule by the other federal departments and agencies that have promulgated it.

The remaining subparts in the final rule, each discussed in a later unit of this preamble, are grouped as follows:

- Subparts A through D apply to EPA as an investigator or sponsor of new research with human subjects, and to second-party investigators whose research EPA supports. Subpart A contains the basic policy for human research (the unchanged Common Rule). Subpart B prohibits EPA human subjects research on any substance involving intentional exposure of pregnant women, fetuses, or children. Subparts C and D provide additional protections for pregnant women, fetuses, and children when they are subjects of observational studies conducted or supported by EPA.
- Subparts K and L apply to third parties as investigators or sponsors of

new research involving intentional exposure of human subjects and intended for submission to EPA under the pesticide laws. Subpart K establishes the basic protections for non-pregnant adult subjects in covered third-party research, corresponding in substance to subpart A. Subpart L prohibits covered third-party human subjects research for pesticides involving intentional exposure of pregnant women or children.

- Subpart M applies to all third parties who submit reports of any research with human subjects to EPA under the pesticide laws, whether or not the research is covered by subpart K, and requires concurrent submission of information documenting the ethical conduct of such research.
- Subparts O—Q apply to EPA in its regulatory capacity. Subpart O identifies potential actions for noncompliance with subparts A through L. Subpart P addresses the establishment and operation of the Human Studies Review Board, and subpart Q defines the ethical standards EPA will use to decide whether to rely on data from human research in EPA actions.

Because this reorganization causes extensive changes in the numbering of the provisions of the final rule, EPA provides the following table to make it easier to follow how the reorganization affects the location of specific provisions.

TABLE 1.—LOCATION IN PROPOSED AND FINAL RULE TEXT OF RULES APPLYING TO EPA AS AN INVESTIGATOR OR SPONSOR OF RESEARCH WITH HUMAN SUBJECTS

Location in Final Rule		Title/Description	Location in Proposed Rule	
Subpart	Section		Subpart	Section
A	§§ 26.201 thru 26.124	Basic Policy for Protection of Subjects in Human Research Conducted or Supported by EPA	A	§§ 26.101 thru 26.124
B	§§ 26.201 thru 26.203	Prohibition of Human Subjects Research Conducted or Supported by EPA Involving Intentional Exposure of Pregnant Women, Fetuses, or Children	B and D	§§ 26.220 and 26.420
B	§ 26.201	To what does this subpart apply?	n/a	n/a
B	§ 26.202(a)	Definition of *research involving intentional exposure of a human subject*	A	§ 26.102(k)
B	§ 26.202(b)	Definition of *child*	D	§ 26.402(a)
B	§ 26.203	Prohibition of EPA human subjects research involving intentional exposure of pregnant women, fetuses, or children	B and D	§§ 26.220 and 26.420
C	§§ 26.301 thru 26.305	Additional Protections for Pregnant Women or Fetuses Involved as Subjects in Observational Research Conducted or Supported by EPA	B	§§ 26.201 thru 26.206
D	§§ 26.401 thru 26.406	Additional Protections for Children Involved as Subjects in Observational Research Conducted or Supported by EPA	D	§ 26.401 thru 26.408

TABLE 2.—LOCATION IN PROPOSED AND FINAL RULE TEXT OF RULES APPLYING TO THIRD PARTIES AS INVESTIGATORS OR SPONSORS OF RESEARCH WITH HUMAN SUBJECTS

Location in Final Rule		Title/Description	Location in Proposed Rule	
Subpart	Section		Subpart	Section
K	§§ 26.1101 thru 26.1125	Basic Ethical Requirements for Third-Party Human Subjects Research for Pesticides Involving Intentional Exposure of Non-Pregnant Adults	A	§§ 26.101 thru 26.124
K	§ 26.1101(a)	To what does this subpart apply?	A	§ 26.101(j)
K	§ 26.1101(b)	Exemption of research involving only the collection or study of existing data . . .	A	§ 26.101(b)(4)
K	§ 26.1101(c)	Administrator retains final judgment as to whether a particular activity is covered by this subpart	A	§ 26.101(c)
K	§ 26.1101(d), (e), and (f)	Relation to other Federal, State, Tribal, Local, or foreign laws or regulations	A	§ 26.101(e), (f), and (g)
K	§ 26.1101(g)	For purposes of determining a person's intent under paragraph (a) of this section . . .	A	§ 26.101(k)

TABLE 2.—LOCATION IN PROPOSED AND FINAL RULE TEXT OF RULES APPLYING TO THIRD PARTIES AS INVESTIGATORS OR SPONSORS OF RESEARCH WITH HUMAN SUBJECTS—Continued

Location in Final Rule		Title/Description	Location in Proposed Rule	
Subpart	Section		Subpart	Section
K	§§ 26.1102(a) thru 26.1102(h)	Definitions	A	§§ 26.102(a) thru 26.102(i)
K	§ 26.1102(i)	Definition of research involving intentional exposure . . .	A	§ 26.102(k)
K	§ 26.1102(j)	Definition of person	n/a	n/a
K	§§ 26.1107 thru 26.1117	IRB and informed consent requirements	A	§§ 26.107 thru 26.117
K	§ 26.1123	Early termination of research	A	§ 26.123(a)
K	§ 26.1125	Prior submission to EPA of proposed human research	A	§ 26.124(b)
L	§§ 1201 thru 26.1203	Prohibition of Third-Party Human Subjects Research for Pesticides Involving Intentional Exposure of Pregnant Women, Fetuses, or Children	B and D	§§ 26.220 and 26.420
M	§§ 1301 thru 26.1303	Requirements for Submission of Information on the Ethical Conduct of Completed Human Research	A	§ 26.124(c)

TABLE 3.—LOCATION IN PROPOSED AND FINAL RULE TEXT OF RULES APPLYING TO EPA IN ITS REGULATORY CAPACITY

Location in Final Rule		Title/Description	Location in Proposed Rule	
Subpart	Section		Subpart	Section
O	§§ 26.1501 thru 26.1503	Administrative Actions for Noncompliance	E	§§ 26.501 thru 26.506
P	§§26.1601 thru 26.1603	Review of Proposed and Completed Human Research	A	§ 26.124(b)
P	§ 26.1601(c)	Determination of Equivalence of Foreign Ethical Standards	A	§ 26.101(h)
P	§ 26.1603	Operation of the Human Studies Review Board	A	§ 26.124(b)(5)
Q	§§ 26.1701 thru 26.1703	Ethical Standards for Assessing Whether to Rely on the Results of Human Subjects Research in EPA Actions	B, D, and F	§§ 26.221, 26.421, 26.601, 26.602, and 26.603
Q	§§ 26.1701 and 26.1702	Applicability and Definitions	n/a	n/a
Q	§ 26.1703	Prohibition of reliance on research involving intentional exposure of pregnant women, fetuses, or children	B and D	§§ 26.221 and 26.421
Q	§ 26.1704	Prohibition of reliance on unethical human research conducted before the effective date of the final rule	F	§ 26.601
Q	§ 26.1705	Prohibition of reliance on unethical human research conducted after the effective date of the final rule	F	§ 26.602
Q	§ 26.1706	Criteria and procedures for decisions to protect public health by relying on otherwise unacceptable research	F	§ 26.603

V. Subpart A—Basic Ethical Protections for Subjects of Human Research Conducted or Supported by EPA

Summary: This unit describes the basic ethical protections that apply to human research conducted or supported by EPA. Unit V.A. discusses the comprehensive system of ethical protections created by the "Basic Federal Policy for Protection of Human Research Subjects," generally referred to as the Common Rule. The Common Rule applies to all human research conducted or supported by EPA and 17 other federal departments and agencies. Unit V.B. discusses the proposed rule, Unit V.C. discusses public comments, and Unit V.D. discusses the final rule.

A. The Common Rule

The Common Rule defines the core protections for human subjects of research, and it is important to understand just what those protections are.

First, the Common Rule requires that research with human subjects be overseen by a qualified, independent

IRB meeting specific requirements laid out in the rule governing membership, procedures, decision-making, recordkeeping, and avoidance of conflicts of interest. The IRB is vested with responsibility to review proposed research, and with authority to approve or disapprove it. The IRB is also responsible for overseeing the conduct of approved research, and investigators are required to report any unanticipated events to the responsible IRB. IRB members must be trained, and must remain current with extensive guidance promulgated by the Office for Human Research Protections in HHS.

Under the Common Rule an IRB may approve proposed human subjects research only when it concludes that *all* of the following conditions are satisfied:

- Risks to subjects have been minimized.
- Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
- Selection of subjects is equitable.
- Informed consent will be sought from each prospective subject or the subject's legally authorized representative.
- Informed consent will be appropriately documented.
- The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
- There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
- Additional safeguards have been included in the study to protect the rights and welfare of subjects who are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

The Common Rule also requires each IRB to maintain records of everything it reviews, of its discussion of controversial issues, and of its decisions and their rationale.

The second major element in the Common Rule is its requirement that no investigator involve a human being as a subject in research without the informed consent of the subject or the subject's legally authorized representative. The Common Rule further specifically requires that:

- An investigator shall seek such consent only under circumstances that provide the prospective subject sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.
- The information given to the subject must be in language understandable to the subject.
- No informed consent, oral or written, may include any exculpatory language through which the subject is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

The Common Rule defines the following *mandatory* elements in informed consent:

- A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
- A description of any reasonably foreseeable risks or discomforts to the subject.
- A description of any benefits to the subject or to others which may reasonably be expected from the research.

A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.
- For research involving more than minimal risk, an explanation as to whether any compensation and any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.
- An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

The Common Rule specifies additional elements of informed consent that are sometimes required, and defines standards for documenting informed consent by use of a written consent form approved by the IRB and signed by the subject. The Common Rule requires that a copy be given to the person signing the form.

The Common Rule extends these core protections to all human subjects of covered research, including those in vulnerable populations. It is to this base of core protections for all subjects that "additional protections" for pregnant women, fetuses, and children as subjects of observational research conducted or supported by EPA, as contained in subparts C and D of this final rule, are added. Vulnerable populations for which no "additional protections" are provided by rule are not left defenseless or exploited; they are covered by these core protections of the Common Rule, including its requirement that IRBs ensure, on a case-by-case basis, that additional safeguards are employed in any study involving vulnerable populations to protect their rights and welfare.

In addition to these substantive protections for research subjects, the Common Rule as it applies to research conducted or supported by EPA or any other signatory department or agency also contains many administrative provisions intended to accommodate the wide range of circumstances in all the departments and agencies to which it applies. Among others, these administrative provisions include:

- Authority for the agency head to extend coverage of the rule to research "otherwise subject to regulation" (§ 26.101(a)) and to determine what is within its scope (§ 26.101(c) and (d)).
- Provision that only certain sections apply to third-party research subject to regulation (§ 26.101(a)(2)).
- A list of six kinds of human research exempted from coverage by the rule (§ 26.101(b)).
- Provision for approving research conducted under foreign standards that "afford protections that are at least equivalent to those provided in" the Common Rule (§ 26.101(h)).
- A grant of discretion to the agency head to waive provisions of the rule, with public notice in the **Federal Register** and to the DHHS Office for Human Research Protections (§ 26.101(i)).
- A grant of discretion to IRBs to waive or alter requirements for informed consent (§ 26.116(c) and (d)) or documentation of informed consent (§ 26.117(c)).

B. The Proposed Rule

The September 12 proposal to extend EPA's Common Rule to third-party research involved extending all the provisions of subpart A, §§26.101 through 26.124, to covered third-party research. It also would have altered the shared text of the Common Rule by adding:

- A new paragraph defining the scope of third-party research to which it applied (proposed § 26.101(j)).

- A new paragraph defining how a party's intent to submit research to EPA would be determined (proposed § 26.101(k)).
- A new definition of *research involving intentional exposure of a human subject* (proposed § 26.102(k)).
- A new requirement for prior submission to EPA of proposals for covered third-party research (proposed § 26.124(b)).
- A new requirement for submission to EPA of documentation of the ethical conduct of completed research (proposed § 26.124(c)).

As noted in the preamble to the proposal, HHS requested EPA not to make any alterations in the text of the shared Common Rule, and to codify the extension of the Common Rule standards to third-party research in the final rule in a way that left subpart A—the Common Rule—intact and unchanged. EPA agreed that the Common Rule should not be altered, and committed to making this change in the final rule.

C. Public Comment

Comment: The proposed extension of the entire Common Rule, including its provisions for administrative waivers of many requirements, alarmed many commenters. These administrative provisions were perceived as loopholes which could be exploited to undermine the whole purpose of extending the Common Rule.

Response: Such exploitation of these provisions was never the Agency's intent, and EPA agrees with the commenters who argued that many of these administrative provisions were not appropriate in a rule applying to third-party research. Thus, while subpart K in the final rule does extend all the substantive core protections of the Common Rule to non-pregnant adult subjects of covered research, it also eliminates or narrows the exceptions in the Common Rule. Unit VII. discusses each change from the Common Rule to subpart K in detail.

D. The Final Rule

In the final rule subpart A is the unaltered Common Rule, exactly as promulgated in 1991 except for its designation as "Subpart A." It applies to all research with human subjects conducted or supported by EPA.

VI. Subpart K—General Provisions Applying to Third Party, Intentional Exposure Human Research under the Pesticide Laws

Summary: Subpart K extends the basic protections of the Common Rule to subjects in certain research conducted or supported by third parties. It applies to third-party human research involving intentional exposure of non-pregnant adult subjects and that is intended to be submitted to EPA under the pesticide laws. In addition to the basic procedures and protections contained in the Common Rule, it also requires researchers who propose to conduct new research covered by the rule to submit protocols and other materials for science and ethics review by both EPA and a newly created Human Studies Review Board (HSRB). Unit VI.A. summarizes EPA's proposal, Unit VI.B. discusses public comment, and Unit VI.C. discusses the provisions of the final rule.

A. EPA's Proposed Rule

EPA's proposal added to the "Scope" section of the Common Rule additional paragraphs, proposed § 26.101(j) and (k), to make the provisions of the Common Rule applicable to certain third-party human research. Thus, the Agency's proposal would have extended the Common Rule requirements to third parties, without substantive or editorial modification.

The scope of the third-party human research covered by the proposal was defined as:

> [A]ll research involving intentional exposure of a human subject if, at any time prior to initiating such research, any person who conducted or supported such research intended:
>
> (1) To submit results of the research to EPA for consideration in connection with any regulatory action that may be performed by EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 *et seq.*) or section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a); or
>
> (2) To hold the results of the research for later inspection by EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 *et seq.*) or section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a).

In effect, this provision would have included all intentional-exposure human research conducted with the intent to submit the results to the Agency under the pesticide laws. The proposal also established a rebuttable presumption that any information submitted by a person regulated under the pesticide laws was generated with the intent to submit it to EPA.

In § 26.102(k), the proposal defined "research involving intentional exposure of a human subject" to mean "a study of a substance in which the exposure to the substance experienced by a human subject participating in the study would not have occurred but for the human subject's participation in the study." The preamble to the proposed rule explained that this term did not include a study that "monitored agricultural workers (such as professional fruit thinners or harvesters or other workers) who perform their usual work in areas that have been treated with pesticides at rates and using methods registered and approved by EPA" (70 FR 53846). The preamble also explained that intentional exposure studies did not include "most occupational exposure studies, and studies involving use of registered pesticides for approved uses according to label directions" (70 FR 53845).

In addition, the proposed rule included a new section, proposed § 26.124, that would have required any person proposing to conduct a new human study covered by the rule to submit the protocol and other materials for a science and ethics review by EPA. The same proposed section also created a new independent panel of experts, called the Human Studies Review Board, to review all proposed new research covered by the rule. The HSRB would also review all completed human research that EPA intended to rely on under the pesticide laws.

B. Public Comments

The major public comments applicable to subpart K of the final rule are discussed in Unit III.

C. The Final Rule

The final rule establishes new requirements for third-party research in a separate subpart K, and the rule text defining the scope of the types of third-party research covered by the proposed rule remains unchanged in the final rule. The Agency, however, has decided that the types of research captured by the definition of "research involving intentional exposure of a human subject" is broader than suggested by the preamble to the proposal. Although the text of the definition remains the same, EPA thinks it is important to clarify that the term covers any research on a substance, unless the subjects of the research retain complete control over whether, when, and how they are exposed to the substance. Thus, if the researcher decides a particular compound will be studied in the research and determines the manner in which subjects will be exposed, the research falls within the scope of "research involving intentional exposure."

The substantive requirements applicable to covered third-party research are similar to the requirements contained in the Common Rule. In most cases the text is identical, and the sections employ a parallel numbering

system. The sections in subpart K are designated as §§ 26.1101 through 26.1125 and correspond to the sections of the Common Rule designated §§ 26.1xx. For example, § 26.1107 in subpart K corresponds to § 26.107 of the Common Rule.

EPA also made a number of minor modifications to the text of the Common Rule in order to reflect the applicability of subpart K to a particular subset of human subjects research studies involving intentional exposure of non-pregnant adults intended for submission under the pesticide laws. These modifications are discussed in paragraph 1 below.

1. *Modifications to the text of the Common Rule in subpart K.* In a number of its provisions the Common Rule refers to itself as a "policy." Throughout subpart K, EPA has replaced the word "policy" with "subpart," to remove any doubt about whether the provisions of subpart K create binding requirements.

Throughout subpart K, EPA replaced references to "department or agency head" with "the Administrator." Section 26.1102 includes a definition stating that Administrator refers to the Administrator of EPA or any officer or employee to whom authority has been delegated.

Section 26.101(b) of the Common Rule exempts research in six categories from the requirements of the Common Rule. These exemptions generally cover:

(i) Research on educational practices conducted in an educational setting.

(ii) Research involving surveys, educational tests, observation, or interviews that involve no collection of sensitive personal information on identifiable individuals.

(iii) Research involving surveys, educational tests, observation, or interviews that involve public officials or candidates for public office.

(iv) Research involving the collection or study of existing data, documents, specimens, etc. from publicly available sources or sources that do not disclose the identity of individual subjects.

(v) Research examining the delivery of public benefit programs.

(vi) Research involving taste and food quality evaluation and consumer acceptance.

Subpart K, however, covers only third-party research for pesticides involving intentional exposure of non-pregnant adults. Because five of these exemptions describe types of research that either could not possibly or should not involve "intentional exposure" to a pesticide, EPA deleted them from subpart K. Because the fourth category, above, could encompass the examination of results from research involving intentional exposure, the Agency did retain exception number 4 in subpart K. See § 26.1101(b) of the regulatory text.

Section 26.101(d) of the Common Rule states that, without prior notice, an agency head may extend the requirements of the Common Rule to specific research activities or classes of research. As a legal and policy matter, EPA believes that the public should receive notice of and an opportunity for public comment on any extension of these requirements to additional categories of third-party research. Accordingly, subpart K does not contain a provision comparable to § 26.101(d).

Section 26.101(f) of the Common Rule indicates that State and local laws may contain additional requirements governing the conduct of human research and that the Common Rule does not supersede those requirements. Recognizing that Native American governmental entities also have legal authority to regulate the conduct of human research, EPA has added Tribal authority to the list of legal sources that may establish additional requirements beyond those in the final rule. See § 26.1101(e) of the regulatory text.

Section 26.101(h) of the Common Rule authorizes the head of an agency to allow human research conducted in a foreign country to proceed in accordance with the requirements of that country, even if foreign authorities require behavior that does not fully comply with the Common Rule, so long as the agency head determines that the requirements of the foreign country provide protections "at least equivalent to those [of the Common Rule.]" This section further provides that when an agency head makes such a decision, he must publish a notice of the action in the **Federal Register**. In promulgating subpart K, EPA retained a comparable provision, but with several changes. First, EPA moved this provision to subpart P of the final rule, which addresses EPA's decisions on the acceptability of proposed research, where it appears as § 26.1601(c). Second, EPA did not adopt the Common Rule's requirement to publish a **Federal Register** Notice announcing such a decision on proposed third-party research. The Agency concluded that such a procedure was redundant with the HSRB process, which will involve both a transparent presentation of EPA's positions regarding proposed research and public meetings about such positions and an opportunity for the public to comment on them.

Section 26.101(i) contains language allowing the Administrator to waive any of the requirements of the Common Rule. While every other federal Common Rule agency and department has such discretion, and while such discretion seems appropriate for first- and second-party research, EPA has never exercised this authority under the Common Rule and sees no need for such discretion under subpart K. Accordingly, subpart K does not contain a provision comparable to § 26.101(i).

The definitions in the Common Rule include the term *research subject to regulation*; see § 26.102(e). Subpart K omits this definition because the types of third-party research covered by the rule are specified by the paragraphs in § 26.1101 delineating the scope of subpart K.

Section 26.102(j) contains a definition of the term *certification*. Because this definition actually establishes a substantive obligation to submit documentation of IRB approval, the substantive requirement appears in § 26.1125 as one of the items that must be submitted to EPA in connection with review of proposed research. See § 26.1125(f) of the regulatory text.

EPA added a new definition of person in § 26.1102(j) of the final rule to clarify that the requirements of subpart K (as well as subparts L and M) do not apply to first-party and second-party human research by other federal departments and agencies that are subject to the Common Rule. Having operated under the Common Rule for many years, these agencies and departments are very familiar with its meaning and application and have well developed procedures for assuring compliance. Therefore, EPA sees no reason either to promulgate requirements that duplicate regulations already in force, or to impose on these agencies the new requirements of subpart K concerning submission of proposals for future research for EPA and HSRB review. Of course, the Agency will, on request, work with other agencies intending to submit the results of human research to EPA to ensure that the results may be considered under subpart Q.

Several sections of the Common Rule—§§ 26.107(a), 26.111(a)(3), 26.111(b), and 26.116(b)(1)—refer to additional measures required when research involves pregnant women, children, or other special populations as subjects. Subpart L, however, prohibits third-party research involving intentional exposure of human subjects who are pregnant women (and therefore their fetuses) or children. Thus subpart K covers only third-party research involving intentional exposure of non-pregnant adults. To be consistent with this scope, EPA removed from subpart

K all references to pregnant women, fetuses, newborns, or children.

The first sentence of § 26.107 of the Common Rule states:

> Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution.

This provision reflects the assumption that IRBs are always associated with an "institution." It also arguably would excuse an IRB from having adequate expertise to assess studies beyond those "commonly conducted" at the institution. EPA believes that IRBs should acquire whatever expertise they need to evaluate the types of studies they agree to review. Accordingly, EPA has revised that sentence to read:

> Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities which are presented for its approval.

Section 26.108(a) of the Common Rule contains a cross-reference to certain earlier sections of the Common Rule. For greater clarity, and consistent with FDA's approach in its similar rules. EPA simply repeated the substantive requirements of the referenced sections in § 26.1108(a) of subpart K. This led to redesignation of some paragraphs.

Section 26.109(c) of the Common Rule includes a reference to § 26.117(c), which gives IRBs the authority, under certain circumstances, to waive the requirement for written documentation of informed consent. Since EPA has not included in subpart K a paragraph comparable to § 26.117(c) of the Common Rule, the Agency has deleted the cross-reference in § 26.1109(c) of subpart K.

Section 26.114 of the Common Rule contains a provision designed to facilitate cooperative research among multiple investigators in different institutions. This section authorizes the head of an agency to accept a joint review or review by a single IRB to avoid duplication of effort. Rather than use the text of the Common Rule provision, EPA has adopted in § 26.1114 a similar but clearer provision from FDA regulation; see 21 CFR 56.114.

Section 26.115(a)(5) of the Common Rule cites another provision of the Common Rule that specifies the information about the members of an IRB which the IRB is required to provide in its records. In the parallel section of subpart K, § 26.1115(a)(5), EPA followed the approach FDA used in its regulations and repeated the substantive provisions of the referenced sections.

Sections 26.116(c) and (d) of the Common Rule authorize an IRB to waive or alter the requirement for informed consent in certain circumstances for research conducted or supported by EPA. EPA deleted these paragraphs from subpart K because of the central importance of informed consent to ensuring ethical treatment of subjects in human research. In addition, EPA concluded that the types of human research covered by subpart K—research involving intentional exposure of non-pregnant adults intended for submission under the pesticide laws—would not meet any of the Common Rule criteria for waiving or altering the informed consent procedures.

EPA added a new paragraph to § 26.1116 to clarify that the informed consent materials for research covered by subpart K must include "the identity of the pesticide and the nature of its pesticidal function." While implicit in the requirements of § 26.1116(a)(1), which is derived from § 26.116(a)(1) of the Common Rule, the Agency thought that the final rule should make this obligation explicit.

In a provision that parallels the waiver authority discussed above, § 26.117(c) of the Common Rule authorizes an IRB to waive the requirement for an investigator to obtain a signed consent form from each subject for research conducted or supported by EPA. Because of the importance of being able to demonstrate that each subject was fully informed and freely volunteered to participate in the types of research covered by subpart K, EPA decided not to adopt this Common Rule provision in subpart K. The Agency also made minor editorial changes to § 26.1117(a) and (b) to reflect the deletion of paragraph (c).

Section 26.101(a)(2) identifies the sections of the Common Rule which apply to "research that is neither conducted nor supported by a Federal department of agency but is subject to regulation as defined in § 26.102(e)." These sections include §§ 26.107 through 26.117, but not § 26.103 or §§ 26.118 through 26.124. Sections 26.118 through 26.124 generally apply to procedures associated only with first-party and second-party research, but which would not be relevant to third-party research. Consistent with the thrust of § 26.101(a)(2) and in order to reduce confusion, EPA has not created parallel sections for § 26.103 or, with two exceptions, any of the sections after § 26.117.

The first of these exceptions is to include in subparts K and P of the final rule two passages parallel to § 26.123 of the Common Rule. Section 26.1123, which corresponds to § 26.123(a) in subpart A, authorizes the Administrator to suspend or terminate research if EPA determines that a sponsor, IRB, or investigator has materially failed to comply with the terms of subpart K. (FDA's regulations contain a similar provision at 21 CFR 56.113.) In addition, EPA has included the substance of § 26.123(b)—authorizing EPA to consider an investigator's record in past ethical (or unethical) human research when reviewing proposals for new research—in § 26.1601(b) of subpart P, which governs EPA's review of proposed new research.

The second exception is to include in subpart P of the final rule a § 26.1601, parallel to § 26.124 of subpart A. This provides that, in its review of proposed new research, EPA may, on a case-by-case basis, impose additional conditions applicable to the conduct of a study that are necessary for the protection of human subjects.

2. *Revisions to the requirements for information concerning proposed research.* In reorganizing the final rule, EPA has moved the substantive content of proposed § 26.125, which would have required third parties to submit proposals for new human research for EPA review, to § 26.1125 of subpart K. In addition, EPA has revised this section in the final rule in two ways. A new § 26.1125(d) adds "a description of the circumstances and methods for presenting information to potential human subjects for the purpose of obtaining their informed consent" to the list of what information must be included with a submitted proposal for new research, and § 26.1125(f) adds an explicit requirement for documentation of IRB approvals.

VII. Intentional Exposure Research: Subparts B and L—Prohibitions of Human Research Involving Intentional Exposure of Pregnant Women, Fetuses, and Children

Summary: Subpart B of the final rule categorically prohibits EPA from conducting or supporting human subjects research on a substance that involves intentional exposure of pregnant women, fetuses, and children to the substance. See 40 CFR 26.203 of the regulatory text.

Subpart L of the final rule prohibits human subjects research for pesticides conducted or supported by third parties that involves intentional exposure of pregnant women, fetuses, or children. See 40 CFR 26.1203 of the regulatory text.

Unit VII.A. summarizes EPA's proposal, Unit VII.B. discusses public comments, and Unit VII.C. discusses the provisions of the final rule.

A. The Proposed Rule

The September 12 proposal contained, in § 26.220 of proposed subpart B, a clear prohibition of any future EPA research involving intentional dosing of pregnant women, fetuses or certain newborns. Section 26.420 of proposed subpart D contained an equally clear prohibition of any future EPA research involving intentional dosing of children.

The same sections of the proposal—§ 26.220 in subpart B and § 26.420 in subpart D—also prohibited any new third-party research intended for submission to EPA under the pesticide laws, and involving intentional dosing of pregnant women, fetuses, or children. The proposed prohibition would, as a practical matter, have applied to any research conducted by pesticide companies or by investigators working on their behalf.

B. Public Comments

Almost without exception, comments on the prohibitions contained in the proposed rule drew no distinction between third-party research and first- and second-party research. Therefore, unless otherwise indicated, the following discussion applies both to the proposed prohibitions against human subjects research conducted or supported by EPA that involves intentional exposure of pregnant women, fetuses, or children and to the prohibitions against such research by third parties who intend to submit the results to EPA under the pesticide laws. In addition, comments generally made the same recommendations regarding the prohibition on research involving intentional exposure of children as for the prohibition on research involving intentional exposure of pregnant women and fetuses. Again, unless otherwise indicated, the discussion below refers to both sets of prohibitions.

Comment: Some commenters argued that the proposed prohibitions were too narrow and should be expanded in order that all potentially affected test subjects received protection. Specifically, these comments recommended that: (1) The prohibition on research with children should not be limited to research involving intentional exposure, but should cover all types of human research (including scientific observation of public behavior of children); (2) the prohibition on research with pregnant women should be similarly broad; and (3) additional groups should be protected under the ban on intentional exposure research, including prisoners, all women of childbearing age, the elderly, and people with chronic diseases or developmental disabilities.

Response: EPA believes that "observational research," i.e., research that does not involve intentional exposure of human subjects, often provides a great deal of valuable scientific information that can be critical for effective environmental and public health regulation. To adopt the commenters' approach would mean, for example, that EPA could not collect, through research involving little or no risk to the subjects, information on the amount of time that children spend outdoors, the types of food consumed by pregnant women, or the possible correlation between air pollution and asthma in newborns. Therefore, EPA has decided not to accept the comments recommending expansion of the prohibitions to cover all types of human research.

EPA agrees with the commenters who point out that other groups deserve special consideration if they are to be included in research as test subjects. The Common Rule and EPA's extension of it to certain types of third-party research already direct IRBs to pay particular attention to the issues involved with research on several of these groups. See § 26.111(b) and § 26.1111(b) of the regulatory text. EPA believes that the approach created by the final rule—which requires both EPA and HSRB review of all future third-party research covered by the rule—will successfully identify those studies that may proceed ethically and those for which it would not be ethical to involve individuals from the identified groups.

Comment: Some commenters argued that the proposed prohibitions were too broad and that certain kinds of research should be excluded from the bans on conduct of future research involving intentional exposure of human subjects. Specifically, these comments recommended exclusion of: (1) Pharmaceutical studies, particularly products for control of head and body lice; (2) nutrition studies with micronutrients that may also be pesticides; (3) research on the efficacy of insect repellents; (4) research involving only use of registered pesticides for approved uses, or "product-in-use" studies; and (5) research on the efficacy of swimming pool and spa sanitizers and disinfectants;

Response: For a variety of reasons, EPA is not persuaded by these comments to modify the scope of its proposed prohibitions.

EPA notes that it does not conduct or support pharmaceutical studies and nutritional studies with any human subjects, and therefore there is no need to modify the proposed prohibitions for first- and second-party research. Further, EPA did not intend its proposed prohibitions to apply to third parties when conducting pharmaceutical or micronutrient research, and believes that such third-party research generally would fall outside the scope of the prohibitions because they would not meet the "intent to submit" criterion in § 26.1201. In fact, EPA thinks it would be contrary to the public interest to ban research of the effects on pregnant women and children of drugs, like streptomycin, or micronutrients, like copper or iodine, simply because these compounds also have approved uses as pesticides. Given that it is unlikely an investigator would undertake such research for submission to EPA in support of a pesticide action, these types of studies would not be prohibited.

EPA believes that there is no need to perform research on the efficacy of insect repellents with pregnant women or children. The efficacy of a repellent depends primarily on the properties of the pesticide formulation and does not vary with the age of the person to whom it is applied. Therefore, studies using non-pregnant adults should provide adequate information to assess how well insect repellents work, and there is no reason to exclude this type of research from the prohibition.

Similarly, EPA does not believe that comments have presented a compelling argument for recommending the Agency exclude from the prohibitions "product-in-use" research on pesticides. The Agency agrees with comments that such product-in-use research will generally pose relatively little risk to test subjects, because the exposures occurring during the research would correspond to exposures authorized by the Agency under its pesticide regulatory program—exposures that EPA has found cause no unreasonable adverse effects on human health or the environment. But these comments contain no satisfactory explanation of why it is necessary to conduct such product-in-use research with pregnant women, fetuses, or children. Like research on insect repellents, the Agency believes that general product-in-use research with non-pregnant adults should provide sufficient information to meet legitimate scientific needs.

Finally, research on the efficacy of antimicrobial agents used in swimming pools, spas, and hot tubs raises unusual and difficult issues. The Agency issues experimental use permits for these studies to determine whether, under typical use conditions, the antimicrobial can successfully control the additional

microbial load introduced by bathers. The Agency, however, does not approve such field research until the Agency can conclude that both the experimental use is likely to be effective and the levels of the antimicrobial in water will pose no risk to the bathers.

EPA, however, does not regard such studies as "research with human subjects" under the definitions in the Common Rule at §§ 26.102 and 26.1102, and therefore does not believe they are subject to the prohibitions or any other provisions in part 26. The definitions of "research" and "human subject" make clear that the phrase "research with a human subject" applies to a systematic investigation in which an investigator collects information through an intervention or interaction with an individual for the purpose of developing generalizable knowledge about humans. In the case of these antimicrobial efficacy studies, the research does not involve interactions with, or collection of information on, identifiable individuals for the purpose of producing generalizable knowledge.

Comment: A number of comments objected to what they perceived to be "loopholes" in the proposed rule's prohibition on research involving intentional exposure of children. Specifically, they argued that: (1) Proposed § 26.401(a)(1) permitted EPA to waive the prohibition when research was conducted outside the United States; (2) proposed § 26.401(a)(2) permitted EPA to waive any provision of proposed subpart D, including the prohibition; and (3) proposed § 26.408, which authorized an IRB to waive the requirement for assent from children lacking the capacity to give it, and to waive the requirement for permission from abusive or neglectful parents, meant that EPA intended to allow research on mentally retarded, abused, or neglected orphans.

Response: Many commenters misinterpreted EPA's proposed language. Contrary to public comments, none of the alleged "loopholes" ever existed, because the prohibition in proposed § 26.420 stated "Notwithstanding any other provision of this part, under no circumstances shall EPA or a person when covered by § 26.101(j) conduct or support research involving intentional dosing of any child." The words, "Notwithstanding any other provision of this part," mean that the provisions in proposed § 26.420 override all other provisions of the entire regulation, including §§ 26.401 and 26.408. Even though those two sections would have given EPA authority to waive certain requirements, they would not have authorized any departure from the ban in proposed § 26.420.

Nonetheless, in order to remove any doubt about the scope of the prohibitions, EPA has made several changes in the final rule. The prohibitions appear in separate subparts so that there is less chance someone will misread the provisions intended to confer flexibility in the approach to observational research as applying to research involving intentional exposure. In subpart D, which addresses observational research with children conducted or supported by EPA, EPA has removed or revised the text of §§ 26.401 and 26.408 to make clear that they do not create an opportunity to relax the protections for children.

C. The Final Rule

After careful consideration of public comments—particularly the thousands of comments expressing strong opposition to EPA's ever conducting human subjects research that involves intentional exposure of pregnant women, fetuses, or children, the Agency has retained in the final rule the proposed prohibitions, essentially without change. Subpart B contains the proposed prohibitions against EPA conducting or supporting new research involving intentional exposure of pregnant women, fetuses, and children. This prohibition applies to EPA's first- and second-party research with any substance, and is not restricted to pesticides.

Subpart L of the final rule contains a parallel prohibition of new third-party human subjects research for pesticides involving intentional exposure of pregnant women, fetuses, or children. Subpart L applies to research conducted or supported by any person who intends to provide the results of the research to EPA under FIFRA or the FFDCA. The final rule retains the text from the proposal establishing how EPA will determine a person's intent for purposes of applying the prohibition.

The Agency recognized that the wording of the proposed prohibitions and other requirements could be interpreted to apply to studies, which do not constitute "research" with "human subjects," as these terms are defined in the Common Rule, but in which humans who are not subjects of the research may be incidentally exposed. The Agency did not intend, for example, that the proposal would affect animal research on a pesticide simply because a person might be intentionally exposed to a test material as a consequence of working as a lab technician. Accordingly, EPA has revised the rule text in subparts B, C, L, and Q to clarify that the prohibitions and other provisions apply only to research with human subjects and not to other types of research.

The Agency hopes that the reorganization of the final rule gives greater prominence to these prohibitions, and clarifies EPA's intent that there be no exceptions to or loopholes in these prohibitions. Both subparts B and L begin by expressly stating the universe of research activities to which they apply. To further reinforce the point that the bans on these types of testing are not subject to any exceptions, the prohibitory provisions use the introductory phrase "Notwithstanding any other provision of this part, under no circumstances . . . ." This language means that this provision is to be enforced over all other provisions of every other subpart of part 26.

VIII. Observational Research: Subparts C and D—Additional Protections for Pregnant Women, Fetuses, and Children Involved as Subjects in Observational Research Conducted or Supported by EPA

Summary: This unit discusses protections additional to the core protections provided by the Common Rule (subpart A), which are established by the final rule for pregnant women and fetuses (subpart C) and children (subpart D) when they are subjects in observational research conducted or supported by EPA. The final rule defines *observational research* as research not involving intentional exposure. The provisions of the final rule are similar to regulations promulgated by HHS to govern studies with these populations when conducted or supported by HHS. Unit VIII.A. summarizes the proposal, Unit VIII.B. discusses public comment, and Unit VIII.C. describes the position taken in the final rule.

A. The Proposed Rule

Most of the provisions of proposed subparts B and D would have defined additional protections for individuals from vulnerable populations when they were subjects in observational research conducted or supported by EPA—i.e., studies that do not involve intentional exposure. Proposed subpart B contained protections for pregnant women, fetuses, and certain newborns, and proposed subpart D contained protections for children. The protections in both proposed subparts were in addition to the basic protections created by the Common Rule, 40 CFR part, 26 subpart A. Because the HHS regulations affording additional protections for

pregnant women and fetuses and for children had been in existence for over 20 years and enjoyed widespread acceptance by the research ethics community, EPA proposed to adopt the HHS rules without substantive change, except as noted below.

1. *Proposed subpart B.* EPA proposed to adopt by reference much of the content of subpart B of the HHS rule, 45 CFR part 46, with only a few changes. Thus, EPA proposed to adopt several sections from the HHS rule:

- In proposed § 26.201, EPA adapted the text of 45 CFR 46.201, thereby defining the scope of the subpart—research conducted or supported by EPA that involved research with pregnant women, fetuses, or certain newborns.
- Proposed § 26.202 cross referenced several paragraphs of 45 CFR 46.202 defining such terms as *delivery*, *fetus*, *neonate*, and *pregnancy*.
- Proposed § 26.203 cross referenced the requirement of 45 CFR 46.203 that assigns to IRBs the primary responsibility for ensuring that investigators follow the requirements of the subpart.
- Proposed § 26.204 cross referenced the requirements of 45 CFR 46.204 defining the findings an IRB must make (in additional to those required by the Common Rule at § 26.111) before approving proposed research with pregnant women or fetuses. (Because of the prohibition in proposed § 26.220, the provisions in proposed §§ 26.204 and 26.205 would have applied only to EPA's observational research.) In summary, these include findings that: Adequate preliminary research exists to characterize potential risk, the risks to pregnant women and fetuses have been minimized, either the risks are minimal or the research holds out the prospect of direct benefit, and appropriate informed consent is obtained, in some cases from both the father and the pregnant woman.
- Proposed § 26.205 cross referenced the requirements of 45 CFR 46.205 defining the findings an IRB must make before approving observational research with certain newborns, including, where applicable, that the observational research has the prospect of improving the chances of survival of neonates of uncertain viability or that the observational research will develop important biomedical knowledge which could not otherwise be obtained.
- Proposed § 26.206 cross referenced the requirements of 45 CFR 46.206 concerning observational research involving, after delivery, the placenta, the dead fetus, or fetal material.

The major substantive change EPA made to the HHS rule in proposed subpart B was the choice not to propose adopting the provisions in 45 CFR 46.207, which provide a special procedure for approving in exceptional cases observational research which does not meet the standards of 45 CFR 46.204 or 46.205. EPA considered such a provision both inappropriate and unnecessary for observational research with environmental substances.

2. *Proposed subpart D.* EPA proposed to adopt much of the content of subpart D of the HHS rule, 45 CFR part 46, specifically:

- In proposed § 26.401, EPA adopted the text of 45 CFR 46.401, thereby defining the scope of the subpart—research conducted or supported by EPA involving children as subjects. The proposed rule text contained the same exceptions that appear in the HHS rule.
- Proposed § 26.402 contained the same definitions that appear in the HHS rule in 45 CFR 46.402, except that EPA proposed to define a *child* as a person younger than 18 years old, in contrast to the HHS definition, which relies on local law to determine when a person becomes an adult.
- Proposed § 26.403 cross referenced the requirement of 45 CFR 46.403 that assigns to IRBs the primary responsibility for ensuring that investigators follow the requirements of the subpart.
- Proposed § 26.404 adapted, essentially verbatim, the text of the HHS regulation in 46 CFR 46.404 that authorizes IRBs to approve observational research with children (which also meets the criteria in § 26.111), which involves "no more than minimal risk" only if there are adequate procedures, as specified in § 26.408, for soliciting the assent of the children and the permission of their parents or guardians. (Because of the prohibition in proposed § 26.420, the provisions in proposed §§ 26.404, 26.405, and 26.408 would have applied only to EPA's observational research.)
- Proposed § 26.405 adopted, essentially verbatim, the text of the HHS regulation in 46 CFR 46.405 that authorizes IRBs to approve observational research with children (which also meets the criteria in § 26.111), which involves "greater than minimal risk" only if the IRB finds the observational research offered the prospect of direct benefit to the individual subjects or would otherwise contribute to their well-being, and there are adequate procedures, as specified in § 26.408, for soliciting the assent of the children and the permission of their parents or guardians.
- Proposed § 26.408 adopted, essentially verbatim, the text of the HHS regulation in 45 CFR 46.408 establishing special requirements for obtaining permission by parents or guardians and for assent by children. Among other provisions this section provided that in some cases an IRB could determine that a child was not capable of assent, in light of their age, maturity, or psychological state. If so, the inability of the investigator to obtain assent could not be a basis for excluding a child from research that held out the prospect of benefit to the child. The proposal also allowed an IRB to waive assent on the same grounds that it could waive informed consent by adults (see § 26.116(d)). This proposed section also granted to IRBs discretion to determine that, in some cases, it would not be reasonable to require the permission of a child's parent or guardian because, for example, the adult abused or neglected the child. In such instances, this section authorizes the IRB to approve an alternative mechanism of obtaining permission from an adult who would better represent the child's interests.

As noted above, most of the proposed rule text came directly from the existing HHS regulations establishing additional protections. The Agency did propose a few revisions. In addition to minor editorial changes necessary to reflect that the proposed rule would be implemented by EPA, the most notable substantive changes were: (1) Defining a child as a person under the age of 18 years, (2) choosing not to propose adopting the provisions in 45 CFR 46.406 and 46.407, and (3) choosing not to propose adopting the provisions in 45 CFR 46.409.

In 45 CFR 46.406 and 46.407, HHS establishes special standards and procedures for approving in exceptional cases research which does not meet the standards of 45 CFR 46.404 or 46.405—i.e., research which poses more than minimal risk to the children in the study but which offers no prospect of direct benefit to them. EPA considers such provisions both inappropriate and unnecessary for research with environmental substances, particularly observational studies. Consistent with the choice not to adopt those two sections, EPA chose to omit 45 CFR 46.409 of the HHS rule as well, since it specifies measures which are required only when the children in a study approved under the authority of 45 CFR 46.406 or 46.407 were wards of the state.

B. Public Comment

Most comments on proposed subparts B and D addressed the proposed

prohibitions on research involving intentional exposure of pregnant women, fetuses, or children. These comments are addressed in Unit VIII. This unit covers the public comments which addressed the adoption of additional protections for pregnant women and children as subjects in observational research conducted or supported by EPA.

Comment: Some commenters supported EPA's proposal to adopt only some of the provisions of the HHS regulations in 45 CFR part 46, subparts B and D that create additional protections for pregnant women, fetuses, and children in observational research. Other comments recommended the Agency adopt these HHS regulations in their entirety. By doing so, EPA and HHS would follow consistent approaches. These comments also noted HHS has operated under these regulations for over 20 years without significant debate over their ethical adequacy.

Response: The Agency agrees there is considerable value in employing consistent approaches in similar areas of research. Consistency makes it easier for affected researchers to comply and helps to build a broader consensus on what constitutes ethical behavior. Accordingly, EPA is adopting large parts of the HHS regulations from 45 CFR part 46, subparts B and D essentially verbatim. The Agency, however, is not promulgating all of these HHS rules because, in EPA's judgment, the omitted provisions would never apply to observational research. Specifically, EPA has not adopted the following sections from the HHS rules: 45 CFR 46.205, 46.207, 46.406, 46.407, and 46.409. These sections would apply only when proposed research would present more than a minimal risk to the subjects and would have no prospect for direct benefit to the subjects. EPA simply cannot conceive of observational research that could not meet such criteria, and in the unlikely event that an investigator proposed such research, EPA would not expect to approve it.

Comment: Some comments objected to the inclusion in the proposed rule of provisions that allowed observational research if an IRB judged the potential risks to subjects as "minimal." These comments claimed that the concept of "minimal risk" was not adequately defined and potentially subject to abuse. These comments recommended that no observational research be allowed unless there was "no risk" to subjects. (Many of these comments further argued that no human research was totally risk free and therefore no human research should be allowed.)

Response: The Common Rule and subpart D of the final rule define minimal risk as "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." 40 CFR 26.402. The Agency agrees that this definition leaves room for the exercise of expert judgment by a person reviewing a proposed protocol, and that different people may disagree on whether a particular research technique poses minimal risk. Nonetheless, this definition has been part of the Common Rule since 1991, and this provision has been in the HHS regulations since 1983. Based on its long history of application and the benefits of consistency with HHS, EPA has decided to retain proposed § 26.404 without change. In addition, EPA thinks the prospects for abuse are extremely small since all research allowed using these criteria would need approval both from a local IRB and from EPA's Human Subjects Research Review Official (HSRRO).

Comment: Some comments objected to EPA's proposal to adopt 45 CFR 46.405, which would allow an IRB to approve observational research with children if the IRB found the risks to children were "greater than minimal," but presented "the prospect of direct benefits to the individual subjects." These comments argued that observational research would never meet such criteria.

Response: EPA rarely expects observational research to pose "greater than minimal risk." By its very nature, observational research leaves all decisions regarding exposure to the subjects. Thus, an investigator ordinarily just measures and records information about exposure and effects that the subjects, in their own discretion, choose to experience. EPA, nonetheless, believes its final rule should include a provision comparable to 45 CFR 46.405. Although unlikely, EPA thinks some measurement techniques used in observational research could theoretically involve more than minimal risk to subjects and therefore would fail to meet the criteria for approval under § 26.304 of the final rule. Consistent with the HHS approach in 45 CFR 46.205, EPA believes that, if such risks exist, the research should not be allowed unless an IRB finds that the "greater than minimal risks" were justified by the prospect of direct benefits to the subjects. Because EPA does not want to prevent potentially valuable research that requires non-standard measurement techniques, EPA has adopted in § 26.305 of its final rule the content of the provision of the HHS regulations.

Comment: Although most comments agreed with EPA's proposal to define *child* as a person younger than 18 years old, some comments recommended using the text in the HHS rule, which defers to the legal standards defining children and adults in the local jurisdictions where the research is conducted. These comments pointed out that EPA's proposed definition could lead to the exclusion of an emancipated minor, typically an older teenager who has married. Excluding these potential subjects could deny them the benefits of participating in the research simply because of their age. Other comments favored raising the age to 21 years old because the human body, particularly the brain, continues to mature after the age of 17 years and research might adversely affect 18–21 year olds during this developmental period of potentially increased sensitivity.

Response: EPA is not persuaded that the potential increased sensitivity of people between the ages of 18 and 20 years to some effects warrants defining a child as a person under 21 years old. The Agency notes that such sensitivity is not likely to exist for all chemicals. If, however, a proposal to perform observational research did raise concerns about an increased sensitivity of subjects, those concerns can be addressed on a case-by-case basis by the IRB and EPA's HSRRO. It is not necessary, in EPA's view, to deal with these theoretical concerns by redefining who is a child.

While EPA sees benefit to using a definition consistent with HHS, the Agency is concerned about the added complexity for investigators who are conducting research in multiple jurisdictions. In addition, EPA questions whether youngsters no older than 15 years, as an adult is defined in some states, are sufficiently mature to make decisions about whether to volunteer to participate in human research. In light of these concerns and the broad support for EPA's proposal, EPA has decided to retain the proposed definition of child as a person younger than 18 years old.

Comment: Some comments found unclear the provisions in proposed subpart D allowing the waiver, under narrow conditions, of the requirements for permission of parents and assent of children to participate in observational research conducted or supported by EPA. Other comments objected to these proposed provisions asserting that children should never become subjects

in research without their parent's permission and without their own assent. Still other commenters asserted that the rule should not allow parents to permit their children's participation in human research unless the children will benefit directly from doing so.

Response: EPA's final rule has retained the proposed rule text, with only minor changes. EPA believes that these provisions give the Agency needed flexibility to protect the interests of the child when either the child or the parent(s) cannot. For example, the proposal would allow waiver of assent when the child is too young or otherwise unable to make responsible choices; and where the child's refusal to assent would cause his or her exclusion from research that provides a direct benefit. The proposal also allows waiver of parental permission from a parent who abuses or neglects their children; clearly such parents do not have adequate concern for the child's welfare to make decisions about whether the child should participate in research. (This provision strengthening the protections for children was widely misinterpreted as indicating EPA's intention to authorize or conduct research involving intentional exposure of mentally retarded, abused, and neglected children.)

To clarify the operation of the provision allowing waiver of parental permission, EPA has modified the text to make clear that any alternative procedure must be "equivalent" to the process of parental permission. By "equivalent" EPA means that the child's participation must be approved by an adult who by position or relationship puts the child's well being foremost and who will exercise sufficient diligence to make a considered and informed decision. Otherwise, EPA has decided not to accept the changes recommended by the commenters. EPA relies on the facts that the concepts in this provision comport with the generally accepted legal principles defining the scope of parental authority and that HHS has operated successfully under these provisions for over 20 years. Finally, as noted above, EPA sees considerable benefit from using an approach consistent with that of HHS.

C. The Final Rule

Subpart C of the Agency's final rule retains most of the rule text appearing in proposed subpart B. The most significant changes from the proposal are the isolation in subparts B and L of the prohibition of new research proposed at § 26.220, and removal to subpart Q of the restriction on EPA reliance on completed research proposed at § 26.221. To make the applicability of the remaining provisions of subpart C as clear as possible, EPA has revised the titles of the subpart and of § 26.301, and reworded the text to emphasize repeatedly that these provisions apply only to observational research, and only to research conducted or supported by EPA. In the final rule *observational research* is defined in § 26.302 as research that does not involve intentional exposure of research subjects. In addition, EPA has deleted from the final rule proposed § 26.205 (which referenced 45 CFR 46.205) because its provisions would never apply to the kinds of observational research that this subpart permits.

Subpart D of the Agency's final rule retains most of the rule text appearing in proposed subpart D. The most significant change from the proposal is the isolation in subparts B and L of the prohibition of new research proposed at § 26.420, and the removal to subpart Q of the restriction on EPA reliance on completed research proposed at § 26.421. To make the applicability of the remaining provisions of subpart D as clear as possible, EPA has revised the titles of the subpart and some of its sections, and reworded the text to emphasize repeatedly that these provisions apply only to observational research, not involving any intentional exposure to any substance, and only to research conducted or supported by EPA.

In addition, EPA has made the following revisions in subpart D to the proposed rule text:

- In § 26.401(a)(2), EPA clarified that the authority to waive requirements related only to the sections of subpart D and did not confer broad authority on the Agency to waive any requirement in any other subpart.
- In § 26.402(a) and (f), EPA added definitions of Administrator and observational research.
- In § 26.403, the text from 45 CFR 46.403 of the HHS regulation is incorporated explicitly, rather than by reference as was done in the proposal.
- In § 26.405, EPA reordered the text to make its applicability clearer. The revision was not intended to make a substantive change.
- In § 26.406(c), EPA has revised the text to clarify that if an IRB determines that it is not appropriate to require the permission of the parent or guardian for a child to participate in a study, the IRB must approve an equivalent, alternative procedure for obtaining permission from another adult who will appropriately represent the interests of the child.

IX. Additional Protections Pertaining to Research Involving Prisoners Involved as Subjects

Summary: Research with prisoners conducted or supported by EPA is subject to basic ethical requirements in the Common Rule; the parallel requirements in subpart K of the final rule apply to the conduct of research by third parties involving intentional dosing of prisoners, if the research is intended to be submitted under the pesticide laws. The Agency has not reached a final position on either the need or the most appropriate form for any additional protections for prisoners beyond these basic requirements. The Agency may, in a future action, issue a final rule to address the aspects of its September 12, 2005, proposal that relate to establishing standards for the ethical protections of imprisoned subjects of research. Unit IX.A. summarizes EPA's proposal and Unit IX.B. explains EPA's decision not to adopt additional protections for prisoners in this final rule.

A. The Proposed Rule

In its September 12, 2005, proposal, EPA noted that HHS has promulgated regulations that provide additional protections for prisoners in research conducted or supported by HHS, codified at 45 CFR part 46, subpart C. The proposal explained that EPA had decided not to propose adoption of the HHS subpart C rules for a number of reasons, among them that HHS and its advisory committee, the Secretary's Advisory Committee on Human Research Protections (SACHRP), were actively considering revisions to the HHS subpart C, unchanged since its adoption in 1978.

In addition, the proposal noted that EPA has never conducted or supported any human studies with prisoner subjects, and has no intention to do so in the future. It also noted that some third-party research with prisoner subjects was submitted to the Agency some 30 or more years ago; since HHS adopted subpart C, this type of research has essentially disappeared, and none has been submitted to EPA for many years. Finally, the proposal noted if either EPA or third parties should consider performing studies with prisoner subjects, such research would be subject to the requirements of the Common Rule and EPA's final rule.

B. The Final Rule

All provisions of the Common Rule would apply to any EPA research with imprisoned subjects. In particular, any such research would be subject to the

Common Rule requirements for IRB review and approval and written informed consent. Sections 26.111(a)(3) and 26.111(b) require an IRB to determine that selection of research subjects is equitable and free from coercion or undue influence, and note that particular attention to these aspects of subject selection is needed when prisoners are involved. Implicit in other sections, e.g., §§ 26.102(i), 26.116, and 26.117, is the concept that research must treat each subject involved ethically, taking into account their particular circumstances.

In addition, the prohibitions in subpart B and the additional protections in subparts C and D would also apply to imprisoned pregnant women or children under the age of 18 years if EPA were to conduct observational research with subjects from those populations.

EPA does not expect third parties to submit to EPA any new studies on prisoners. In the unlikely event that a third party wished to conduct or sponsor research involving intentional exposure of prisoners for submission under the pesticide laws, it would be covered under subparts K and L. Unless prohibited by subpart L, such research would have to meet the requirements of subpart K, which parallel the provisions of the Common Rule. In addition, an investigator would also be required to submit for EPA and HSRB review a proposal describing in detail how the study would be carried out in an ethical manner. Should such a study proposal involve prisoners, it would receive extremely close review, and EPA almost certainly would not approve it, absent a compelling justification.

The Agency has concluded that the requirements of this final rule should provide adequate protections for prisoners, especially since there are not likely to be any such studies. Nonetheless, the Agency is still considering the recommendation from public comments to prohibit both EPA and third-parties to conduct certain types of research with prisoners. EPA may, at a later date, adopt such a provision, if it determines that such a measure is needed and cannot be effectuated under existing regulations. In addition, EPA will continue to monitor the work of the SACHRP committee on prisoner protections, and will reconsider adopting additional protections for prisoners as subjects of research when its recommendations are known.

X. Subpart M—Requirements for Submission of Information on the Ethical Conduct of Completed Human Research

Summary: Subpart M of the final rule requires third parties who submit the results of completed human research to EPA for consideration under the pesticide laws to document the ethical conduct of that research. Subpart M specifies the range of information required, including documentation of any IRB reviews, documentation of informed consent by subjects, and other information required to support third-party proposals to conduct new human research for pesticides involving intentional exposure of non-pregnant adults. The final rule directs submitters to provide this information about completed research to the extent it is available, and if any of it is not available, to describe the efforts made to obtain it. Unit X.A. describes the proposed rule, Unit X.B. addresses the major public comments, and Unit X.C. discusses the final rule.

A. The Proposed Rule

In the September 12 proposal, § 26.124(c) required "any person who submits to EPA data derived from human research covered by this subpart" to provide information documenting compliance with the requirements of the subpart. The required information included records required of the IRBs that approved the research; copies of sample informed consent documents; and copies of correspondence between EPA and the investigator or sponsor about the proposed protocol.

In addition, although the proposal contained no provision directed at data submitters requiring documentation of ethical conduct of completed research, the proposal indicated that EPA would not rely on the results of research conducted after the effective date of the final rule unless the Agency had "adequate information to determine the research was conducted in a manner that substantially complied" with the requirements of the rule.

B. Public Comments

EPA received no major public comments on the proposed provisions addressing the content of reports of completed human research.

C. The Final Rule

EPA has created a new subpart M that requires people who submit data from completed human research to EPA to accompany that submission with information documenting the ethical conduct of the research. The final rule requires that reports on completed human research contain essentially the same range of information concerning the ethical conduct of the research as would have been required by the proposal.

The final rule, however, differs from the proposal in several respects. First, the final rule clarifies that it applies only to reports of completed human research submitted after the effective date of the final rule.

Second, EPA has broadened the scope of the proposed requirement to apply to reports on all types of human research submitted to the Agency for consideration under the pesticide laws, FIFRA and FFDCA. This provision of the final rule is broader than the proposal in two ways: It applies to all persons who submit data, whether or not they developed the data with the intent to provide it to EPA; and it applies to all types of human research, not only to research involving intentional exposure of human subjects. The Agency decided to extend the scope of this reporting requirement because it expects to make ethical assessments of all human research it receives under the pesticide laws, irrespective of who did it, who submitted it, or what type of human research was involved. Obtaining the information specified by subpart M as part of the initial submission will improve the efficiency and quality of such ethical assessments. Under FIFRA sections 3(c)(2)(A) and 3(c)(2)(B), EPA has the authority to require information necessary to support both applications for new registration and for continued registration of a pesticide. Since the Agency regards information about the ethical conduct of human research as relevant to the assessment of the acceptability of such research, the Agency concludes that the reporting provision is consistent with these sections of FIFRA.

Finally, the Agency made two changes to minimize the burden of reporting information on the ethical conduct of completed research. First, the final rule provides that information need not be resubmitted if it has previously been provided to the Agency, for example as part of the submission required for protocol review under § 26.1125. Second, recognizing that not all of the information specified by subpart M may be available to the data submitter in some cases—for example, if the research were conducted in the past, or if the submitter did not conduct the study, § 26.1303 states that the specified information should be provided "to the extent available" and asks the submitter to describe the efforts made to obtain

information which he or she was unable to provide.

XI. Subpart O—Administrative Actions for Noncompliance

Summary: Subpart O contains provisions, adapted from similar regulations issued by FDA, that describe the range of administrative actions EPA could take to address noncompliance by third parties with the requirements of part 26. These actions include: Withdrawal or suspension of a research institution's Federal wide assurance; disqualification of an institution or an IRB; debarment; and public censure. This subpart describes procedures EPA would follow in reaching a decision to take any of these administrative actions. Other than the addition of a new section explaining the scope of research to which these actions could be applied, the final rule is unchanged from the proposal.

A. The Proposed Rule

In proposed subpart E the Agency identified a number of specific administrative actions that could be taken, as circumstances warrant, against any person or organization that failed to comply with requirements of the rule. These actions included: (1) Withdrawal or suspension of a research institution's FWA; (2) disqualification of a research institution or its IRB; (3) debarment of an entity from receiving federal funds for research; or (4) public censure—presenting for public review an objective analysis of the ethical deficiencies of any human research relied upon by EPA for regulatory decision-making under any statutory authority. The provisions in proposed §§ 26.501 through 26.504 and § 26.506 closely follow FDA's existing regulations in 21 CFR 56.120 through 56.124.

B. Public Comment

EPA received only a few public comments on this subpart, most supporting the appropriate use of the actions identified in proposed subpart E to promote compliance. EPA also agreed with several commenters that refusal to rely on completed research provided the strongest incentives for investigators to follow the new requirements. Other major comments, discussed below, addressed the operation of EPA's compliance oversight program.

Comment: One comment complained that the proposal gives EPA discretion not to impose any of these sanctions at all, even for the most egregiously unethical research, and argued that only mandatory sanctions could effectively deter unethical human research. Another commenter recommended that EPA explain what types of actions it would apply to different types of violations.

Response: EPA generally believes that enforcement programs work best when they employ a system of graduated penalties that increase as the gravity of the violation increases. Such an approach requires the exercise of discretion, but that discretion should not operate entirely free from constraints. Accordingly, the Agency intends to establish policies to guide its exercise of discretion about the imposition of the sanctions. Although EPA does not regard such policies or penalty structure as appropriate for inclusion in this rulemaking, the Agency does intend to explain in guidance how it will encourage compliance with the new requirements in the final rule.

Comment: Several comments urged EPA to adopt procedures similar to those of FDA by which it would decide whether to disqualify an institution for violating the requirement of the final rule.

Response: EPA agrees it should have a procedure for deciding whether to disqualify an IRB or institution, and that it may be appropriate to establish such procedures through rulemaking. EPA will further consider adopting procedures similar to those used by FDA and promulgated in 21 CFR part 16, but has decided not to adopt them at this time.

C. The Final Rule

Subpart O of the final rule is substantively unchanged from subpart E of the proposal. EPA has added a new § 26.1501 entitled "To what does this subpart apply?" which clarifies that EPA will consider using the administrative actions identified in the subpart only to address instances of non-compliance with the requirements of the new rule occurring after the new rule takes effect. Thus, actions debarring an institution from receiving federal funds for research or disqualifying an institution from performing research covered by subpart K could not be taken on the basis of events that happened before the final rule becomes effective. The Agency notes, however, that actions which violate the requirements of FIFRA section 12(a)(2)(P) would be subject to civil or criminal penalties if they happened at any time after that provision became law in 1972. The Agency also made minor wording changes in § 26.1502 of the final rule to reflect FIFRA terminology and enforcement practices.

EPA recognizes the importance of an effective program to ensure compliance with the requirements of the final rule. The office of the Agency's Human Subjects Research Review Official (HSRRO) will have responsibility for ensuring compliance with the new rule. The HSRRO will also have responsibility for managing the development of any new guidelines needed to explain or implement the provisions of the final rule.

The Agency thinks that one of the most important ways to encourage and monitor compliance is through the review of proposals for new research before it is conducted, as required by the final rule at § 26.1125. Once such studies are initiated, EPA's Office of Enforcement and Compliance Assurance, through its laboratory audit program, can monitor facilities that conduct human research covered by the rule.

EPA inspectors conduct inspections and audit studies under EPA's good laboratory practice (GLP) regulations. As stated in the GLP regulations (40 CFR 160.15), EPA will not consider reliable for purposes of supporting an application for a research or marketing permit any data developed by a testing facility or sponsor that refuses to permit such inspection. In addition, the recordkeeping provisions of FIFRA which cover records of any tests conducted on human beings and records containing research data relating to registered pesticides including all test reports submitted to the Agency in support of registration or in support of a tolerance petition also apply to studies conducted under this rule.

Finally, the close examination of reports on completed research represents another important part of the compliance program. EPA will train scientists who conduct, approve, or review human research about the provisions of the final rule so they can identify possible violations. Throughout all of these efforts, the Agency hopes to work with the HHS Office for Human Research Protections and FDA, to ensure that sponsors, investigators, and IRBs understand and fulfill their responsibilities under the final rule.

XII. Subpart P—Review of Proposed and Completed Human Studies

Summary: This subpart of the final rule provides that EPA will review all proposals by third parties to conduct research covered by subpart K, i.e., all research involving the intentional exposure of human subjects, if the research is intended for submission to EPA under the pesticide laws. The subpart also requires EPA to establish

an independent group of experts, referred to as the Human Studies Review Board (HSRB), to assist EPA in evaluating such proposals. In addition, the subpart requires that EPA review reports submitted by third parties on completed human research and, if EPA decides to rely on information from such research in an action under the pesticide laws, to submit the results of its assessment of the research to the HSRB. The HSRB would perform science and ethics reviews of proposals from third parties to conduct specified types of human research and of the results of specified types of human research if EPA intended to rely on the information in its decision-making under the pesticide laws. Further, when HSRB review is not required by the final rule, EPA would nonetheless retain discretion to ask the HSRB to review studies or to offer advice on other issues.

Finally, although not required by the final rule, EPA has decided to establish the HSRB under the authority of the Federal Advisory Committee Act. By operating as a federal advisory committee, the HSRB will be required to use procedures that ensure transparency in its operation and that afford opportunities for the public to express their views on issues being considered by the HSRB.

A. The Proposed Rule

Proposed § 26.124 would have required third parties to submit to EPA detailed information concerning any proposed new research covered by the new rule at least 90 days before initiating of the research. The proposal would also have established a HSRB to address in an integrated fashion the scientific and ethical issues raised by human research covered by the proposal. Specifically, the Agency proposed to convene a small group of appropriately qualified experts and to enlist their support in reviewing covered research proposals, i.e., third-party research involving intentional exposure of human subjects, when the results of such research are intended to be submitted to EPA under the pesticide laws.

The same section also provided that EPA would review the results of completed research covered by the rule. This section of the proposal also stated that, after completing its initial staff assessment of a research proposal or a completed study if EPA intended to rely on the results in its decision-making under the pesticide laws, the Agency would send its review and supporting materials concerning the study to the HSRB for further review and comment.

EPA's proposal did not specify any details of how the HSRB would function, other than to state that the members would not be EPA employees, would meet the conflict of interest standards applying to special government employees, and would have expertise appropriate for the review of human research. The Agency invited public comment on whether the final rule should specify the functions of the HSRB. The preamble also indicated that, as recommended by the NAS, EPA intended to reexamine the functions of the HSRB after 5 years.

B. Public Comment

EPA received a great many public comments on its proposal to require submission of proposed protocols and other information relating to proposed new human research and to submit its assessments of the proposed new human research to a new HSRB for further review. The Agency's Response to Comments document, in the docket for this action, provides a full response to these comments. EPA agrees with comments that stressed the importance of having the HSRB use the substantive standards contained in EPA's final rule when reviewing the ethics of proposed and completed human research. As an entity intended to help the Agency make ethical and scientific judgments, the HSRB will use the provisions of this final rule in the formulation of their advice. The major issues raised by the comments are discussed below under three headings: HSRB procedures; HSRB membership and qualifications; and the scope of research subject to HSRB review.

1. *HSRB procedures.* The Agency notes that most, if not all, comments on the HSRB implicitly accepted EPA's proposal that HSRB review of proposed new research would occur following its review and approval by a local IRB and after EPA developed its review.

Comment: Many comments addressed whether EPA should charter the HSRB under the Federal Advisory Committee Act (FACA). Environmental and public health advocacy groups favored this approach because it would assure the use of procedures that provided opportunities for public comment and transparency. Others, primarily commenters affiliated with the pesticide industry, objected on the grounds that a FACA-chartered HSRB would be inefficient, and the ensuing delays would affect Agency decision-making, particularly about new products. These comments recommended either staffing the HSRB only with EPA employees or relying on the HHS Office for Human Research Protections (OHRP) for the kinds of reviews described in the proposed rule. Industry commenters also expressed concern that a FACA process might lead to public disclosure of CBI.

Response: EPA has decided to charter the HSRB under FACA. While operating under the requirements for advisory committees adds some procedural steps to the review process, it is not apparent, given the intensity of public concern about the use of data from human research, that a FACA process would necessarily take longer than a process involving internal EPA review. More important, in EPA's view, the benefits of the transparency and opportunities for public participation outweigh any potential delays. Given the difficult nature of the issues, EPA sees significant advantages in ensuring that all the considerations influencing the Agency's final position have been publicly identified, carefully weighed, and commented on by independent experts.

The Agency recognizes the need to manage aggressively to ensure both the HSRB's and its own review processes operate efficiently. As part of its commitment to effective management, the Agency intends to acknowledge receipt of new research proposals and to respond promptly with a projected timeline for completing EPA and HSRB review. In addition, upon completion of its internal reviews, EPA will send copies to the submitter of the protocol and the schedule for HSRB review. EPA expects that it will continue to meet the statutory deadlines for reaching decisions on new applications for pesticide registrations, even if HSRB review is required.

Finally, the Agency notes that under FIFRA and FACA, EPA follows procedures designed to protect CBI from disclosure. Whenever EPA provides CBI to a federal advisory committee, that information is not placed in a public docket or discussed in a public meeting, and special steps are taken to maintain its confidentiality.

Comment: Many comments asked EPA to clarify in the final rule the procedures that the HSRB would use. In particular, many suggested that the rule require that the HSRB meetings afford an opportunity for public comment.

Response: The Agency believes that, at this early stage, the HSRB should have the flexibility to adopt procedures which best allow it to meet its responsibilities. Since the HSRB will function as a federal advisory committee, FACA will dictate many of its procedures, including key procedures relating to transparency and public participation. Since these were

the areas of greatest concern for most commenters, EPA believes that its decision to establish the HSRB under FACA adequately addresses these comments.

Comment: Some comments complained that the proposed rule did not vest the HSRB with authority to disapprove proposed new research or EPA decisions to rely on the results of completed human studies. Other comments supported giving the HSRB only an advisory role.

Response: EPA believes the HSRB should have an advisory role. The decision to disapprove proposed new research or to decide whether or not to rely on the results of completed studies is inherently governmental. The Agency cannot legally confer authority to make such decisions on an advisory committee. The Agency notes, however, that it expects to give considerable weight to the advice of the HSRB.

2. *HSRB membership and qualifications.*

Comment: Many comments emphasized that the HSRB must be independent, that its members must have no conflicts of interest, including any financial relationships with the pesticide industry.

Response: EPA agrees. Chartering the HSRB as a federal advisory committee to provide expert advice means that all candidates for membership on the HSRB must meet the federal requirements governing conflicts of interest. Although other requirements relating to the operation of the HSRB as an advisory committee are not specified in the final rule, EPA did retain in the final rule a requirement that members have no conflicts of interest. Specifically, the final rule provides that HSRB members must "meet the ethics and other requirements for special government employees." See § 26.1603(a) of the regulatory text.

Comment: Several comments stressed the importance of having HSRB members with sufficient expertise in the substantive disciplines raised by the types of human research covered under the rule. They specifically identified the disciplines of clinical toxicology, research ethics and the Common Rule, and public health. Comments also noted that the Agency might need to supplement the HSRB to obtain expertise to address particular types of research covered by the rule.

Response: EPA generally agrees with the comment and on January 3, 2006, issued a **Federal Register** Notice inviting nominations of experts to serve on the HSRB (71 FR 116). The Notice described the following areas of expertise: Bioethics, human toxicology, biostatistics, and human risk assessment. Under FACA, EPA has the authority to appoint consultants to the HSRB who can provide additional expertise when needed.

Comment: Several comments recommended that the members of the HSRB include non-scientists who are members of the community and who could represent the views of special populations that could be the focus of proposed human research.

Response: EPA does not believe that it is necessary to include non-expert community members on the HSRB. However, under FACA, the public, including non-expert community representatives have opportunities to provide both written and oral public comment to the HSRB. In addition, the HSRB has the flexibility under FACA to ask representatives of community groups to make presentations to the committee on specific topics. EPA also notes that, before a proposal reaches the HSRB, an IRB will have reviewed and approved it. Such IRBs are required by the new rules (§ 26.1107), to include people familiar with the concerns arising in research with special populations. Thus, EPA expects in most cases that the concerns of community-based representatives will be a part of the information before the HSRB.

3. *Scope of research subject to HSRB review.*

Comment: Some comments favored expanding the scope of studies reviewed by the HSRB to include all first-party and second-party research, as well as third-party research; all types of human research, not only research involving intentional exposure of human subjects; studies performed with any substance regulated by EPA, not only studies with pesticides; and all human research considered by EPA, not only the completed studies on which EPA intends to rely.

Response: EPA agrees that it may sometimes be appropriate to obtain HSRB review of some of these types of studies. The final rule gives EPA discretion to seek the advice of the HSRB on additional types of studies beyond those for which HSRB review is required. For the reasons explained earlier, however, the Agency has decided not to expand the scope of subpart K now, and therefore sees no reason to expand the scope of required EPA or HSRB review of proposed new research. Similarly, the Agency has decided not to extend without further analysis and public discussion the ethical framework in subpart Q to decisions made under statutory authorities other than FIFRA or FFDCA. It would make no sense to require the HSRB to review human research that fell outside the scope of the other substantive provisions of the rule. Finally, EPA has decided that it would not be an efficient use of resources to require HSRB review of human research that the Agency had decided not to rely on, typically because it falls short of contemporary standards of scientific validity. The Agency does not anticipate that the HSRB would often disagree with such conclusions, and therefore EPA will use its discretion to determine whether such scientific judgments warrant HSRB review.

Comment: Many comments generally supported the proposed review of new research and completed research reports by both EPA staff and the HSRB, at least in some cases. A number of commenters, however, suggested ways to narrow the scope of the reviews performed by the HSRB, including: (1) By having the HSRB review only studies intended to identify or measure toxic effects, (2) by exempting from HSRB review consumer acceptance studies, insect repellent efficacy tests, or other "product-in-use" studies; (3) by exempting from HSRB review proposals to employ protocols for "routine" exposures or other studies that follow established EPA guidelines; and (4) by exempting from HSRB review the results of research which the HSRB had previously reviewed and approved as a proposal, unless the investigator failed to follow the approved protocol. Finally, some comments recommended that the HSRB be restricted to considering ethical issues, but not scientific issues.

Response: EPA disagrees with the comments suggesting a narrowed scope for HSRB review. EPA agrees that each of the categories described above may contain at least some studies that present no difficult scientific or ethical issues. To the extent EPA's review indicates that a study presents no difficult science or ethics issues, the Agency would expect the HSRB to agree and quickly conclude its review. But any research involving intentional exposure may present risks to individual human subjects greater than those they would receive in their normal activities, and therefore warrants careful examination, even if the purpose of the study is not to identify or measure toxic effects. Similarly, while EPA anticipates that many consumer acceptance tests, insect repellent efficacy tests, and other "product-in-use" studies will raise no difficult scientific or ethical issues, the Agency has relatively little experience with assessing explicitly the ethical attributes of such research. Therefore the Agency thinks it would be imprudent to exclude

HSRB review of these studies. EPA likewise recognizes that following established guidelines may reduce the chances of scientific deficiencies in a study, but EPA's guidelines do not address the full range of potential ethical issues that should be considered on a case-by-case basis. Finally, EPA believes that even if a study follows an established protocol, unanticipated scientific and ethical issues may arise that will warrant expert advice.

C. The Final Rule

As a result of the reorganization of the final rule, all provisions relating to EPA and HSRB review of proposals for new, third-party research or reports of completed studies, or to the establishment of the HSRB, now appear in subpart P.

The final rule reflects one significant change from the proposal. Under the final rule, the HSRB will review all research involving intentional exposure conducted after the effective date of the final rule, as well as all research involving intentional exposure performed before the rule takes effect, if the purpose of the research was to identify or measure a toxic effect. But the final rule grants to the Agency discretion to decide whether studies performed before the effective date of the final rule that do not measure toxicity should undergo HSRB review.

After publishing the proposal, EPA examined how the proposal would affect its plans to complete tolerance reassessment by August 2006, as required by the 1996 FQPA amendments to FFDCA. The Agency reviewed the existing toxicity and exposure databases for upcoming tolerance reassessment decisions and determined that as many as several hundred studies relevant to the risk assessments for these actions appeared to meet the definition of "research involving intentional exposure of human subjects." Only a relative few of these intentional exposure studies measure the toxicity of a pesticide; the great majority of them measure the levels of potential human exposure resulting from pesticide use, the efficacy of insect repellents, or the absorption, distribution, metabolism, and excretion of pesticides.

Since the enactment of the Food Quality Protection Act in 1996 EPA has relied on many of these non-toxicity, intentional-exposure human studies in its registration and reregistration decisions. Moreover, the Agency has afforded multiple opportunities for public comment on several hundred draft and final Reregistration Eligibility Decision (RED) documents and Interim RED (IRED) documents, but has never received any public comment on a RED or IRED concerning the ethics of intentional-exposure human studies other than a toxicity study. Taking all of these non-toxicity, intentional-exposure studies to the HSRB would significantly increase its workload and expand the number of pending regulatory decisions affected. Accordingly, EPA has decided that while the final rule should require the Agency to send to the HSRB all completed toxicity studies on which it intends to rely, it need not require all non-toxicity studies in its existing databases to undergo HSRB review. Thus, under the final rule, the Agency will retain the discretion to submit additional types of old studies to the HSRB, and will consider public comments on its upcoming pesticide actions for tolerance reassessment in deciding which of the non-toxicity studies raise significant ethical or scientific issues warranting HSRB review.

In addition, subpart P in the final rule reflects a few other minor revisions to the proposal. The provisions governing Agency review of proposals for new third-party research were placed in subpart P in preference to subpart K, so that subpart P would apply only to EPA, and subpart K would apply only to regulated third parties.

To help ensure effective implementation of the final rule, EPA has made several administrative decisions affecting the HSRB. Most important, the Agency has decided to establish the HSRB as a separately chartered advisory committee under the Federal Advisory Committees Act (FACA). FACA requires the HSRB, as a federal advisory committee, to follow certain basic procedures designed to promote transparency and to ensure public participation. These include timely public notice of meetings, public access to meetings, and opportunity for the public to comment; public availability of documents considered by the HSRB and meeting minutes; and a Federal officer or employee attending each meeting. Of course, the HSRB will be required to protect materials designated as confidential from public disclosure. Finally, EPA is also committing to aggressive management of the process to promote efficient use of resources and timely decisions, and to ensure affected stakeholders have complete information about the status of ongoing reviews.

XIII. Subpart Q—Ethical Standards for Assessing Whether to Rely on the Results of Human Research in EPA Regulatory Decisions

This unit discusses the ethical standards EPA will use to guide its decisions whether to rely in its actions under the pesticide laws on the results from completed human research. Unit XIII.A. summarizes EPA's proposal, Unit XIII.B. discusses public comment, and Unit XIII.C. describes the positions taken in the final rule.

Summary: The final rule is substantively unchanged from the proposal, although the provisions have been revised to make them clearer. One new section (§ 26.1701) clarifies the applicability of this subpart to EPA decisions to rely on relevant, scientifically valid "data from research involving intentional exposure of human subjects to a pesticide" in its actions under the pesticide laws, FIFRA and FFDCA. A second new section (§ 26.1702) provides needed definitions of terms. The remaining four sections in the final rule together delineate the framework within which EPA will decide whether to rely on the results of certain types of human research.

This framework rests on the basic principle that EPA will not rely in its actions on data derived from unethical research. Section 26.1703 forbids EPA to rely on data from any study involving intentional exposure of pregnant women, fetuses, or children. Section 26.1704 forbids EPA to rely on data from "old" research—i.e., covered studies initiated before the effective date of the final rule—concluded to be fundamentally unethical or significantly deficient with respect to the ethical standards prevailing when it was conducted. Section 26.1705 forbids EPA to rely on data from any "new" research—i.e., research initiated after the effective date of the final rule—unless EPA finds that the research complied with the new requirements. Finally, § 26.1706 creates a very narrow exception to the Agency's general refusal to rely on unethical data, one that allows reliance on unethical data when it is crucial to supporting more stringent regulatory measures to protect public health.

A. The Proposed Rule

In proposed subpart F of 40 CFR part 26, EPA set out ethical standards for its decisions to rely on or not to rely in its regulatory decisions under FIFRA or FFDCA on reports of completed intentional-dosing research with human subjects. For covered research initiated after the effective date of the rule, EPA

proposed to refuse to rely on data from scientifically sound and relevant human research unless EPA had adequate information demonstrating that the research complied with the Common Rule. For covered research initiated before the effective date of the rule, EPA proposed to rely on data from scientifically sound and relevant human research unless there was clear evidence to show the conduct of the research was fundamentally unethical or was significantly deficient relative to the ethical standards prevailing when it was conducted. EPA also proposed a formal exception to these standards when to rely on scientifically sound but ethically deficient research would give crucial support to a regulatory action more protective of public health than could be justified without relying on the ethically deficient research.

B. Public Comments

EPA received many public comments on proposed subpart F. The major issues raised by the comments are grouped and summarized below under these four headings:

- Comments advocating a broader or narrower scope for this subpart—a change to the kinds of research and the range of EPA decisions the framework should cover.
- Comments questioning the proposed framework itself, including arguments to include standards for scientific validity of human research, and arguments that EPA should never reject scientifically sound data for ethical reasons.
- Comments on the substantive ethical standard to be applied to "old" research initiated before this final rule takes effect.
- Comments on the proposed "public health exception" to the general refusal to rely on unethical research.

The Agency notes that, although some comments favored more specificity in EPA's final rule, many comments expressed support for EPA's proposal to rely on the Common Rule as the ethical benchmark for judging the acceptability of research conducted after the effective date of the final rule.

1. *The scope of application of EPA's ethical framework.*

Comment: Some comments advocated expanding the application of the ethical framework beyond research involving intentional exposure of human subjects to cover all types of human subjects research considered by the Agency, or to embrace consideration of human subjects research conducted with pesticides under EPA statutes other than the pesticide laws, or to cover research involving intentional exposure of human subjects to any environmental substance, not only to pesticides.

Response: The Agency has decided not to expand the application of the ethical standards in this subpart to encompass all types of human subjects research relied on by EPA, to research involving substances other than pesticides, or to actions taken under authorities other than the pesticide laws. In the future, the Agency will consider further actions to address these and other issues beyond the scope of this final rule.

The Agency believes an initial focus on research involving intentional exposure is warranted in that potential risks to research subjects are generally greater when exposure is intentional than in other types of studies. It is reasonable to scrutinize such research closely to ensure that research subjects are fully protected and the research is ethical. EPA has not fully considered, and public comments have not thoughtfully addressed, what protective measures would be appropriate for research that does not involve intentional exposure. Thus, the Agency thinks it premature to conclude that all of the provisions applying to research involving intentional exposure should apply more widely.

EPA thinks there has also been inadequate consideration of the consequences of expanding the scope of the ethical framework to embrace research with substances other than pesticides. Most of the comments favoring expansion of the rule beyond pesticides came primarily from stakeholders affiliated with the pesticide industry, and EPA received essentially no meaningful response to its requests for comment from other stakeholder interests, including those likely to be affected by such an expansion. Given the mandate of the 2006 Appropriations Act to address research "for pesticides," the final rule retains the proposed focus on human research for pesticides.

Finally, the Agency has decided to retain the proposed applicability of the framework to actions taken under the pesticide laws. Although EPA recognizes the theoretical possibility that human research with a pesticide may be considered under other statutes, the Agency notes that the 2006 Appropriation Act does not require the adoption of a broader scope than decisions under FIFRA and FFDCA. Also, the Agency has not received meaningful public comment on whether its authorities under other statutes permit it to refuse to rely on relevant, scientifically sound data which were derived from an unethical study. Because of the questions about the Agency's legal authorities and the absence of a clear mandate, EPA has decided not to require the application of the ethical framework to actions taken under its other laws.

Comment: Other comments argued for restricting the application of the ethical framework to only certain kinds of human research—to research intended to identify or measure toxic effects, to research conducted in a laboratory or clinical setting, or to exclude research involving only exposures that EPA had already approved (e.g., studies of registered pesticides used in accordance with their approved labeling). Two general reasons were offered for these recommendations: (i) Public controversy has focused exclusively on a narrower set of studies than those falling within the scope of proposed subpart F, and (ii) there is so little risk from the types of studies suggested for exclusion that no additional measures would be needed to protect subjects.

Response: Because EPA finds these reasons unpersuasive, the Agency has decided to retain, at this time, the scope of the proposal for its final rule. Thus, EPA is not narrowing the scope of its framework in any of the ways recommended above.

Although recent controversy has focused on "intentional dosing, human toxicity testing for pesticides" (see the Appropriations Act discussed in Unit XIV.A.), there has also been public debate about other kinds of human research, including product-in-use studies using registered pesticides, studies performed outside the laboratory setting, and studies which do not measure toxicity. To promote public confidence in its operations and judgments EPA must address this larger universe of research. Second, EPA thinks that it is important to examine the risks of studies involving intentional exposure of research subjects—even when comparable exposures have already been approved for the general public under a pesticide registration. While the risks experienced by the research subjects and the general public may not differ, the risks experienced by the particular subjects may exceed what they would otherwise receive, and therefore researchers must provide each potential subject a full explanation of the potential for any additional risk they might assume by volunteering for a study. For its part, EPA should ensure that, in their interactions with subjects, the sponsors and investigators have acted ethically.

2. *The adequacy of the ethical standards.*

Comment: Although nearly all comments supported EPA's application of an explicit ethical standard in deciding whether or not to rely on data from completed human research, one significant line of comment argued that EPA should never refuse to rely on relevant, scientifically sound research even if it were conducted unethically. This conclusion rested on three arguments: (i) Rejecting scientifically sound data would deprive decision-makers of information that would serve the mission of protecting public health; (ii) applying a new standard of ethical acceptability retroactively to completed research would be unfair; and (iii) refusing to rely on data from unethical research could do nothing to remedy any harm done to the subjects in the research.

Response: While EPA sees some merit in each of these arguments, the Agency disagrees with the conclusion. EPA believes that rejecting unethical data is an appropriate and powerful means of promoting compliance with ethical standards, and that rejecting unethical data generally meets public expectations about conduct of the government.

First, EPA agrees that it is important to consider all available information in carrying out its mission to protect public health. This is especially important when reliable data show humans to be more sensitive than animals. Sometimes, however, data from human research will show that humans are less sensitive—or no more sensitive—than animals, and that a less restrictive regulatory measure may provide adequate protection for public health. This is important to know because the Agency is interested in cost-efficient regulations. Finally, human research often confirms a risk assessment based on animal toxicity data. Such confirmation increases confidence in the Agency's decisions. Therefore, the Agency agrees that it is always important to assess data from available human research.

The Agency also agrees that it is generally inappropriate to apply current ethical standards to judge the acceptability of research completed before such standards were articulated. Not only could that lead to declaring unethical much completed research which was considered ethical when it was conducted, it would also set a standard for ethical conduct—adherence to standards not yet articulated—that even the most ethically concerned investigators and sponsors could never meet. To avoid such an outcome EPA will generally judge the ethical acceptability of research initiated before the effective data of this rule in terms of the ethical standards prevailing when it was performed.

The Agency also agrees that no actions taken after research is completed can undo any harm experienced by the human subjects in the research. But this point ignores the deterrent value of government actions that "punish" unacceptable conduct. EPA believes that by refusing to rely on unethical data it creates a strong incentive for the scientific community to conduct future research ethically. If investigators and sponsors understand that EPA will not rely on the results of their research unless it is performed ethically, they will not wish to risk losing either their direct investment in the research or any benefit its use might bring to them.

Finally, EPA believes that the public expects its government to apply a clear standard of ethical acceptability in deciding whether to rely on the results of completed research. Such an expectation, evident in thousands of public comments on the proposed rule, provides additional reason for establishing an explicit ethical framework for making these decisions, and for refusing to rely on unethically obtained data. (As discussed below, EPA believes that in certain very limited circumstances the ethical course of conduct may require reliance on ethically deficient research when to do so is crucial to supporting more stringent regulatory measures to protect public health.)

Comment: Some comments, noting that scientifically unsound research is always unethical, argued that the proposed framework should articulate explicit standards of scientific validity.

Response: EPA agrees that its ethical framework should exclude data which are not scientifically sound, and thus the final rule clarifies that subpart Q applies only to "scientifically valid and relevant data." The Agency has not, however, attempted to define a standard for scientific validity and relevance, because this is necessarily a case-by-case judgment. EPA has long had in place policies and procedures to ensure rigorous scientific review of research it is considering, including procedures for formal peer review of research and assessments critical to Agency actions. In addition, § 26.1603(b) of the final rule provides that the HSRB "shall review and comment on the scientific and ethical aspects of research proposals and reports of completed intentional exposure research. . . ." Over time the results of HSRB review of the scientific aspects of both proposed and completed human research will support articulation of general principles for the scientifically sound and ethical conduct of different types of human research.

3. *The ethical standard for accepting "old" research.* Opinions about research conducted before the final rule varied widely, and are summarized below under these headings:

- The proposed standard is too weak; the Common Rule should be applied to all research, regardless of when it was conducted;
- The rule should define such terms as "standards prevailing when research was conducted"; "fundamentally unethical"; and "significantly deficient."
- Rejection of any research involving intentional exposure of pregnant women, fetuses, or children is inconsistent with "standards prevailing when research was conducted."
- The standard of "clear evidence" should be different;

Comment: Many comments favored application of the Common Rule to all research, regardless of when it was performed. These comments argued that the standard in proposed § 26.601 was unacceptably weak because it failed to reflect contemporary ethical standards.

Response: EPA believes it would be unreasonable to apply to completed research ethical standards articulated after the research was conducted. Thus, the final rule retains the proposed standard for judging the acceptability of completed "old" research—i.e., research initiated before the final rule becomes effective.

First, for many years the prevailing ethical standard in the U.S. has been the Common Rule, and with respect to biomedical research, the earlier DHHS rules that form the basis for the Common Rule. Consequently, as a practical matter, the same standard of ethical acceptability—the Common Rule or its foreign equivalent—would apply to research conducted since its promulgation in 1991.

Thus, reference to ethical standards prevailing at the time of the research makes a practical difference only when considering the acceptability of research which meets today's standards of scientific validity but which was conducted before today's ethical standards were articulated. Codes of ethical research conduct require investigators to do certain things in certain ways before and during the research. It is reasonable to expect investigators to follow ethical codes that prevail when they do their work; it is unreasonable to expect them to anticipate and follow standards developed after their work is done. EPA believes that scientifically meritorious research which adhered to accepted

ethical norms when it was conducted should not be set aside because ethical standards have subsequently changed. EPA also believes that ethical standards are likely to continue to change in the future and that if and when they do, such a change should not invalidate or make unacceptable otherwise meritorious research conducted now, in conformity with the ethical standards of today.

It is sometimes argued that to accept "old" research falling short of today's standards would encourage others to conduct unethical research in the future. EPA disagrees. With respect to new research, the principal incentive to conduct research ethically is the prospect that the Agency might refuse to rely on research that doesn't comply with contemporary ethical standards. A refusal by EPA to rely on new human research would carry serious economic consequences for the investigator and sponsor. Much third-party research is conducted by private, for-profit organizations in the hope that the results will lead to financial benefits, often through changes in government regulation. For example, the current controversy over pesticide studies centers on research conducted by pesticide companies who hoped to demonstrate through human studies that their products were safer than was indicated by available animal studies, and thus that their market could expand—or at least need not shrink—because of concerns about risk. An Agency refusal to rely on data would deprive the investigator and sponsor of such potential financial benefits. Importantly, under § 26.1705 of the final rule, the Common Rule's provisions will guide EPA's decisions about reliance on the results of *new* research, i.e., studies conducted after the rule takes effect. The fact that EPA may apply a different standard to "old" studies is irrelevant. An investigator conducting a new, covered study after these final rules take effect would be very foolish to think that the Agency will judge its ethical acceptability by any standard other than the Common Rule.

Comment: A number of comments called for the rule to specify that certain documents—the Nuremberg Code, various editions of the Declaration of Helsinki, the Belmont Report, and the Common Rule, among others—would serve as the point of reference in identifying the "standards prevailing at the time the research was conducted." Other comments asked that the Agency explain and give examples of the types of ethical deficiencies that it would deem "fundamentally unethical" or "significantly deficient" in the provision codified as § 26.1704 of the final rule.

Response: In recent years, EPA has reviewed numerous reports of completed research on pesticides involving intentional exposure of human subjects. These studies have been conducted over many years, in many places, under a variety of ethical policies and regulatory schemes; they have addressed a wide range of research questions, and they have presented a wide spectrum of ethical shortcomings, from minor flaws to more serious deficiencies. Given these variations, the Agency believes that its ethical framework must retain sufficient flexibility to judge each situation on its merits, in the context of the time and place the research was conducted. While the historical documents cited in the comments reflected widely shared views about what constitutes ethical conduct, they were not necessarily universal or comprehensive in their coverage. Certainly they are among the standards which may have prevailed when specific research was conducted, and EPA will rely on them when they are appropriate to the evaluation of a particular study. But it adds nothing to list them in the final rule.

EPA also thinks it unnecessary to elaborate on the meaning of the narrative standards "fundamentally unethical," "significantly deficient" or "substantial compliance." The gravity of a particular ethical lapse depends not only on the details of the deficiency; but also on the circumstances in which it occurred. EPA agrees with the NAS that each study requires case-by-case evaluation. EPA expects these terms to acquire greater clarity over time, through HSRB and public review of Agency decisions concerning reliance on completed human research.

Comment: Some comments objected to the proposed prohibition of EPA's reliance in its pesticide decisions on data from human subjects research involving intentional exposure of pregnant women, fetuses, or children. These comments argued that if such research was not considered unethical under the standards prevailing when it was conducted EPA should accept and consider it, and that exclusion of such research could deprive EPA of potentially valuable information.

Response: EPA agrees that existing research involving intentional exposure of pregnant women, fetuses, or children may have been considered ethical according to the standards prevailing when the studies were conducted. Nonetheless, in light of the provisions of the 2006 Appropriations Act and the thousands of public comments on the proposal condemning research of this kind, the Agency believes it must generally refuse to rely on such research. The Agency knows of only a very few existing studies involving intentional exposure of pregnant women or children. If it were determined that reliance on any of them were crucial to a decision that would impose a more stringent regulatory restriction to protect public health than could otherwise be justified, the exception procedure defined in § 26.1706 in the final rule could be invoked.

Comment: Several comments recommended revising the evidentiary standard for accepting "old" studies. Some suggested a change from "clear evidence" to a less demanding test, such as "any evidence." Others recommended adoption of the exact wording of the NAS recommendation on which EPA based the proposal, changing "clear evidence" to "clear and convincing evidence."

Response: It is conceivable that the standard requiring "clear evidence" could lead the Agency to accept data from research which it suspected but could not prove had serious ethical flaws. The Agency agrees this would be unfortunate, but believes a change to a standard of "any evidence" would likely lead to even more unfortunate outcomes. Because reliable information about its conduct is often very limited, in many cases it is difficult or impossible to prove that older research was ethical. An unsupported accusation of unethical conduct should thus not in itself be sufficient to force rejection of completed research. Rejection of research on the basis of weak or suggestive evidence of unethical conduct could deprive the Agency of information important to sound decisions. Because EPA can see no benefit that would flow from changing the standard to "any evidence," EPA is not accepting this recommendation.

On the other hand EPA agrees with the comments urging a return to the exact wording of the evidentiary test in NAS Recommendation 5–7. Since the Agency did not intend to alter the standard, and since "clear and convincing evidence" has an accepted meaning under administrative law, EPA has changed the final rule to read, in pertinent part:

> . . . EPA shall not rely on data from any research initiated before April 7, 2006 if there is clear and convincing evidence that the conduct of that the research was fundamentally unethical . . .

4. *The exception allowing use of unethical data to justify more stringent regulatory restrictions to protect public health.*

Comment: One group of comments argued that the Agency should, without exception, never rely on data derived from unethical research because to do otherwise would condone unethical research. Many of these commenters also misunderstood the proposed exception as authorizing the conduct of unethical future research.

Response: Although EPA thinks there will rarely, if ever, be situations requiring the use of this exception, EPA can easily imagine a circumstance in which ethical behavior could require Agency decision-makers to rely on unethical data. (See Unit II.) The exception would be used when scientifically sound but ethically flawed data show that the Agency needs to take a more protective action than could be justified without considering the human research. Invoking the exception would allow EPA to protect the health of many people—perhaps millions; a greater public good than any benefits that would flow from refusing to rely on the data. In EPA's moral calculus, the greater good should and will guide the choice whether to use unacceptable data.

The Agency disagrees with the argument that the final rule should contain no exceptions to the basic principle of refusing to rely on unethical research, because an exception would encourage the conduct of unethical research. A public refusal by EPA to rely on unethical data brings shame to the investigator who acted unethically, and in most cases also directly affects the financial interests of the investigator, sponsor, or both. Such a refusal serves as an important deterrent to other investigators, discouraging unethical research in the future.

To further ensure that EPA's exceptional use of ethically flawed data does not encourage unethical research conduct, § 26.1706 expressly requires the Agency to publish "a full explanation of its decision to rely on otherwise unacceptable data, including a thorough discussion of the ethical deficiencies of the study . . . ." In addition, the Agency will have recourse to any of the other measures identified in subpart O to promote compliance with standards of ethical research. EPA believes the exception as defined in the final rule, allowing for EPA consideration of unethical research under well defined and narrow conditions and requiring a full public discussion of its ethical deficiencies, will not in any way encourage other investigators to conduct unethical research.

Comment: Some comments argued for a broad interpretation of the concept of "protection of public health," such that it would not be limited to cases involving imposition of more stringent regulatory restrictions. Some comments suggested, for example, that a more accurate assessment of risks to humans should be interpreted as "protection of public health." Other comments called upon EPA to clarify in the final rule that "protection of public health" does not encompass the ability of American agriculture to produce more crops at a lower cost.

Response: EPA does not agree that the public health exception should be interpreted to permit reliance on unethical research to support more accurate risk assessments or more efficient or lower cost agricultural production. EPA's ethical framework is built on the principle that unethical research should not be relied on in Agency actions except in the most extraordinary circumstances; such interpretations would amount to abandoning this principle altogether, and could severely undermine incentives for compliance with the new requirements.

The Agency does agree, however, that the proposal was unclear with respect to what would constitute a "public health" benefit justifying invocation of the exception. EPA has thus revised the final rule to clarify that invoking the public health exception would only permit the Agency to "impose a more stringent regulatory restriction that would improve protection of public health . . . ." See § 26.1706 of the regulatory text.

C. The Final Rule

Subpart Q of the final rule corresponds in substance to subpart F of the proposal. In this final rule EPA has moved the rule text to a new subpart, and has rewritten the proposed provisions to express the standards more clearly.

Section 26.1701 of the final rule describes the scope of subpart Q; it applies to:

> . . . EPA's decisions whether to rely in its actions under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 *et seq.*) or section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a) on scientifically valid and relevant data from research involving intentional exposure of human subjects.

The Agency has chosen to retain the scope of the proposed rule because it believes that the 2006 Appropriations Act does not require this rule to address a broader scope of issues, and because there has not been adequate consideration of the consequences of adopting a more expansive scope.

Section 26.1703 prohibits EPA's reliance on data from research involving intentional exposures of pregnant women, fetuses, or children. Derived from proposed §§ 26.221 and 26.421, this section states:

> Except as provided in § 26.1706, in actions within the scope of § 26.1701, EPA shall not rely on data from any research involving intentional exposure of any human subjects who is a pregnant woman (and therefore her fetus) or child.

This provision makes clear that the Agency will not rely in its actions on the results of research that EPA and third parties are prohibited from conducting under subparts B and L, except under the narrow exception provided by § 26.1706. To clarify that this prohibition applies to EPA's non-regulatory actions (such as issuance of a risk assessment or a health advisory level) as well as to its regulatory decisions, EPA has changed the phrase "regulatory decision-making" in the proposal to "actions" in the final rule.

Section 26.1704 defines the ethical standard EPA will use to decide whether to rely on the results of research conducted with non-pregnant adults before the effective date of the rule. It provides:

> Except as provided in § 26.1706, in actions within the scope of § 26.1701, EPA shall not rely on data from any research initiated before April 7, 2006, if there is clear and convincing evidence that the conduct of the research was fundamentally unethical (e.g., the research was intended to seriously harm participants or failed to obtain informed consent), or was significantly deficient relative to the ethical standards prevailing at the time the research was conducted. This prohibition is in addition to the prohibition in § 26.1703.

The above rule text is derived from proposed § 26.601, and follows the language of the NAS recommendation 5–7. In response to public comment, the evidentiary standard for concluding research was unethical has been changed from "clear evidence" to "clear and convincing evidence." The Agency made this change to minimize confusion, to conform to the wording of the NAS recommendation, and to use a formulation of the evidentiary standard that has an accepted legal meaning in administrative law. For purposes of clarity, the section also reaffirms that the prohibition in § 26.1703 against relying on research involving pregnant women and children is unaffected by this provision.

Section 26.1705 describes the ethical standard EPA will use to decide whether to rely on the results of human subjects research conducted with non-pregnant adults after the effective date

of the rule. It provides that the Agency will not rely on data from such research:

Except as provided in § 26.1706, in actions within the scope of § 26.1701, EPA shall not rely on data from any research initiated after April 7, 2006, unless EPA has adequate information to determine that the research was conducted in substantial compliance with subparts A through M of this part, or if conducted in a foreign country, under procedures at least as protective as those in subparts A through L. This prohibition is in addition to the prohibition in § 26.1703.

This rule text is based on proposed § 26.602. It has been revised to make clear that EPA may accept and rely on data from human research conducted in a foreign country if EPA has adequate information to determine the research was "conducted . . . under procedures at least as protective as those in subparts A through L." Allowing the use of foreign research provided the research meets ethical norms equivalent to those of the Common Rule is consistent with the Common Rule at § 26.101(h). Like § 26.1704, § 26.1705 reaffirms, for the sake of clarity, that the prohibition in § 26.1703 against relying on research involving pregnant women and children is unaffected by this provision.

Finally § 26.1706 provides for an exception to the general refusal to rely on the results of unethical research. This section defines the specific circumstance in which the Agency will use data from research judged unacceptable under § 26.1703, § 26.1704, or § 26.1705, and the procedures EPA must follow in reaching that decision, as follows:

EPA may rely on such data only if all the conditions in paragraphs (a) through (d) of this section are satisfied:

(a) EPA has obtained the views of the Human Studies Review Board concerning the proposal to rely on the otherwise unacceptable data,

(b) EPA has provided an opportunity for public comment on the proposal to rely on the otherwise unacceptable data,

(c) EPA has determined that relying on the data is crucial to a decision that would impose a more stringent regulatory restriction that would improve protection of public health than could be justified without relying on the data, and

(d) EPA publishes a full explanation of its decision to rely on the otherwise unacceptable data, including a thorough discussion of the ethical deficiencies of the study and the full rationale for finding that the standard in paragraph (c) of this section was met.

The text of this section of the final rule contains a number of minor revisions to clarify the substantive and procedural requirements. Most notably, EPA changed the wording for the substantive standard for using the exception from "crucial to the protection of public health" in the proposal to "crucial to a decision that would impose a more stringent regulatory restriction that would improve protection of public health" in the final rule. This change reflects the Agency's intent to limit the exception to a very narrow circumstance and to prevent use of the exception in a way that could benefit a person responsible for the unethical conduct.

XIV. EPA's 2006 Appropriations Act and the Final Rule

This unit discusses how today's final rule meets the requirements of the Department of the Interior, Environment, and Related Agencies Appropriations Act, 2006, Public Law No. 109–54 (Appropriations Act), which required EPA to promulgate a final rule relating to intentional dosing human toxicity studies for pesticides within 180 days of enactment of the Act, and included various mandates concerning the promulgated final rule.

A. Section 201 of EPA's FY 2006 Appropriations Act

On August 2, 2005, the President signed into law the Department of the Interior, Environment, and Related Agencies Appropriations Act, 2006, Public Law No. 109–54 (Appropriations Act), which provides appropriated funds for EPA and other federal departments and agencies. Section 201 of the Appropriations Act addresses EPA activities regarding intentional dosing human toxicity studies for pesticides as follows:

None of the funds made available by this Act may be used by the Administrator of the Environmental Protection Agency to accept, consider or rely on third-party intentional dosing human toxicity studies for pesticides, or to conduct intentional dosing human toxicity studies for pesticides until the Administrator issues a final rulemaking on this subject. The Administrator shall allow for a period of not less than 90 days for public comment on the Agency's proposed rule before issuing a final rule. Such rule shall not permit the use of pregnant women, infants or children as subjects; shall be consistent with the principles proposed in the 2004 report of the National Academy of Sciences on intentional human dosing and the principles of the Nuremberg Code with respect to human experimentation; and shall establish an independent Human Subjects Review Board. The final rule shall be issued no later than 180 days after enactment of this Act.

B. Compliance of the Final Rule with the Appropriations Act

The first requirement of the Appropriations Act is that EPA not "accept, consider or rely on third-party intentional dosing human toxicity studies for pesticides, or . . . conduct intentional dosing human toxicity studies for pesticides until the Administrator issues a final rulemaking on this subject." EPA has not accepted, considered, or relied on any third-party intentional dosing human toxicity studies in its actions under FIFRA and FFDCA since September 2005. EPA has further neither conducted nor supported any intentional dosing human toxicity study for pesticides during this rulemaking period.

The second requirement of the Appropriations Act is to "allow for a period of not less than 90 days for public comment on the Agency's proposed rule before issuing a final rule." A notice of proposed rulemaking addressing both third-party intentional dosing human toxicity studies for pesticides and EPA's conduct of intentional dosing human studies was published in the **Federal Register** on September 12, 2005 (70 FR 53838); the public comment period ended on December 12, 2005.

EPA's proposed rule addressed first-, second-, and third-party human subjects testing for pesticides. In particular, the proposal defined the scope of third-party human research covered by the proposal as:

[A]ll research involving intentional exposure of a human subject if, at any time prior to initiating such research, any person who conducted or supported such research intended:

(1) To submit results of the research to EPA for consideration in connection with any regulatory action that may be performed by EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 *et seq.*) or section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a); or

(2) To hold the results of the research for later inspection by EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 *et seq.*) or section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a).

EPA used the act of submitting, or the intent to submit, to the Agency under FIFRA or FFDCA as a surrogate for the Appropriations Act's requirement that EPA promulgate a rule addressing "third-party intentional dosing human toxicity studies *for pesticides.*" The use, sale, and distribution of pesticides are exclusively regulated by EPA under FIFRA and FFDCA. Moreover, as discussed above, the ongoing controversy over EPA's use of human research data in its risk assessments has focused almost exclusively on the use of such data in risk assessments under FIFRA and FFDCA. Indeed, the Congressional debate that resulted in the passage of section 201 of the Appropriations Act focused entirely on

human subjects research related to Agency actions under FIFRA and FFDCA. Therefore, EPA believes that interpreting the phrase "third-party intentional dosing human toxicity studies for pesticides" to require either submission or intent to submit under FIFRA or FFDCA reflects the intent of the Congress as expressed in section 201 of the Appropriations Act.

The third requirement of the Appropriations Act is that the final rule "not permit the use of pregnant women, infants or children as subjects." Today's final rule effectuates this mandate by: (1) Categorically prohibiting EPA from conducting or supporting research involving intentional exposure to any substance of human subjects who are pregnant women or children (subpart B of the final rule, § 26.203); and (2) prohibiting third-party research for pesticides involving intentional exposure of human subjects who are pregnant women or children (subpart L of the final rule, § 26.1203).

The fourth requirement of the Appropriations Act is that the final rule "shall be consistent with the principles proposed in the 2004 report of the National Academy of Sciences on intentional human dosing." Based on a careful review of the NAS report, EPA concludes that the underlying principles intended by the NAS committee to be reflected in its recommendations are the three "fundamental ethical principles" identified by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (National Commission) in its report, Ethical Principles and Guidelines for the Protection of Human Subjects of Research (the "Belmont Report"). These three fundamental principles are respect for persons, beneficence, and justice. See NAS Report at pp. 49–50, 98, and 113–14.

The NAS committee makes the point clearly that they did not propose new principles:

> [T]he committee was not required to invent the basic standards that govern human research in the United States. These standards are already embodied in the Federal Policy for the Protection of Human Subjects (the Common Rule.) NAS Report pp. 4, 33.

The NAS committee further stated that the fundamental principles articulated in the Belmont Report both undergird and are made operational by the procedural requirements of the Common Rule. The following quotations express this view:

> Federal regulations incorporate the obligation of beneficence by requiring IRBs to ensure that risks are minimized to the extent possible, given the research question, and are reasonable in relation to potential benefits to the participant or to the importance of the knowledge to be gained through the research (40 CFR 26.111(a)(1)–(2)). NAS Report at 56.
>
> [D]etermining whether the principle of beneficence has been satisfied requires balancing the anticipated risks to study participants against the anticipated benefits of the study to society. The risks to participants must be reasonable in relation to the societal benefit. In the words of the Common Rule, the risks must be reasonable in relation to the importance of the knowledge that may reasonably be expected to result (40 CFR 26.111 (a)(2)). NAS Report at 107.
>
> According to the Common Rule, IRBs should not approve a research protocol involving humans unless "selection of subjects is equitable" (40 CFR 26.111(3)). This requirement derives from the principle of justice identified in the Belmont Report. NAS Report at 114.
>
> Voluntary, informed consent by research participants . . . is a major element in the system of protection of research participants. The consent requirement expresses the principle of respect for persons, including respect for and promotion of autonomous choices. The Common Rule stresses this requirement, as do other codes of research ethics, including the Nuremberg Code (1949), the Declaration of Helsinki, and the Good Clinical Practice guidelines. NAS Report at 120.

Accordingly, EPA concludes that the "principles proposed in the 2004 report of the National Academy of Sciences on intentional human dosing" are, in fact, the three fundamental principles of respect for persons, beneficence, and justice articulated in the Belmont Report, and that the Common Rule rests on the foundation of those principles. Today's final rule extending the substantive requirements of EPA's Common Rule to additional categories of regulated third-party research is thus consistent with those principles, as required by the Appropriations Act.

The fifth requirement of the Appropriations Act is that the final rule "shall be consistent with the principles . . . of the Nuremberg Code with respect to human experimentation."

The NAS report (p. 47) explains the history of the Nuremberg Code as follows:

> Public policies regarding the ethical treatment of humans in research began forming in the late 1940's, largely in response to the atrocities committed by Nazi investigators who were tried before the Nuremberg Military Tribunal (*United States* v. *Karl Brandt, et al.*) In 1946, the American Medical Association adopted its first code of research ethics, which ultimately influenced the Nuremberg Tribunal's standards for ethical research, embodied in the ten "basic principles" for human research now known as the Nuremberg Code. [Footnotes and references omitted]

Before publishing the NPRM, EPA carefully assessed whether the proposed provisions were consistent with the 10 principles of the Nuremberg Code as a guide, and concluded that it was consistent with such principles. EPA believes this final rule remains consistent with the principles of the Nuremberg Code. An analysis explaining this conclusion is in the docket for this action, and comments on this issue have been addressed in our Response to Comments document.

The sixth requirement of the Appropriations Act is that the final rule "shall establish an independent Human Subjects Review Board." EPA believes that the entity required by the Appropriations Act is intended to be substantially identical to the "Human Studies Review Board" recommended by Chapter 6 of the NAS Report. Consistent with both the requirement of the Appropriations Act and the recommendations of the NAS, this final rule establishes an independent HSRB. The HSRB will review proposed human subjects research after review by a local IRB and EPA staff. This sequence is consistent both with EPA's current practice for reviewing first- and second-party human research proposals and with the practice of FDA for reviewing human research proposals. Although the NAS Report recommended that the EPA and HSRB reviews come before the IRB review, EPA believes that HSRB review after local IRB and EPA review will better serve the purposes for which HSRB review of proposed research is intended.

The final requirement of the Appropriations Act is that the final rule "shall be issued no later than 180 days after enactment of this Act." This requirement was met when EPA Administrator Stephen L. Johnson signed the final rule before January 29, 2006, and it was made publicly available.

XV. Effective Date of the Final Rule

EPA noted in the preamble to the proposed rule that it considered the expeditious application of the new protections in the final rule to be in the public interest. Accordingly the Agency explained that it would provide no longer period than is essential between publication of the final rule and its effective date. Since the final rule is being promulgated under the authority of FIFRA, EPA is subject to FIFRA section 25(a)(4), 7 U.S.C. 136w(a)(4), which provides that:

> Simultaneously with the promulgation of any rule or regulation under this Act, the Administrator shall transmit a copy thereof to the Secretary of the Senate and the Clerk

of the House of Representatives. The rule or regulation shall not become effective until the passage of 60 calendar days after the rule or regulation is so transmitted.

Therefore, EPA proposed that the final rule would be effective 60 days after its promulgation and transmittal to Congress.

EPA received only one comment on the effective date, arguing that the requirements of the rule should not apply retroactively. EPA agrees that the provisions of the final rule should not apply retroactively, and the final rule contains no retroactive requirements. Specifically, the final rule establishes standards for the conduct by EPA and by third parties, in the future, of certain types of research. The Agency notes that the actions to promote compliance identified in subpart O of the final rule would only be applied to those whose actions, following the effective date of the final rule, did not comply with applicable requirements. Actions occurring before the final rule takes effect would not be subject to direct sanctions under subpart O, such as civil penalties or debarment. In addition, the final rule establishes standards to guide future Agency decisions about the ethical acceptability of completed research. While some of the research that EPA will evaluate under the new standards for ethical acceptability was conducted prior to the effective date of the final rule, such studies will be judged by the ethical standards prevailing when the research was performed. Thus, even the standard of acceptability is not "retroactive" in the sense that conduct would be judged using a standard created after the conduct occurred.

The Agency has decided to make the final rule effective 60 days after the date of publication of its Notice of Final Rulemaking in the **Federal Register**. As required by FIFRA section 25(a)(4), the Agency has previously transmitted copies of the signed final rule to the Secretary of the Senate and the Clerk of the House of Representatives. Although technically the rule could take effect a few days earlier, EPA concluded that allowing 60 days from the date of publication of this **Federal Register** document was appropriate. Accordingly, this rule takes effect on April 7, 2006.

The Agency notes that a number of the provisions of the rule apply to research "initiated" after the effective date of this rule. For purposes of research conducted or supported by EPA, the Agency will consider that an investigator has initiated a study once the Agency's HSRRO has approved the protocol for the study. For purposes of research that is covered by subparts K or L or by § 26.1705, a study was "initiated" when the first subject was enrolled. If that date cannot be determined, EPA will consider the earliest date on which experimental activity involved a subject to be the date of initiation of the research.

XVI. FIFRA Review Procedures for the Final Rule

FIFRA section 25(a)(2)(B) provides: "[a]t least 30 days prior to signing any regulation in final form for publication in the **Federal Register**, the Administrator shall provide the Secretary of Agriculture a copy of such regulation." This section also authorizes the Secretary to waive the opportunity to review and comment on final regulations. FIFRA section 25(d)(1) states that "[t]he Administrator shall submit to an advisory panel for comment [the] final form of regulations issued under section 25(a) within the same time periods as provided for the comments of the Secretary of Agriculture . . . ." This section also authorizes the FIFRA Scientific Advisory Panel to waive the opportunity for review. Both, the FIFRA Scientific Advisory Panel (SAP) and the U.S. Department of Agriculture (USDA) have waived the opportunity under FIFRA to review the final rule.

In addition, FIFRA section 25(a)(3) states that "[a]t such time as the Administrator is required under paragraph (2) to provide the Secretary of Agriculture with . . . a copy of the final form of regulations, the Administrator shall also furnish a copy of such regulations to the Committee on Agriculture in the House of Representatives, and the Committee on Agriculture, Nutrition, and Forestry in the United States Senate." Because USDA waived review under FIRFA section 25(a)(2)(B), EPA is not required to furnish a copy of the final regulations to the specified committees 30 days prior to signature of the final rule. The Agency, nonetheless, provided copies of the final rule to the Congressional committees prior to its publication.

XVII. Statutory and Executive Order Reviews

A. Executive Order 12866

Under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), the Office of Management and Budget (OMB) has determined that this final rule is a "significant regulatory action" under section 3(f) of the Executive Order because this action might raise novel legal or policy issues. Accordingly, this action was submitted to OMB for review under Executive Order 12866 and any changes made based on OMB recommendations have been documented in the docket for this rulemaking as required by section 6(a)(3)(E) of the Executive Order.

In addition, EPA prepared an economic analysis of the potential costs and benefits associated with this action. This analysis is contained in a document entitled "Economic Analysis of the Human Studies Final Rule" (Economic Analysis). A copy of the Economic Analysis is available in the docket for this rulemaking and is briefly summarized here.

The Economic Analysis describes the benefits of the rulemaking in qualitative terms. These benefits include greater protections for test subjects, and a corresponding reduction in their risks, to the extent that affected third-party researchers are not already following the Common Rule. The benefits to sponsors of third-party human research include a better understanding of the standards that EPA will apply in determining whether to rely on the results of their studies, and thus, the opportunity to design and perform studies that are more likely to meet EPA standards, leading to more efficient Agency reviews. The Agency believes the general public will also benefit from this action because the rule will strengthen the protections for human subjects and reinforce the Agency's strong commitment to base its decisions on scientifically sound information.

The Economic Analysis also estimates the costs of the final rule by focusing on the costs to third parties of complying with the new requirements and the costs to EPA of implementing the new requirements. In general, EPA believes that most, if not all, recent third-party research intended for submission to EPA that involves intentional exposure of human subjects already complies with the Common Rule or an equivalent foreign standard. For purposes of this analysis, EPA assumed that current practice was in full compliance with the Common Rule.

After reviewing the history of EPA's consideration of research involving human subjects in its various program offices, EPA estimates that this action will affect only a limited number of third-party studies involving human subjects each year. EPA also collected data on the cost per study of compliance with the Common Rule. These costs include preparing documents to support review by an IRB and the expense associated with the IRB review. These costs are very minor relative to the overall cost of conducting the studies.

For EPA, the costs are associated with the review of protocols and the review of completed human studies by EPA staff and the Human Studies Review Board.

As detailed in the Economic Analysis prepared for this final rule, this action is estimated to result in a total annual incremental cost to third parties of approximately $39,000, and an estimated annual cost to EPA of approximately $808,000.

B. Paperwork Reduction Act

The information collection requirements contained in this final rule have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, under OMB control number 2070–0169. In accordance with the procedures at 5 CFR 1320.11, EPA sought comment on the Information Collection Request (ICR) document that was submitted to OMB in conjunction with the proposed rule (identified under EPA ICR No. 2195.01). Revised to reflect the provisions in this final rule, the ICR document (identified under EPA ICR No. 2195.02) was prepared and submitted to OMB and serves as the basis for OMB's approval. A copy of this ICR document has been placed in the docket for this rulemaking.

Under the PRA, an agency may not conduct or sponsor, and a person is not required to respond to an information collection request unless it displays a currently valid OMB control number. The OMB control numbers for the EPA regulations codified in Chapter 40 of the CFR, after appearing in the preamble of the final rule, are listed in 40 CFR part 9, displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers in certain EPA regulations is consolidated in 40 CFR part 9. For this ICR activity, in addition to displaying the applicable OMB control number in this unit, the Agency is amending the table in 40 CFR 9.1 to list the OMB control number assigned to this ICR activity. Due to the technical nature of the table, EPA finds that further notice and comment about amending the table is unnecessary. As a result, EPA finds that there is "good cause" under section 553(b)(B) of the Administrative Procedures Act (APA), 5 U.S.C. 553(b)(B), to amend this table without further notice and comment.

EPA estimates that respondents may submit to the Agency each year under FIFRA or FFDCA, approximately 33 reports of research involving intentional exposure of human subjects. The Agency expects extremely limited submission of toxicity studies per year (i.e., 0–4 studies), with the bulk of the 33 studies being composed of efficacy and skin sensitization studies. (See also the response to comment on this topic that appears in Unit III.) EPA estimates that it may receive approximately 29 reports each year of other types of pesticide research involving human subjects. EPA estimates that preparation of the required information will require about 32 hours per study, for a total estimated annual burden for affected entities of 1,984 hours, at an estimated cost of $1,927 per study, or a total estimated annual paperwork cost to respondents of $84,647. This total annual paperwork burden and cost estimate includes activities related to initial rule familiarization, as well as activities that researchers already perform and would continue to perform even without the Agency's rulemaking in this area (i.e., developing a protocol and maintaining records). The average annual burden on EPA for reviewing this information for each study submission is estimated to be 80 hours per study (in total 4,960 hours), representing a paperwork related labor cost of about $14,672 per response and a total annual cost of $909,664.

In the context of the PRA, "burden" means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

The information collection activity imposed by this final rule is planned to ensure that sound and appropriate scientific data are available to EPA when making regulatory decisions, and to protect the interests, rights and safety of those individuals who are participants in the type of research activity that is the subject of this rule. Specifically, this new information collection activity consists of reporting and recordkeeping requirements. Whenever respondents intend to conduct research for submission to EPA under the pesticide laws that involves intentional dosing of human subjects, they will be required to submit study protocols to EPA and a cognizant local IRB before such research is initiated so that the scientific design and ethical standards that will be employed during the proposed study may be reviewed and approved. Respondents will also be required to submit information about the ethical conduct of completed research that involved intentional dosing of human subjects when such research is submitted to EPA.

FIFRA sections 3(c)(1)(F) and 3(c)(2)(B) authorize EPA to require various data in support of a pesticide's continued registration or an application for a new or amended pesticide registration. FIFRA section 12(a)(2)(P) forbids any person "to use any pesticide in tests on human beings unless such human beings (i) are fully informed of the nature and purposes of the test and of any physical and mental health consequences which are reasonably foreseeable therefrom, and (ii) freely volunteer to participate in the test."

C. Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.*, after considering the potential economic impacts of today's rule on small entities, the Agency hereby certifies that this final rule will not have a significant adverse economic impact on a substantial number of small entities. This determination is based on the Agency's economic analysis performed for this rulemaking, summarized in Unit XVI.A., and a copy of which is available in the docket for this rulemaking. The following is a brief summary of the factual basis for this certification.

Small entities include small businesses, small organizations, and small governmental jurisdictions. For purposes of assessing the impacts of today's rule on small entities, small entity is defined in accordance with the RFA as: (1) A small business as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district, or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

Although we cannot predict whether or how many small entities might engage in the subject matter research in the future, as estimated in the Economic Analysis, the cost to researchers covered by this rule is estimated to be $5,200 per study. This is a trivially small portion of the overall cost of performing such

studies, each of which is estimated to cost from $125,000 to $500,000. After reviewing the history of EPA's consideration on human research in its various program offices, EPA estimates that this rule would affect only a limited number of third-party human studies each year. Because both the number of affected studies is relatively small and the estimated current costs of compliance with the Common Rule are low, the potential overall costs from this rule to third parties are also estimated to be small.

D. Unfunded Mandates Reform Act

Under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4), EPA has determined that this action does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any one year. As described in Unit XVI.A. the estimated total costs associated with this action are approximately $38,837 per year. This cost represents the incremental cost to researchers attributed to the additional procedural requirements contained in this final rule. Based on historical submissions, EPA has determined that State, local, and tribal governments rarely perform human research intended for submission to EPA under FIFRA or FFDCA. In addition, the final rule is not expected to significantly or uniquely affect small governments. Accordingly, this action is not subject to the requirements of sections 202 and 205 of UMRA.

E. Executive Order 13132

Pursuant to Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999), EPA has determined that this rule does not have "federalism implications," because it will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government, as specified in the Order. As indicated earlier, instances where a state performs human research intended for submission to EPA under FIFRA or FFDCA are rare. Therefore, this final rule may seldom affect a state government. Thus, Executive Order 13132 does not apply to this rule.

F. Executive Order 13175

As required by Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (59 FR 22951, November 6, 2000), EPA has determined that this final rule does not have tribal implications because it will not have substantial direct effects on tribal governments, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in the Order. As indicated previously, instances where a tribal government performs human research intended for submission to EPA under FIFRA or FFDCA are extremely rare. Thus, Executive Order 13175 does not apply to this rule.

G. Executive Order 13045

Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997) does not apply to this rule because this action is not designated as an "economically significant" regulatory action as defined by Executive Order 12866. Furthermore, this final rule does not establish an environmental standard that is intended to have a negatively disproportionate effect on children. To the contrary, this action will provide added protections for children with regard to the research covered by the rule.

H. Executive Order 13211

This final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) because this rule does not have any significant adverse effect on the supply, distribution, or use of energy.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), 15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures) that are developed or adopted by voluntary consensus standards bodies. NTTAA directs EPA to provide Congress, through OMB, with explanations when the Agency decides not to use available and applicable voluntary consensus standards. This action does not require specific methods or standards to generate data. Therefore, this final rule does not impose any technical standards that would require Agency consideration of voluntary consensus standards.

J. Executive Order 12898

This final rule does not have an adverse impact on the environmental and health conditions in low-income and minority communities. Therefore, under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), the Agency is not required to consider environmental justice-related issues. Although not directly impacting environmental justice-related concerns, the provisions of this rule will require researchers to use procedures to ensure equitable selection of test subjects in covered human research.

XVIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report that includes a copy of the rule to each House of the Congress and the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 9

Environmental protection, Reporting and recordkeeping requirements.

List of Subjects in 40 CFR Part 26

Environmental protection, Human research subjects, Reporting and recordkeeping requirements.

Dated: January 26, 2006.

Stephen L. Johnson,

Administrator.

■ Therefore, 40 CFR chapter I is amended as follows:

■ 1. Part 9 is amended as follows:

PART 9—[AMENDED]

■ a. The authority citation for part 9 continues to read as follows:

Authority: 7 U.S.C. 135 *et seq.*, 136–136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601–2671, 21 U.S.C. 331j, 346a, 348; 31 U.S.C. 9701; 33 U.S.C. 1251 *et seq.*, 1311, 1313d, 1314, 1318, 1321, 1326, 1330, 1342, 1344, 1345 (d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971–1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–1, 300j–2, 300j–3, 300j–4, 300j–9, 1857 *et seq.*,

6901–6992k, 7401–7671q, 7542, 9601–9657, 11023, 11048.

■ b. In § 9.1 the table is amended by adding the following new entries under the new heading "Protection of Human Subjects" to read as follows:

§ 9.1 OMB approvals under the Paperwork Reduction Act.

* * * * *

40 CFR citation	OMB Control No.
* *	* * *
Protection of Human Subjects	
26.1125	2070–0169
26.1303	2070–0169
* *	* * *

* * * * *

PART 26—[AMENDED]

■ 2. Part 26 is amended as follows:

■ a. By revising the authority citation for part 26 to read as follows:

Authority: 5 U.S.C. 301; 7 U.S.C. 136w(a)(1); 21 U.S.C. 346a(e)(1)(C); section 201 of Public Law No. 109–54; and 42 U.S.C. 300v–1(b).

■ b. By redesignating §§ 26.101 through 26.124 as subpart A and adding a new subpart heading to read as follows:

Subpart A—Basic EPA Policy for Protection of Subjects in Human Research Conducted or Supported by EPA

■ c. By adding new subparts B through Q as follows:

Subpart B—Prohibition of Research Conducted or Supported by EPA Involving Intentional Exposure of Human Subjects who are Pregnant Women or Children

Sec.
26.201 To what does this subpart apply?
26.202 Definitions.
26.203 Prohibition of research conducted or supported by EPA involving intentional exposure of any human subject who is a pregnant woman (and therefore her fetus) or child.

Subpart C—Observational Research: Additional Protections for Pregnant Women and Fetuses Involved as Subjects in Observational Research Conducted or Supported by EPA

26.301 To what does this subpart apply?
26.302 Definitions.
26.303 Duties of IRBs in connection with observational research involving pregnant women and fetuses.
26.304 Additional protections for pregnant women and fetuses involved in observational research.
26.305 Protections applicable, after delivery, to the placenta, the dead fetus, or fetal material.

Subpart D—Observational Research: Additional Protections for Children Involved as Subjects in Observational Research Conducted or Supported by EPA

26.401 To what does this subpart apply?
26.402 Definitions.
26.403 IRB duties.
26.404 Observational research not involving greater than minimal risk.
26.405 Observational research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.
26.406 Requirements for permission by parents or guardians and for assent by children.

Subpart E—[Reserved]

Subpart F—[Reserved]

Subpart G—[Reserved]

Subpart H—[Reserved]

Subpart I—[Reserved]

Subpart J—[Reserved]

Subpart K—Basic Ethical Requirements for Third-Party Human Research for Pesticides Involving Intentional Exposure of Non-pregnant Adults

26.1101 To what does this subpart apply?
26.1102 Definitions.
26.1103—26.1106 [Reserved]
26.1107 IRB membership.
26.1108 IRB functions and operations.
26.1109 IRB review of research.
26.1110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.
26.1111 Criteria for IRB approval of research.
26.1112 Review by institution.
26.1113 Suspension or termination of IRB approval of research.
26.1114 Cooperative research.
26.1115 IRB records.
26.1116 General requirements for informed consent.
26.1117 Documentation of informed consent.
26.1118—26.1122 [Reserved]
26.1123 Early termination of research.
26.1124 [Reserved]
26.1125 Prior submission of proposed human research for EPA review.

Subpart L—Prohibition of Third-Party Research for Pesticides Involving Intentional Exposure of Human Subjects who are Pregnant Women or Children

26.1201 To what does this subpart apply?
26.1202 Definitions.
26.1203 Prohibition of research involving intentional exposure of any pregnant woman, fetus, or child.

Subpart M—Requirements for Submission of Information on the Ethical Conduct of Completed Human Research

26.1301 To what does this subpart apply?
26.1302 Definitions.
26.1303 Submission of information pertaining to ethical conduct of completed human research.

Subpart N—[Reserved]

Subpart O—Administrative Actions for Noncompliance

26.1501 To what does this subpart apply?
26.1502 Lesser administrative actions.
26.1503 Disqualification of an IRB or an institution.
26.1504 Public disclosure of information regarding revocation.
26.1505 Reinstatement of an IRB or an institution.
26.1506 Debarment.
26.1507 Actions alternative or additional to disqualification.

Subpart P—Review of Proposed and Completed Human Research

26.1601 EPA review of proposed human research.
26.1602 EPA review of completed human research.
26.1603 Operation of the Human Studies Review Board.

Subpart Q—Ethical Standards for Assessing Whether to Rely on the Results of Human Research in EPA Actions

26.1701 To what does this subpart apply?
26.1702 Definitions.
26.1703 Prohibition of reliance on research involving intentional exposure of human subjects who are pregnant women (and therefore their fetuses) or children.
26.1704 Prohibition of reliance on unethical human research with non-pregnant adults conducted before April 7, 2006.
26.1705 Prohibition of reliance on unethical human research with non-pregnant adults conducted after April 7, 2006.
26.1706 Criteria and procedure for decisions to protect public health by relying on otherwise unacceptable research.

Subpart B—Prohibition of Research Conducted or Supported by EPA Involving Intentional Exposure of Human Subjects who are Pregnant Women or Children.

§ 26.201 To what does this subpart apply?

(a) This subpart applies to all research involving intentional exposure of any human subject who is a pregnant woman (and her fetus) or a child conducted or supported by the Environmental Protection Agency (EPA). This includes research conducted in EPA facilities by any person and research conducted in any facility by EPA employees.

(b) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

§ 26.202 Definitions.

The definitions in § 26.102 shall be applicable to this subpart as well. In addition, the definitions at 45 CFR

46.202(a) through (f) and at 45 CFR 46.202(h) are applicable to this subpart.

(a) *Research involving intentional exposure of a human subject* means a study of a substance in which the exposure to the substance experienced by a human subject participating in the study would not have occurred but for the human subject's participation in the study.

(b) A *child* is a person who has not attained the age of 18 years.

§ 26.203 Prohibition of research conducted or supported by EPA involving intentional exposure of any human subject who is a pregnant woman (and therefore her fetus) or child.

Notwithstanding any other provision of this part, under no circumstances shall EPA conduct or support research involving intentional exposure of any human subject who is a pregnant woman (and therefore her fetus) or child.

Subpart C—Observational Research: Additional Protections for Pregnant Women and Fetuses Involved as Subjects in Observational Research Conducted or Supported by EPA

§ 26.301 To what does this subpart apply?

(a) Except as provided in paragraph (b) of this section, this subpart applies to all observational research involving human subjects who are pregnant women (and therefore their fetuses) conducted or supported by the Environmental Protection Agency (EPA). This includes research conducted in EPA facilities by any person and research conducted in any facility by EPA employees.

(b) The exemptions at § 26.101(b)(1) through (b)(6) are applicable to this subpart.

(c) The provisions of § 26.101(c) through (i) are applicable to this subpart. References to State or local laws in this subpart and in § 26.101(f) are intended to include the laws of federally recognized American Indian and Alaska Native Tribal Governments.

(d) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

§ 26.302 Definitions.

The definitions in §§ 26.102 and 26.202 shall be applicable to this subpart as well. In addition, *observational research* means any human research that does not meet the definition of *research involving intentional exposure of a human subject* in § 26.202(a).

§ 26.303 Duties of IRBs in connection with observational research involving pregnant women and fetuses.

The provisions of 45 CFR 46.203 are applicable to this section.

§ 26.304 Additional protections for pregnant women and fetuses involved in observational research.

The provisions of 45 CFR 46.204 are applicable to this section.

§ 26.305 Protections applicable, after delivery, to the placenta, the dead fetus, or fetal material.

The provisions of 45 CFR 46.206 are applicable to this section.

Subpart D—Observational Research: Additional Protections for Children Involved as Subjects in Observational Research Conducted or Supported by EPA

§ 26.401 To what does this subpart apply?

(a) This subpart applies to all observational research involving children as subjects, conducted or supported by EPA. References to State or local laws in this subpart and in § 26.101(f) are intended to include the laws of federally recognized American Indian and Alaska Native Tribal Governments. This includes research conducted in EPA facilities by any person and research conducted in any facility by EPA employees.

(b) Exemptions at § 26.101(b)(1) and (b)(3) through (b)(6) are applicable to this subpart. The exemption at § 26.101(b)(2) regarding educational tests is also applicable to this subpart. However, the exemption at § 26.101(b)(2) for research involving survey or interview procedures or observations of public behavior does not apply to research covered by this subpart, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.

(c) The exceptions, additions, and provisions for waiver as they appear in § 26.101(c) through (i) are applicable to this subpart.

§ 26.402 Definitions.

The definitions in § 26.102 shall be applicable to this subpart as well. In addition, the following terms are defined:

(a) For purposes of this subpart, *Administrator* means the Administrator of the Environmental Protection Agency and any other officer or employee of the Environmental Protection Agency to whom authority has been delegated by the Administrator.

(b) *Assent* means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

(c) *Permission* means the agreement of parent(s) or guardian to the participation of their child or ward in research.

(d) *Parent* means a child's biological or adoptive parent.

(e) *Guardian* means an individual who is authorized under applicable State, Tribal, or local law to consent on behalf of a child to general medical care.

(f) *Observational research* means any research with human subjects that does not meet the definition of research involving intentional exposure of a human subject in § 26.202(a).

(g) *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

§ 26.403 IRB duties.

In addition to other responsibilities assigned to IRBs under this part, each IRB shall review observational research covered by this subpart and approve only research that satisfies the conditions of all applicable sections of this subpart.

§ 26.404 Observational research not involving greater than minimal risk.

EPA will conduct or fund observational research in which the IRB finds that no greater than minimal risk to children is presented, only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in § 26.406.

§ 26.405 Observational research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.

If the IRB finds that an intervention or procedure presents more than minimal risk to children, EPA will not conduct or fund observational research that includes such an intervention or procedure unless the IRB finds and documents that:

(a) The intervention or procedure holds out the prospect of direct benefit to the individual subject or is likely to contribute to the subject's well-being;

(b) The risk is justified by the anticipated benefit to the subjects;

(c) The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and

(d) Adequate provisions are made for soliciting the assent of the children and

permission of their parents or guardians, as set forth in § 26.406.

§ 26.406 Requirements for permission by parents or guardians and for assent by children.

(a) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the observational research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the observational research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with § 26.116(d).

(b) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine, in accordance with and to the extent that consent is required by § 26.116, that adequate provisions are made for soliciting the permission of each child's parents or guardian. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted under § 26.404 or § 26.405.

(c) In addition to the provisions for waiver contained in § 26.116, if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may replace the consent requirements in subpart A of this part and paragraph (b) of this section with provided an appropriate, equivalent mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with Federal, State, or local law. The choice of an appropriate, equivalent mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

(d) Permission by parents or guardians shall be documented in accordance with and to the extent required by § 26.117.

(e) When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

Subpart E—[Reserved]

Subpart F—[Reserved]

Subpart G—[Reserved]

Subpart H—[Reserved]

Subpart I—[Reserved]

Subpart J—[Reserved]

Subpart K—Basic Ethical Requirements for Third-Party Human Research for Pesticides Involving Intentional Exposure of Non-pregnant Adults

§ 26.1101 To what does this subpart apply?

(a) Except as provided in paragraph (b) of this section, subpart K of this part applies to all research initiated after April 7, 2006 involving intentional exposure of a human subject if, at any time prior to initiating such research, any person who conducted or supported such research intended:

(1) To submit results of the research to EPA for consideration in connection with any action that may be performed by EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 *et seq.*) or section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a); or

(2) To hold the results of the research for later inspection by EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 *et seq.*) or section 408 of the Federal Food, Drug, and Cosmetic Act 21 U.S.C. 346a).

(b) Unless otherwise required by the Administrator, research is exempt from this subpart if it involves only the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens from previously conducted studies, and if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(c) The Administrator retains final judgment as to whether a particular activity within the scope of paragraphs (a) and (b) of this section is covered by this subpart.

(d) Compliance with this subpart requires compliance with pertinent Federal laws or regulations which provide additional protections for human subjects.

(e) This subpart does not affect any State or local laws or regulations which may otherwise be applicable and which provide additional protections for human subjects. Reference to State or local laws in this subpart is intended to include the laws of federally recognized American Indian and Alaska Native Tribal Governments.

(f) This subpart does not affect any foreign laws or regulations which may otherwise be applicable and which provide additional protections to human subjects of research.

(g) For purposes of determining a person's intent under paragraph (a) of this section, EPA may consider any available information relevant to determining the intent of a person who conducts or supports research with human subjects after the effective date of the rule. EPA shall rebuttably presume such intent existed if:

(1) The person or the person's agent has submitted or made available for inspection the results of such research to EPA; or

(2) The person is a member of a class of people who, or whose products or activities, are regulated by EPA under FIFRA or the FFDCA and, at the time the research was initiated, the results of the research would be relevant to EPA's exercise of its authority under FIFRA or the FFDCA with respect to that class of people, products, or activities.

§ 26.1102 Definitions.

(a) For purposes of this subpart, *Administrator* means the Administrator of the Environmental Protection Agency (EPA) and any other officer or employee of EPA to whom authority has been delegated.

(b) *Institution* means any public or private entity or agency (including Federal, State, and other agencies).

(c) *Legally authorized representative* means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

(d) *Research* means a systematic investigation, including research, development, testing and evaluation,

designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this subpart, whether or not they are considered research for other purposes. For example, some demonstration and service programs may include research activities.

(e) *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains:

(1) Data through intervention or interaction with the individual, or

(2) Identifiable private information.

(3) "Intervention" includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. "Private information" includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

(f) *IRB* means an institutional review board established in accord with and for the purposes expressed in this part.

(g) *IRB approval* means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and Federal requirements.

(h) *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

(i) *Research involving intentional exposure of a human subject means* a study of a substance in which the exposure to the substance experienced by a human subject participating in the study would not have occurred but for the human subject's participation in the study.

(j) *Person* means any person, as that term is defined in FIFRA section 2(s) (7 U.S.C. 136), except:

(1) A federal agency that is subject to the provisions of the Federal Policy for the Protection of Human Subjects of Research, and

(2) A person when performing human research supported by a federal agency covered by paragraph (j)(1) of this section.

§§ 26.1103 through 26.1106 [Reserved]

§ 26.1107 IRB membership.

(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities which are presented for its approval. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as prisoners or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

(b) Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.

(c) Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

(d) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

(e) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

(f) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

§ 26.1108 IRB functions and operations.

In order to fulfill the requirements of this subpart each IRB shall:

(a) Follow written procedures:

(1) For conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution;

(2) For determining which projects require review more often than annually and which projects need verification from sources other than the investigator that no material changes have occurred since previous IRB review;

(3) For ensuring prompt reporting to the IRB of proposed changes in research activity; and

(4) For ensuring that changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the human subjects.

(b) Follow written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the Environmental Protection Agency of:

(1) Any unanticipated problems involving risks to human subjects or others;

(2) Any instance of serious or continuing noncompliance with this subpart of the requirements or determinations of the IRB; or

(3) Any suspension or termination of IRB approval.

(c) Except when an expedited review procedure is used (see § 26.1110), review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

§ 26.1109 IRB review of research.

(a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this subpart.

(b) An IRB shall require that information given to subjects as part of informed consent is in accordance with § 26.1116. The IRB may require that information, in addition to that specifically mentioned in § 26.1116 be given to the subjects when, in the IRB's judgment, the information would meaningfully add to the protection of the rights and welfare of subjects.

(c) An IRB shall require documentation of informed consent in accordance with § 26.1117.

(d) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

(e) An IRB shall conduct continuing review of research covered by this subpart at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

§ 26.1110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

(a) The Secretary, HHS, has established, and published as a Notice in the **Federal Register**, a list of categories of research that may be reviewed by the IRB through an expedited review procedure. The list will be amended, as appropriate after consultation with other departments and agencies, through periodic republication by the Secretary, HHS, in the **Federal Register**. A copy of the list is available from the Office for Human Research Protections, HHS, or any successor office.

(b)(1) An IRB may use the expedited review procedure to review either or both of the following:

(i) Some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk,

(ii) Minor changes in previously approved research during the period (of 1 year or less) for which approval is authorized.

(2) Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in § 26.1108(b).

(c) Each IRB which uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure.

(d) The Administrator may restrict, suspend, or terminate, an institution's or IRB's use of the expedited review procedure for research covered by this subpart.

§ 26.1111 Criteria for IRB approval of research.

(a) In order to approve research covered by this subpart the IRB shall determine that all of the following requirements are satisfied:

(1) Risks to subjects are minimized:

(i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and

(ii) Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as prisoners, mentally disabled persons, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by § 26.1116.

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by § 26.1117.

(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as prisoners, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

§ 26.1112 Review by institution.

Research covered by this subpart that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.

§ 26.1113 Suspension or termination of IRB approval of research.

An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the Administrator of EPA.

§ 26.1114 Cooperative research.

In complying with this subpart, sponsors, investigators, or institutions involved in multi-institutional studies may use joint review, reliance upon the review of another qualified IRB, or similar arrangements aimed at avoidance of duplication of effort.

§ 26.1115 IRB records.

(a) An IRB shall prepare and maintain adequate documentation of IRB activities, including the following:

(1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

(2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the

discussion of controverted issues and their resolution.

(3) Records of continuing review activities.

(4) Copies of all correspondence between the IRB and the investigators.

(5) A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution, for example, full-time employee, a member of governing panel or board, stockholder, paid or unpaid consultant.

(6) Written procedures for the IRB in the same detail as described in § 26.1108(a) and § 26.1108(b).

(7) Statements of significant new findings provided to subjects, as required by § 26.1116(b)(5).

(b) The records required by this subpart shall be retained for at least 3 years, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of EPA at reasonable times and in a reasonable manner.

§ 26.1116 General requirements for informed consent.

No investigator may involve a human being as a subject in research covered by this subpart unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

(a) Basic elements of informed consent. In seeking informed consent the following information shall be provided to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject may become pregnant) which are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) The approximate number of subjects involved in the study.

(c) The informed consent requirements in this subpart are not intended to preempt any applicable Federal, State, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(d) Nothing in this subpart is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable Federal, State, or local law.

(e) If the research involves intentional exposure of subjects to a pesticide, the subjects of the research must be informed of the identity of the pesticide and the nature of its pesticidal function.

§ 26.1117 Documentation of informed consent.

(a) Informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

(b) The consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by § 26.1116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

(2) A short form written consent document stating that the elements of informed consent required by § 26.1116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

§§ 26.1118 through 26.1122 [Reserved]

§ 26.1123 Early termination of research.

The Administrator may require that any project covered by this subpart be terminated or suspended when the

Administrator finds that an IRB, investigator, sponsor, or institution has materially failed to comply with the terms of this subpart.

§ 26.1124 [Reserved]

§ 26.1125 Prior submission of proposed human research for EPA review.

Any person or institution who intends to conduct or sponsor human research covered by § 26.1101(a) shall, after receiving approval from all appropriate IRBs, submit to EPA prior to initiating such research all information relevant to the proposed research specified by § 26.1115(a), and the following additional information, to the extent not already included:

(a) A discussion of:

(1) The potential risks to human subjects;

(2) The measures proposed to minimize risks to the human subjects;

(3) The nature and magnitude of all expected benefits of such research, and to whom they would accrue;

(4) Alternative means of obtaining information comparable to what would be collected through the proposed research; and

(5) The balance of risks and benefits of the proposed research.

(b) All information for subjects and written informed consent agreements as originally provided to the IRB, and as approved by the IRB.

(c) Information about how subjects will be recruited, including any advertisements proposed to be used.

(d) A description of the circumstances and methods proposed for presenting information to potential human subjects for the purpose of obtaining their informed consent.

(e) All correspondence between the IRB and the investigators or sponsors.

(f) Official notification to the sponsor or investigator, in accordance with the requirements of this subpart, that research involving human subjects has been reviewed and approved by an IRB.

Subpart L—Prohibition of Third-Party Research for Pesticides Involving Intentional Exposure of Human Subjects who are Pregnant Women or Children

§ 26.1201 To what does this subpart apply?

Subpart L applies to any person who, after April 7, 2006, conducts or supports research with a human subject intended:

(1) For submission to EPA for consideration in connection with any action that may be performed by EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 *et seq.*) or section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a); or

(2) To be held for later inspection by EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 *et seq.*) or section 408 of the Federal Food, Drug, and Cosmetic Act 21 U.S.C. 346a).

(b) For purposes of determining a person's intent under paragraph (a) of this section, EPA may consider any available information relevant to determining the intent of a person who conducts or supports research with human subjects after the effective date of the rule. EPA shall rebuttably presume such intent existed if:

(1) The person or the person's agent has submitted or made available for inspection the results of such research to EPA; or

(2) The person is a member of a class of people who, or whose products or activities, are regulated by EPA under FIFRA or the FFDCA and, at the time the research was initiated, the results of the research would be relevant to EPA's exercise of its authority under FIFRA or the FFDCA with respect to that class of people, products, or activities.

§ 26.1202 Definitions.

The definitions in § 26.1102 shall be applicable to this subpart as well. In addition, the definitions at 45 CFR 46.202(a) through (f) and at 45 CFR 46.202(h) are applicable to this subpart. In addition, a child is a person who has not attained the age of 18 years.

§ § 26.1203 Prohibition of research involving intentional exposure of any pregnant woman, fetus, or child.

Notwithstanding any other provision of this part, under no circumstances shall a person conduct or sponsor research covered by § 26.1201 that involves intentional exposure of any human subject who is a pregnant woman (and therefore her fetus) or child.

Subpart M—Requirements for Submission of Information on the Ethical Conduct of Completed Human Research

§ 26.1301 To what does this subpart apply?

This subpart applies to any person who submits a report containing the results of any human research if:

(a) The report is submitted after April 7, 2006, and

(b) The report is submitted for consideration in connection with any action that may be performed by EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 *et seq.*) or section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a).

§ 26.1302 Definitions.

The definitions in § 26.102 shall apply to this subpart as well.

§ 26.1303 Submission of information pertaining to ethical conduct of completed human research.

Any person who submits to EPA data derived from human research covered by this subpart shall provide at the time of submission information concerning the ethical conduct of such research. To the extent available to the submitter and not previously provided to EPA, such information should include:

(a) Copies of all of the records relevant to the research specified by § 26.1115(a) to be prepared and maintained by an IRB.

(b) Copies of all of the records relevant to the information identified in § 26.1125(a) through (f).

(c) Copies of sample records used to document informed consent as specified by § 26.1117, but not identifying any subjects of the research.

(d) If any of the information listed in paragraphs (a) through (c) of this section is not provided, the person shall describe the efforts made to obtain the information.

Subpart N—[Reserved]

Subpart O—Administrative Actions for Noncompliance

§ 26.1501 To what does this subpart apply?

This subpart applies to any human research subject to subparts A through L of this part. References to State or local laws in this subpart are intended to include the laws of federally recognized American Indian and Alaska Native Tribal Governments.

§ 26.1502 Lesser administrative actions.

(a) If apparent noncompliance with the applicable regulations in subparts A through L of this part concerning the operation of an IRB is observed by an officer or employee of EPA or of any State duly designated by the Administrator during an inspection, EPA may send a letter describing the noncompliance to the IRB and to the parent institution. The agency will require that the IRB or the parent institution respond to this letter within a reasonable time period specified by EPA and describe the corrective actions that will be taken by the IRB, the institution, or both to achieve compliance with these regulations.

(b) On the basis of the IRB's or the institution's response, EPA may

schedule a reinspection to confirm the adequacy of corrective actions. In addition, until the IRB or the parent institution takes appropriate corrective action, the Agency may:

(1) Withhold approval of new studies subject to the requirements of this part that are conducted at the institution or reviewed by the IRB;

(2) Direct that no new subjects be added to ongoing studies subject to this part;

(3) Terminate ongoing studies subject to this part when doing so would not endanger the subjects; or

(4) When the apparent noncompliance creates a significant threat to the rights and welfare of human subjects, notify relevant State and Federal regulatory agencies and other parties with a direct interest of the deficiencies in the operation of the IRB.

(c) The parent institution is presumed to be responsible for the operation of an IRB, and EPA will ordinarily direct any administrative action under this subpart against the institution. However, depending on the evidence of responsibility for deficiencies, determined during the investigation, EPA may restrict its administrative actions to the IRB or to a component of the parent institution determined to be responsible for formal designation of the IRB.

§ 26.1503 Disqualification of an IRB or an institution.

(a) Whenever the IRB or the institution has failed to take adequate steps to correct the noncompliance stated in the letter sent by the Agency under § 26.1502(a) and the EPA Administrator determines that this noncompliance may justify the disqualification of the IRB or of the parent institution, the Administrator may institute appropriate proceedings.

(b) The Administrator may disqualify an IRB or the parent institution from studies subject to this part if the Administrator determines that:

(1) The IRB has refused or repeatedly failed to comply with any of the regulations set forth in this part, and

(2) The noncompliance adversely affects the rights or welfare of the human subjects of research.

(c) If the Administrator determines that disqualification is appropriate, the Administrator will issue an order that explains the basis for the determination and that prescribes any actions to be taken with regard to ongoing human research, covered by subparts A through L of this part, conducted under the review of the IRB. EPA will send notice of the disqualification to the IRB and the parent institution. Other parties with a direct interest, such as sponsors and investigators, may also be sent a notice of the disqualification. In addition, the agency may elect to publish a notice of its action in the **Federal Register**.

(d) EPA may refuse to consider in support of a regulatory decision the data from human research, covered by subparts A through L of this part, that was reviewed by an IRB or conducted at an institution during the period of disqualification, unless the IRB or the parent institution is reinstated as provided in § 26.1505, or unless such research is deemed scientifically sound and crucial to the protection of public health, under the procedure defined in § 26.1706.

§ 26.1504 Public disclosure of information regarding revocation.

A determination that EPA has disqualified an institution from studies subject to this part and the administrative record regarding that determination are disclosable to the public under 40 CFR part 2.

§ 26.1505 Reinstatement of an IRB or an institution.

An IRB or an institution may be reinstated to conduct studies subject to this part if the Administrator determines, upon an evaluation of a written submission from the IRB or institution that explains the corrective action that the institution or IRB has taken or plans to take, that the IRB or institution has provided adequate assurance that it will operate in compliance with the standards set forth in this part. Notification of reinstatement shall be provided to all persons notified under § 26.1502(c).

§ 26.1506 Debarment.

If EPA determines that an institution or investigator repeatedly has not complied with or has committed an egregious violation of the applicable regulations in subparts A through L of this part, EPA may recommend that institution or investigator be declared ineligible to participate in EPA-supported research (debarment). Debarment will be initiated in accordance with procedures specified at 40 CFR part 32.

§ 26.1507 Actions alternative or additional to disqualification.

Disqualification of an IRB or of an institution is independent of, and neither in lieu of nor a precondition to, other statutorily authorized proceedings or actions. EPA may, at any time, on its own initiative or through the Department of Justice, institute any appropriate judicial proceedings (civil or criminal) and any other appropriate regulatory action, in addition to or in lieu of, and before, at the time of, or after, disqualification. The Agency may also refer pertinent matters to another Federal, State, or local government agency for any action that that agency determines to be appropriate.

Subpart P—Review of Proposed and Completed Human Research

§ 26.1601 EPA review of proposed human research.

(a) EPA shall review all protocols submitted under § 26.1125 in a timely manner. With respect to any research or any class of research, the Administrator may recommend additional conditions which, in the judgment of the Administrator, are necessary for the protection of human subjects.

(b) In reviewing proposals covered by this subpart, the Administrator may take into account factors such as whether the applicant has been subject to a termination or suspension under § 26.123(a) or § 26.1123 and whether the applicant or the person or persons who would direct or has/have directed the scientific and technical aspects of an activity has/have, in the judgment of the Administrator, materially failed to discharge responsibility for the protection of the rights and welfare of human subjects (whether or not the research was subject to Federal regulation).

(c) When research covered by subpart K takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in subpart K. (An example is a foreign institution which complies with guidelines consistent with the World Medical Assembly Declaration of Helsinki, issued either by sovereign states or by an organization whose function for the protection of human research subjects is internationally recognized.) In these circumstances, if the Administrator determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided in subpart K, the Administrator may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in subpart K.

(d) Following initial evaluation of the protocol by Agency staff, EPA shall submit the protocol and all supporting materials, together with the staff evaluation, to the Human Studies Review Board.

(e) EPA shall notify the submitter of the proposal of the results of the EPA and Human Studies Review Board reviews.

§ 26.1602 EPA review of completed human research.

(a) When considering data under FIFRA or FFDCA from research involving intentional exposure of humans, EPA shall review the material submitted under § 26.1303 and other available, relevant information and document its conclusions regarding the scientific and ethical conduct of the research.

(b) EPA shall submit its review of data from human research covered by subpart Q, together with the available supporting materials, to the Human Studies Review Board if EPA decides to rely on the data and:

(1) The data are derived from research initiated after April 7, 2006, or

(2) The data are derived from research initiated before April 7, 2006, and the research was conducted for the purpose of identifying or measuring a toxic effect.

(c) In its discretion, EPA may submit data from research not covered by paragraph (b) of this section to the Human Studies Review Board for their review.

(d) EPA shall notify the submitter of the research of the results of the EPA and Human Studies Review Board reviews.

§ 26.1603 Operation of the Human Studies Review Board.

EPA shall establish and operate a Human Studies Review Board as follows:

(a) *Membership.* The Human Studies Review Board shall consist of members who are not employed by EPA, who meet the ethics and other requirements for special government employees, and who have expertise in fields appropriate for the scientific and ethical review of human research, including research ethics, biostatistics, and human toxicology.

(b) *Responsibilities.* The Human Studies Review Board shall comment on the scientific and ethical aspects of research proposals and reports of completed research with human subjects submitted by EPA for its review and, on request, advise EPA on ways to strengthen its programs for protection of human subjects of research.

Subpart Q—Ethical Standards for Assessing Whether to Rely on the Results of Human Research in EPA Actions

§ 26.1701 To what does this subpart apply?

This subpart applies to EPA's decisions whether to rely in its actions taken under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 *et seq.*) or section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a) on scientifically valid and relevant data from research involving intentional exposure of human subjects.

§ 26.1702 Definitions.

The definitions in § 26.1102 and § 26.1202 shall apply to this subpart as well.

§ 26.1703 Prohibition of reliance on research involving intentional exposure of human subjects who are pregnant women (and therefore their fetuses) or children.

Except as provided in § 26.1706, in actions within the scope of § 26.1701, EPA shall not rely on data from any research involving intentional exposure of any human subject who is a pregnant woman (and therefore her fetus) or child.

§ 26.1704 Prohibition of reliance on unethical human research with non-pregnant adults conducted before April 7, 2006.

Except as provided in § 26.1706, in actions within the scope of § 26.1701, EPA shall not rely on data from any research initiated before April 7, 2006, if there is clear and convincing evidence that the conduct of the research was fundamentally unethical (*e.g.*, the research was intended to seriously harm participants or failed to obtain informed consent), or was significantly deficient relative to the ethical standards prevailing at the time the research was conducted. This prohibition is in addition to the prohibition in § 26.1703.

§ 26.1705 Prohibition of reliance on unethical human research with non-pregnant adults conducted after April 7, 2006.

Except as provided in § 26.1706, in actions within the scope of § 26.1701, EPA shall not rely on data from any research initiated after April 7, 2006, unless EPA has adequate information to determine that the research was conducted in substantial compliance with subparts A through L of this part, or if conducted in a foreign country, under procedures at least as protective as those in subparts A through L of this part. This prohibition is in addition to the prohibition in § 26.1703.

§ 26.1706 Criteria and procedure for decisions to protect public health by relying on otherwise unacceptable research.

This section establishes the exclusive criteria and procedure by which EPA may decide to rely on data from research that is not acceptable under the standards in §§ 26.1703 through 26.1705. EPA may rely on such data only if all the conditions in paragraphs (a) through (d) of this section are satisfied:

(a) EPA has obtained the views of the Human Studies Review Board concerning the proposal to rely on the otherwise unacceptable data,

(b) EPA has provided an opportunity for public comment on the proposal to rely on the otherwise unacceptable data,

(c) EPA has determined that relying on the data is crucial to a decision that would impose a more stringent regulatory restriction that would improve protection of public health, such as a limitation on the use of a pesticide, than could be justified without relying on the data, and

(d) EPA publishes a full explanation of its decision to rely on the otherwise unacceptable data, including a thorough discussion of the ethical deficiencies of the underlying research and the full rationale for finding that the standard in paragraph (c) of this section was met.

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Federal Register

Monday,
February 6, 2006

Part III

Department of Education

Office of Innovation and Improvement; Overview Information; Congressional Academies for Students of American History and Civics Education; Notice

DEPARTMENT OF EDUCATION

Office of Innovation and Improvement; Overview Information; Congressional Academies for Students of American History and Civics Education

Notice inviting applications for new awards for fiscal year (FY) 2006.

Catalog of Federal Domestic Assistance (CFDA) Number: 84.215D.

Dates: Applications Available: February 6, 2006.

Deadline for Notice of Intent to Apply: March 8, 2006.

Deadline for Transmittal of Applications: April 7, 2006.

Deadline for Intergovernmental Review: June 6, 2006.

Eligible Applicants: Institutions of higher education (IHEs), museums, libraries, and other public and private agencies, organizations, and institutions (including for-profit organizations) or a consortium of such agencies, organizations, and institutions.

Applicants are required to submit in their applications evidence of their organization's demonstrated expertise in historical methodology or the teaching of history.

Note: If more than one eligible entity wishes to form a consortium and jointly submit a single application, they must follow the procedures for group applications described in 34 CFR 75.127 through 34 CFR 75.129 of the Education Department General Administrative Regulations (EDGAR).

Estimated Available Funds: $700,000.

Estimated Range of Awards: $250,000 to $700,000 for each 12-month budget period (up to 3 budget periods). Funding for the subsequent years is subject to the availability of funds and the approval of continuation awards (see 34 CFR 75.253).

Estimated Number of Awards: 1–2.

The number of awards made under this competition will depend upon the quality of the applications received. The size of the awards will depend upon the scope of the projects proposed. Contingent upon the availability of funds and the quality of applications, the Department may make additional awards in FY 2007 from the list of unfunded applications from this competition.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 36 months.

Budget Period: 12 months. (The first budget period is the first 12 months of the project period; the second budget period commences on the first day following the first budget period and so on.)

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: This program supports the establishment of Congressional Academies for Students of American History and Civics for students to develop a broader and deeper understanding of these subject matters (Congressional Academies).

Priorities: This competition contains one absolute priority and one invitational priority. We are establishing the absolute priority in accordance with section 437(d)(1) of the General Education Provisions Act (GEPA).

Absolute Priority: For FY 2006 and any subsequent year in which we make awards from the list of unfunded applicants from this competition, this priority is an absolute priority. Under 34 CFR 75.105(c)(3) we consider only applications that meet this absolute priority.

This priority is:

Absolute Priority—Congressional Academies for Students of American History and Civics

An applicant for a Congressional Academy must—

(a) Propose a project that would serve high school students and be designed to enrich their understanding of American history and civics;

(b) Propose a project that would provide a summer residential Academy that does not replace a current, established program;

(c) Demonstrate, in its application, how specific civics and traditional American history content will be covered by the project, including the following:

(1) *Civics content:* The development and function of local, State, and Federal governments and citizens' responsibilities with respect to these institutions.

(2) *Traditional American history content:*

(i) Significant issues, episodes, and turning points in the history of the United States.

(ii) How the words and deeds of individuals have determined the course of the United States.

(iii) How the principles of freedom and democracy articulated in the founding documents of the United States have shaped the Nation's struggles and achievements as well as its social, political, and legal institutions and relations; and

(d) Propose an evaluation of the success of the project in achieving project objectives that will provide quality data related to the performance measure for this program listed in section VI. 4 of this notice.

The evaluation plan must be designed to shape the development of the project from the beginning of the project period. The plan must include benchmarks that monitor progress toward specific project objectives and performance measures in order to assess the project's impact on teaching, learning, and other important outcomes for project participants. More specifically, the plan must identify the individual(s) or organization(s) that will evaluate the project and describe their qualifications. The plan must describe the evaluation design, indicating: (1) What types of data will be collected; (2) when various types of data will be collected; (3) what methods of evaluation will be used; (4) what instruments will be developed and when; (5) how the data will be analyzed; (6) when reports of results and outcomes will be available; and (7) how the applicant will use the evaluation to monitor progress of the project and to provide accountability information both about success at the initial site and about effective strategies for replication of the academy in other settings. Applicants are encouraged to devote an appropriate level of resources to the project evaluation.

Invitational Priority: For FY 2006 this priority is an invitational priority. Under 34 CFR 75.105(c)(1) we do not give an application that meets this invitational priority a competitive or absolute preference over other applications.

This priority is:

Invitational Priority—Schools in High-Need Local Educational Agencies (LEAs)

The proposed project will include a significant proportion of project participants from schools in high-need LEAs. As defined in section 2102(3) of the Elementary and Secondary Education Act of 1965, as amended (ESEA), a "high-need" LEA is an LEA—

(a)(1) That serves not fewer than 10,000 children from families with incomes below the poverty line (as defined in section 9101(33) of ESEA), or (2) for which not less than 20 percent of the children served by the LEA are from families with incomes below the poverty line; or

(b) For which there is (1) a high percentage of teachers not teaching in the academic subjects or grade levels the teachers were trained to teach, or (2) a high percentage of teachers with emergency, provisional, or temporary certification or licensing.

Waiver of Proposed Rulemaking: Under the Administrative Procedure Act (5 U.S.C. 553) the Department generally offers interested parties the opportunity

to comment on proposed priorities, selection criteria, and eligibility requirements. Section 437(d)(1) of GEPA (20 U.S.C. 1232(d)(1)), however, allows the Secretary to exempt from rulemaking requirements, regulations governing the first grant competition under a new or substantially revised program authority. This is the first grant competition for the Congressional Academies for Students of American History and Civics Education program under the American History and Civics Education Act of 2004 and, therefore, it qualifies for this exemption. In order to ensure timely grant awards, the Secretary has decided to forgo public comment on the absolute priority, selection criteria, and eligibility requirements in this notice under section 437(d)(1) of GEPA. This absolute priority and these selection criteria and eligibility requirements will apply to the FY 2006 grant competition and any subsequent year in which we make awards based on the list of unfunded applicants from this competition.

Program Authority: 20 U.S.C. 6713.

Applicable Regulations: EDGAR in 34 CFR parts 74, 75, 77, 79, 80, 81, 82, 84, 85, 86, 97, 98, and 99.

Note: The regulations in 34 CFR part 79 apply to all applicants except federally recognized Indian tribes.

Note: The regulations in 34 CFR part 86 apply to IHEs only.

Note: The regulations in 34 CFR part 99 apply to an educational agency or institution.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: $700,000.

Estimated Range of Awards: $250,000 to $700,000 for each 12-month budget period (up to 3 budget periods). Funding for the subsequent years is subject to the availability of funds and the approval of continuation awards (see 34 CFR 75.253).

Estimated Number of Awards: 1–2.

The number of awards made under this competition will depend upon the quality of the applications received. The size of the awards will depend upon the scope of the projects proposed. Contingent upon the availability of funds and the quality of applications, we may make additional awards in FY 2007 from the list of unfunded applications from this competition.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 36 months.

Budget Period: 12 months. (The first budget period is the first 12 months of the project period; the second budget period commences on the first day following the first budget period and so on.)

III. Eligibility Information

1. Eligible Applicants

Institutions of higher education (IHEs), museums, libraries, and other public and private agencies, organizations, and institutions (including for-profit organizations) or a consortium of such agencies, organizations, and institutions.

Applicants are required to submit in their application evidence of their organization's demonstrated expertise in historical methodology or the teaching of history.

Note: If more than one eligible entity wishes to form a consortium and jointly submit a single application, they must follow the procedures for group applications described in 34 CFR 75.127 through 34 CFR 75.129 of EDGAR.

2. Cost Sharing or Matching

This competition does not involve cost sharing or matching.

IV. Application and Submission Information

1. Address To Request Application Package

Education Publications Center (ED Pubs), P.O. Box 1398, Jessup, MD 20794–1398. Telephone (toll free): 1–877–433–7827. Fax: (301) 470–1244. If you use a telecommunications device for the deaf (TDD), you may call (toll free): 1–877–576–7734.

You may also contact ED Pubs at its Web site: *http://www.ed.gov/pubs/edpubs.html* or you may contact ED Pubs at its e-mail address: *edpubs@inet.ed.gov.*

If you request an application from ED Pubs, be sure to identify this competition as follows: CFDA number 84.215D.

Individuals with disabilities may obtain a copy of the application package in an alternative format (*e.g.*, Braille, large print, audiotape, or computer diskette) by contacting the program contact person listed under **FOR FURTHER INFORMATION CONTACT** in Section VII of this notice.

2. Content and Form of Application Submission

Requirements concerning the content of an application, together with the forms you must submit, are in the application package for this competition.

Notice of Intent to Apply: The Department is requesting those entities that are considering submitting an application to indicate their intent in a short e-mail addressed to Kelly O'Donnell at *Academies@ed.gov.* The e-mail should include the name of the organization that will be submitting the application(s). The e-mail need not include information regarding the content of the proposed application, only the applicant's intent to submit it. Applicants that fail to supply this e-mail notification may still apply for funding under this program.

Page Limit: The application narrative is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. *All of the information addressing the selection criteria and the priorities must be included in the narrative section of the application.* It is strongly suggested that you limit the narrative of your application to the equivalent of no more than 25 pages, using the following standards:

- A "page" is 8.5" x 11", on one side only, with 1" margins at the top, bottom, and both sides.
- Double space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, references, and captions, as well as all text in charts, tables, figures, and graphs.
- Use a font that is either 12 point or larger or no smaller than 10 pitch (characters per inch).

The suggested page limit does not apply to the cover sheet; the budget section, including the narrative budget justification; the assurances and certifications; or the one-page abstract, the resumes, the bibliography, the evidence of eligibility, or the letters of support.

3. Submission Dates and Times

Applications Available: February 6, 2006.

Deadline for Notice of Intent To Apply: March 8, 2006.

Deadline for Transmittal of Applications: April 7, 2006.

Applications for grants under this competition must be submitted electronically using the Grants.gov Apply Site (Grants.gov). For information (including dates and times) about how to submit your application electronically or by mail or hand delivery if you qualify for an exception to the electronic submission requirement, please refer to section IV.6. *Other Submission Requirements* in this notice.

We do not consider an application that does not comply with the deadline requirements.

Deadline for Intergovernmental Review: June 6, 2006.

4. Intergovernmental Review

This competition is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this competition.

5. Funding Restrictions

We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

6. Other Submission Requirements

Applications for grants under this competition must be submitted electronically unless you qualify for an exception to this requirement in accordance with the instructions in this section.

a. Electronic Submission of Applications

Applications for grants under the Congressional Academies for American History and Civics Education competition—CFDA Number 84.215D must be submitted electronically using the Grants.gov Apply site at: *http://www.grants.gov*. Through this site, you will be able to download a copy of the application package, complete it offline, and then upload and submit your application. You may not e-mail an electronic copy of a grant application to us.

We will reject your application if you submit it in paper format unless, as described elsewhere in this section, you qualify for one of the exceptions to the electronic submission requirement *and* submit, no later than two weeks before the application deadline date, a written statement to the Department that you qualify for one of these exceptions. Further information regarding calculation of the date that is two weeks before the application deadline date is provided later in this section under *Exception to Electronic Submission Requirement.*

You may access the electronic grant application for Congressional Academies for American History and Civics at: *http://www.grants.gov*. You must search for the downloadable application package for this program by the CFDA number. Do not include the CFDA number's alpha suffix in your search.

Please note the following:

- When you enter the Grants.gov site, you will find information about submitting an application electronically through the site, as well as the hours of operation.
- Applications received by Grants.gov are time and date stamped. Your application must be fully uploaded and submitted, and must be date/time stamped by the Grants.gov system no later than 4:30 p.m., Washington, DC time, on the application deadline date. Except as otherwise noted in this section, we will not consider your application if it is date/time stamped by the Grants.gov system later than 4:30 p.m., Washington, DC time, on the application deadline date. When we retrieve your application from Grants.gov, we will notify you if we are rejecting your application because it was date/time stamped by the Grants.gov system after 4:30 p.m., Washington, DC time, on the application deadline date.
- The amount of time it can take to upload an application will vary depending on a variety of factors including the size of the application and the speed of your Internet connection. Therefore, we strongly recommend that you do not wait until the application deadline date to begin the submission process through Grants.gov.
- You should review and follow the Education Submission Procedures for submitting an application through Grants.gov that are included in the application package for this competition to ensure that you submit your application in a timely manner to the Grants.gov system. You can also find the Education Submission Procedures pertaining to Grants.gov at *http://e-Grants.ed.gov/help/GrantsgovSubmissionProcedures.pdf*.
- To submit your application via Grants.gov, you must complete all of the steps in the Grants.gov registration process (see *http://www.Grants.gov/GetStarted*). These steps include (1) registering your organization, (2) registering yourself as an Authorized Organization Representative (AOR), and (3) getting authorized as an AOR by your organization. Details on these steps are outlined in the Grants.gov 3-Step Registration Guide (see *http://www.grants.gov/assets/GrantsgovCoBrandBrochure8X11.pdf*). You also must provide on your application the same D-U-N-S Number used with this registration. Please note that the registration process may take five or more business days to complete, and you must have completed all registration steps to allow you to successfully submit an application via Grants.gov.
- You will not receive additional point value because you submit your application in electronic format, nor will we penalize you if you qualify for an exception to the electronic submission requirement, as described elsewhere in this section, and submit your application in paper format.
- You must submit all documents electronically, including all information typically included on the Application for Federal Education Assistance (ED 424), Budget Information—Non-Construction Programs (ED 524), and all necessary assurances and certifications. You must attach any narrative sections of your application as files in a .DOC (document), .RTF (rich text), or .PDF (Portable Document) format. If you upload a file type other than the three file types specified above or submit a password protected file, we will not review that material.
- Your electronic application must comply with any page limit requirements described in this notice.
- After you electronically submit your application, you will receive an automatic acknowledgment from Grants.gov that contains a Grants.gov tracking number. The Department will retrieve your application from Grants.gov and send you a second confirmation by e-mail that will include a PR/Award number (an ED-specified identifying number unique to your application).
- We may request that you provide us original signatures on forms at a later date.

Application Deadline Date Extension in Case of Technical Issues with the Grants.gov System: If you are prevented from electronically submitting your application on the application deadline date because of technical problems with the Grants.gov system, we will grant you an extension until 4:30 p.m., Washington, DC time, the following business day to enable you to transmit your application electronically, or by hand delivery. You also may mail your application by following the mailing instructions as described elsewhere in this notice. If you submit an application after 4:30 p.m., Washington, DC time, on the deadline date, please contact the person listed elsewhere in this notice under **FOR FURTHER INFORMATION CONTACT**, and provide an explanation of the technical problem you experienced with Grants.gov, along with the Grants.gov Support Desk Case Number (if available). We will accept your application if we can confirm that a technical problem occurred with the Grants.gov system and that that problem affected your ability to submit your application by 4:30 p.m., Washington, DC time, on the application deadline date. The Department will contact you after a determination is made on

whether your application will be accepted.

Note: Extensions referred to in this section apply only to the unavailability of or technical problems with the Grants.gov system. We will not grant you an extension if you failed to fully register to submit your application to Grants.gov before the deadline date and time or if the technical problem you experienced is unrelated to the Grants.gov system.

Exception to Electronic Submission Requirement: You qualify for an exception to the electronic submission requirement, and may submit your application in paper format, if you are unable to submit an application through the Grants.gov system because—

- You do not have access to the Internet; or
- You do not have the capacity to upload large documents to the Grants.gov system; *and*
- No later than two weeks before the application deadline date (14 calendar days or, if the fourteenth calendar day before the application deadline date falls on a Federal holiday, the next business day following the Federal holiday), you mail or fax a written statement to the Department, explaining which of the two grounds for an exception prevent you from using the Internet to submit your application. If you mail your written statement to the Department, it must be postmarked no later than two weeks before the application deadline date. If you fax your written statement to the Department, we must receive the faxed statement no later than two weeks before the application deadline date.

Address and mail or fax your statement to: Kelly O'Donnell, U.S. Department of Education, 400 Maryland Avenue, SW., room 4W253, Washington, DC 20202–5960. Fax: (202) 401–8466.

Your paper application must be submitted in accordance with the mail or hand delivery instructions described in this notice.

b. Submission of Paper Applications by Mail

If you qualify for an exception to the electronic submission requirement, you may mail (through the U.S. Postal Service or a commercial carrier) your application to the Department. You must mail the original and two copies of your application, on or before the application deadline date, to the Department at the applicable following address:

By mail through the U.S. Postal Service: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.215D), 400 Maryland Avenue, SW., Washington, DC 20202–4260; or

By mail through a commercial carrier: U.S. Department of Education, Application Control Center—Stop 4260, Attention: (CFDA Number 84.215D), 7100 Old Landover Road, Landover, MD 20785–1506.

Regardless of which address you use, you must show proof of mailing consisting of one of the following:

(1) A legibly dated U.S. Postal Service postmark,

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service,

(3) A dated shipping label, invoice, or receipt from a commercial carrier, or

(4) Any other proof of mailing acceptable to the Secretary of the U.S. Department of Education.

If you mail your application through the U.S. Postal Service, we do not accept either of the following as proof of mailing:

(1) A private metered postmark, or

(2) A mail receipt that is not dated by the U.S. Postal Service.

If your application is postmarked after the application deadline date, we will not consider your application.

Note: The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, you should check with your local post office.

c. Submission of Paper Applications by Hand Delivery

If you qualify for an exception to the electronic submission requirement, you (or a courier service) may deliver your paper application to the Department by hand. You must deliver the original and two copies of your application by hand, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.215D), 550 12th Street, SW., Room 7041, Potomac Center Plaza, Washington, DC 20202–4260.

The Application Control Center accepts hand deliveries daily between 8 a.m. and 4:30 p.m., Washington, DC time, except Saturdays, Sundays and Federal holidays.

Note for Mail or Hand Delivery of Paper Applications: If you mail or hand deliver your application to the Department:

(1) You must indicate on the envelope and—if not provided by the Department—in Item 4 of the ED 424 the CFDA number—and suffix letter, if any—of the competition under which you are submitting your application.

(2) The Application Control Center will mail a grant application receipt acknowledgment to you. If you do not receive the grant application receipt acknowledgment within 15 business days from the application deadline date, you should call the U.S. Department of Education Application Control Center at (202) 245–6288.

V. Application Review Information

Selection Criteria: We will use the following selection criteria to evaluate applications under this competition. The maximum score for all of these criteria is 100 points. The maximum score for each criterion is indicated in parentheses.

a. *Quality of the project design* (25 points). In determining the quality of the design of the proposed project, the Secretary considers the following factors:

(i) The extent to which the proposed project represents an exceptional approach to the absolute priority established for the competition.

(ii) The extent to which the proposed project is designed to build capacity and yield results that will extend beyond the period of Federal financial assistance.

b. *Significance* (40 points). In determining the significance of the proposed project, the Secretary considers the following factors:

(i) The demonstrated expertise and experience of the organization in history or civics or the teaching of history or civics.

(ii) The format in which the project will deliver the history and civics content, including but not limited to, the reading list and syllabus for the academy.

(iii) The quality of the staff and consultants responsible for conducting project activities, emphasizing, where relevant, their teaching experience and scholarship in subject areas relevant to the teaching of traditional American history and civics. The applicant should include the curriculum vitae for these individuals in appendices to the grant application.

c. *Quality of Management Plan* (15 points). In determining the quality of the management plan for the proposed project, the Secretary considers the following factors:

(i) The adequacy of the management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks.

(ii) The extent to which the time commitments of the project director and other key project personnel are appropriate and adequate to meet the objectives of the proposed project.

d. *Quality of Project Evaluation* (20 points). In determining the quality of the evaluation, the Secretary considers the extent to which the methods of evaluation include the use of objective performance measures that are clearly related to the intended outcomes of the project and will produce quantitative and qualitative data to the extent possible.

VI. Award Administration Information

1. Award Notices

If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN). We may also notify you informally.

If your application is not evaluated or not selected for funding, we notify you.

2. Administrative and National Policy Requirements

We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. Reporting

At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multi-year award, you must submit an annual performance report that provides the most current performance and financial expenditure information as specified by the Secretary in 34 CFR 75.118. For specific requirements on grantee reporting, please go to: *http://www.ed.gov/fund/grant/apply/appforms/appforms.html.*

4. Performance Measures

In response to the Government Performance and Results Act of 1993 (GPRA), the Department has established one overall performance indicator for assessing the effectiveness of the Congressional Academies for Students of American History and Civics Education program: Students will demonstrate through pre- and post-assessments an increased understanding of American history and civics that can be directly linked to their participation in the Congressional Academy. We will track this indicator through the use of the following measure. We will gather the data for this measure from the grantees.

Measure: The average percentage gain on a student assessment after participation in the Congressional Academy.

VII. Agency Contact

FOR FURTHER INFORMATION CONTACT: Kelly O'Donnell, U.S. Department of Education, 400 Maryland Avenue, SW., room 4W253, Washington, DC 20202–5960. Telephone: (202) 205–5231 or by e-mail: *Academies@ed.gov.*

If you use a telecommunications device for the deaf (TDD), you may call the Federal Relay Service (FRS) at 1–800–877–8339.

Individuals with disabilities may obtain this document in an alternative format (*e.g.*, Braille, large print, audiotape, or computer diskette) on request to the program contact person listed in this section.

VIII. Other Information

Electronic Access to This Document: You may view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at the following site: *http://www.ed.gov/news/fedregister.*

To use PDF you must have Adobe Acrobat Reader, which is available free at this site. If you have questions about using PDF, call the U.S. Government Printing Office (GPO), toll free, at 1–888–293–6498; or in the Washington, DC, area at (202) 512–1530.

Note: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: *http://www.gpoaccess.gov/nara/index.html.*

Dated: February 1, 2006.

Christopher J. Doherty,

Acting Assistant Deputy Secretary for Innovation and Improvement.

[FR Doc. 06–1077 Filed 2–3–06; 8:45 am]

BILLING CODE 4000–01–P

Federal Register

Monday,
February 6, 2006

Part IV

Department of Education

Office of Innovation and Improvement; Overview Information; Arts in Education Model Development and Dissemination Grant Program; Notice Inviting Applications for New Awards for Fiscal Year (FY) 2006; Notice

DEPARTMENT OF EDUCATION

Office of Innovation and Improvement; Overview Information; Arts in Education Model Development and Dissemination Grant Program; Notice Inviting Applications for New Awards for Fiscal Year (FY) 2006

Catalog of Federal Domestic Assistance (CFDA) Number: 84.351D.

Dates:

Applications Available: February 6, 2006.

Deadline for Notice of Intent to Apply: March 8, 2006. Deadline for Transmittal of Applications: April 7, 2006. Deadline for Intergovernmental Review: June 6, 2006.

Eligible Applicants: (1) One or more local educational agencies (LEAs), including charter schools that are considered LEAs under State law and regulations, that may work in partnership with one or more of the following:

- A State or local non-profit or governmental arts organization,
- A State educational agency (SEA) or regional educational service agency,
- An institution of higher education, or
- A public or private agency, institution, or organization, such as a community- or faith-based organization; or

(2) One or more State or local non-profit or governmental arts organizations that must work in partnership with one or more LEAs and may partner with one or more of the following:

- An SEA or regional educational service agency,
- An institution of higher education, or
- A public or private agency, institution, or organization, such as a community-or faith-based organization.

Note: If more than one LEA or arts organization wishes to form a consortium and jointly submit a single application, they must follow the procedures for group applications described in 34 CFR 75.127 through 34 CFR 75.129 of the Education Department General Administrative Regulations (EDGAR).

Estimated Available Funds: $8.7 million. Contingent upon the availability of funds and the quality of applications, we may make additional awards in FY 2007 from the list of unfunded applications from this competition.

Estimated Range of Awards: $225,000–$275,000 for the first year of the project. Funding for the second, third and fourth years is subject to the availability of funds and the approval of continuation awards (see 34 CFR 75.253).

Estimated Average Size of Awards: $250,000.

Estimated Number of Awards: 35.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 48 months.

Note: The first 12 months may be used to build capacity to effectively carry out the comprehensive activities involved in the evaluation plan described in the competitive preference priority.

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The Arts in Education Model Development and Dissemination (AEMDD) program supports the enhancement, expansion, documentation, evaluation, and dissemination of innovative, cohesive models that are based on research and have demonstrated that they effectively: (1) Integrate standards-based arts education into the core elementary and middle school curricula; (2) strengthen standards-based arts instruction in these grades; and (3) improve students' academic performance, including their skills in creating, performing, and responding to the arts. Projects funded through the AEMDD program are intended to increase the amount of nationally available information on effective models for arts education that integrate the arts with standards-based education programs.

Priorities: This competition includes one absolute priority and one competitive preference priority.

Absolute Priority: This priority is from the notice of final priorities for this program, published in the **Federal Register** on March 30, 2005 (70 FR 16234). For FY 2006, and any subsequent year in which we make awards based on the list of unfunded applicants from this competition, this priority is an absolute priority. Under 34 CFR 75.105(c)(3) we consider only applications that meet this priority.

This priority is:

This priority supports projects that enhance, expand, document, evaluate, and disseminate innovative cohesive models that are based on research and have demonstrated their effectiveness in (1) integrating standards-based arts education into the core elementary or middle school curriculum, (2) strengthening standards-based arts instruction in the elementary or middle school grades, and (3) improving the academic performance of students in elementary or middle school grades, including their skills in creating, performing, and responding to the arts.

In order to meet this priority, an applicant must demonstrate that the model project for which it seeks funding (1) serves only elementary school or middle school grades, or both, and (2) is linked to State and national standards intended to enable all students to meet challenging expectations and to improve student and school performance.

Competitive Preference Priority: This priority is from the notice of final priority published in the **Federal Register** on January 25, 2005 (70 FR 3586). For FY 2006 and any subsequent years in which we make awards based on the list of unfunded applicants from this competition, this priority is a competitive preference priority. Under 34 CFR 75.105(c)(2)(i), we award up to an additional 20 points to an application, depending on how well the application meets this priority. These points are in addition to any points the application earns under the selection criteria.

When using the priority to give competitive preference to an application, the Secretary will review applications using a two-stage process. In the first stage, the application will be reviewed without taking the priority into account. In the second stage of review, the applications rated highest in stage one will be reviewed for competitive preference. We will consider awarding additional (competitive preference) points only to those applicants with top-ranked scores on their selection criteria. We expect that up to 30 applicants will receive these additional competitive preference points.

This priority is:

The Secretary establishes a priority for projects proposing an evaluation plan that is based on rigorous scientifically based research methods to assess the effectiveness of a particular intervention. The Secretary intends that this priority will allow program participants and the Department to determine whether the project produces meaningful effects on student achievement or teacher performance.

Evaluation methods using an experimental design are best for determining project effectiveness. Thus, when feasible, the project must use an experimental design under which participants—e.g., students, teachers, classrooms, or schools—are randomly assigned to participate in the project activities being evaluated or to a control group that does not participate in the project activities being evaluated.

If random assignment is not feasible, the project may use a quasi-

experimental design with carefully matched comparison conditions. This alternative design attempts to approximate a randomly assigned control group by matching participants—e.g., students, teachers, classrooms, or schools—with non-participants having similar pre-program characteristics.

In cases where random assignment is not possible and participation in the intervention is determined by a specified cutting point on a quantified continuum of scores, regression discontinuity designs may be employed.

For projects that are focused on special populations in which sufficient numbers of participants are not available to support random assignment or matched comparison group designs, single-subject designs such as multiple baseline or treatment-reversal or interrupted time series that are capable of demonstrating causal relationships can be employed.

Proposed evaluation strategies that use neither experimental designs with random assignment nor quasi-experimental designs using a matched comparison group nor regression discontinuity designs will not be considered responsive to the priority when sufficient numbers of participants are available to support these designs. Evaluation strategies that involve too small a number of participants to support group designs must be capable of demonstrating the causal effects of an intervention or program on those participants.

The proposed evaluation plan must describe how the project evaluator will collect—before the project intervention commences and after it ends—valid and reliable data that measure the impact of participation in the program or in the comparison group.

If the priority is used as a competitive preference priority, points awarded under this priority will be determined by the quality of the proposed evaluation method. In determining the quality of the evaluation method, we will consider the extent to which the applicant presents a feasible, credible plan that includes the following:

(1) The type of design to be used (that is, random assignment or matched comparison). If matched comparison, include in the plan a discussion of why random assignment is not feasible.

(2) Outcomes to be measured.

(3) A discussion of how the applicant plans to assign students, teachers, classrooms, or schools to the project and control group or match them for comparison with other students, teachers, classrooms, or schools.

(4) A proposed evaluator, preferably independent, with the necessary background and technical expertise to carry out the proposed evaluation. An independent evaluator does not have any authority over the project and is not involved in its implementation.

In general, depending on the implemented program or project, under a competitive preference priority, random assignment evaluation methods will receive more points than matched comparison evaluation methods.

Application Requirement

To be eligible for AEMDD funds, applicants must propose to address the needs of children from low-income families by carrying out projects that serve at least one elementary or middle school in which 35 percent or more of the children enrolled are from low-income families (based on data used in meeting the poverty criteria in Title I, Section 1113(a)(5) of the Elementary and Secondary Education Act of 1965, as amended by the No Child Left Behind Act of 2001 (ESEA)).

Definitions

As used in the absolute priority in this notice—

Arts includes music, dance, theater, media arts, and visual arts. including folk arts.

Integrating means (i) encouraging the use of high-quality arts instruction in other academic/content areas and (ii) strengthening the place of the arts as a core academic subject in the school curriculum.

Based on research, when used with respect to an activity or a program, means that, to the extent possible, the activity or program is based on the most rigorous theory, research, and evaluation available and is effective in improving student achievement and performance and other program objectives.

As used in the competitive preference priority in this notice—

Scientifically based research (section 9101(37) of the ESEA as amended by NCLB, 20 U.S.C. 7801(37)):

(A) Means research that involves the application of rigorous, systematic, and objective procedures to obtain reliable and valid knowledge relevant to education activities and programs; and

(B) Includes research that—

(i) Employs systematic, empirical methods that draw on observation or experiment;

(ii) Involves rigorous data analyses that are adequate to test the stated hypotheses and justify the general conclusions drawn;

(iii) Relies on measurements or observational methods that provide reliable and valid data across evaluators and observers, across multiple measurements and observations, and across studies by the same or different investigators;

(iv) Is evaluated using experimental or quasi-experimental designs in which individuals, entities, programs, or activities are assigned to different conditions and with appropriate controls to evaluate the effects of the condition of interest, with a preference for random-assignment experiments, or other designs to the extent that those designs contain within-condition or across-condition controls;

(v) Ensures that experimental studies are presented in sufficient detail and clarity to allow for replication or, at a minimum, offer the opportunity to build systematically on their findings; and

(vi) Has been accepted by a peer-reviewed journal or approved by a panel of independent experts through a comparably rigorous, objective, and scientific review.

Random assignment or experimental design means random assignment of students, teachers, classrooms, or schools to participate in a project being evaluated (treatment group) or not participate in the project (control group). The effect of the project is the difference in outcomes between the treatment and control groups.

Quasi-experimental designs include several designs that attempt to approximate a random assignment design.

Carefully matched comparison groups design means a quasi-experimental design in which project participants are matched with non-participants based on key characteristics that are thought to be related to the outcome.

Regression discontinuity design means a quasi-experimental design that closely approximates an experimental design. In a regression discontinuity design, participants are assigned to a treatment or control group based on a numerical rating or score of a variable unrelated to the treatment such as the rating of an application for funding. Eligible students, teachers, classrooms, or schools above a certain score ("cut score") are assigned to the treatment group and those below the score are assigned to the control group. In the case of the scores of applicants' proposals for funding, the "cut score" is established at the point where the program funds available are exhausted.

Single subject design means a design that relies on the comparison of treatment effects on a single subject or group of single subjects. There is little confidence that findings based on this

design would be the same for other members of the population.

Treatment reversal design means a single subject design in which a pre-treatment or baseline outcome measurement is compared with a post-treatment measure. Treatment would then be stopped for a period of time, a second baseline measure of the outcome would be taken, followed by a second application of the treatment or a different treatment. For example, this design might be used to evaluate a behavior modification program for disabled students with behavior disorders.

Multiple baseline design means a single subject design to address concerns about the effects of normal development, timing of the treatment, and amount of the treatment with treatment-reversal designs by using a varying time schedule for introduction of the treatment and/or treatments of different lengths or intensity.

Interrupted time series design means a quasi-experimental design in which the outcome of interest is measured multiple times before and after the treatment for program participants only.

Program Authority: 20 U.S.C. 7271.

Applicable Regulations: (a) EDGAR in 34 CFR parts 74, 75, 77, 79, 80, 81, 82, 84, 85, 86, 97, 98, and 99. (b) The notice of final priorities for this program, published in the **Federal Register** on March 30, 2005 (70 FR 16234). (c) The notice of final priority for Scientifically Based Evaluation Methods, published in the **Federal Register** on January 25, 2005 (70 FR 3586).

Note: The regulations in 34 CFR part 79 apply to all applicants except federally recognized Indian tribes.

Note: The regulations in 34 CFR part 86 apply to institutions of higher education only.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: $8.7 million. Contingent upon the availability of funds and quality of applications, we may make additional awards in FY 2007 from the list of unfunded applications from this competition.

Estimated Range of Awards: $225,000–$275,000 for the first year of the project. Funding for the second, third and fourth years is subject to the availability of funds and the approval of continuation awards (see 34 CFR 75.253).

Estimated Average Size of Awards: $250,000.

Estimated Number of Awards: 35.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 48 months.

Note: The first 12 months may be used to build capacity to effectively carry out the comprehensive activities involved in the evaluation plan described in the competitive preference priority.

III. Eligibility Information

1. *Eligible Applicants:*

(1) One or more LEAs, including charter schools that are considered LEAs under State law and regulations, that may work in partnership with one or more of the following:

- A State or local non-profit or governmental arts organization,
- An SEA or regional educational service agency,
- An institution of higher education, or
- A public or private agency, institution, or organization, such as a community- or faith-based organization; or

(2) One or more State or local non-profit or governmental arts organizations that must work in partnership with one or more LEAs and may partner with one or more of the following:

- An SEA or regional educational service agency,
- An institution of higher education, or
- A public or private agency, institution, or organization, such as a community- or faith-based organization.

Note: If more than one LEA or arts organization wish to form a consortium and jointly submit a single application, they must follow the procedures for group applications described in 34 CFR 75.127 through 34 CFR 75.129 of EDGAR.

2. *Cost Sharing and Matching:* This program does not involve cost sharing or matching but does involve supplement-not-supplant funding provisions.

Under section 5551(f)(2) of the ESEA, the Secretary requires that assistance provided under this subpart be used only to supplement, and not to supplant, other assistance or funds made available from non-Federal sources for the activities assisted under this subpart.

This restriction also has the effect of allowing projects to recover indirect costs only on the basis of a restricted indirect cost rate, according to the requirements in 34 CFR 75.563 and 34 CFR 76.564 through 34 CFR 76.569. As soon as they decide to apply, applicants are urged to contact the ED Indirect Cost Group at (202) 377–3833 for guidance about obtaining a restricted indirect cost rate to use on the Budget Information form (ED Form 524) included with the application package.

3. *Coordination Requirement:* Under section 5551(f)(1) of the ESEA, the Secretary requires that each entity funded under this program coordinate, to the extent practicable, each project or program carried out with funds awarded under this program with appropriate activities of public or private cultural agencies, institutions, and organizations, such as museums, arts education associations, libraries, and theaters.

IV. Application and Submission Information

1. *Address to Request Application Package:* Education Publications Center (ED Pubs), P.O. Box 1398, Jessup, MD 20794–1398. Telephone (toll free): 1–877–433–7827. FAX: (301) 470–1244. If you use a telecommunications device for the deaf (TDD), you may call (toll free): 1–877–576–7734.

You may also contact ED Pubs at its Web site: *http://www.ed.gov/pubs/edpubs.html* or you may contact ED Pubs at its e-mail address: *edpubs@inet.ed.gov.*

If you request an application from ED Pubs, be sure to identify this competition as follows: CFDA number 84.351D.

You may also obtain the application package for the program via the Internet at the following address: *http://www.ed.gov/programs/artsedmodel/applicant.html.*

Individuals with disabilities may obtain a copy of the application package in an alternative format (e.g., Braille, large print, audiotape, or computer diskette) by contacting the program contact person listed in section VII of this notice.

2. *Content and Form of Application Submission:* Requirements concerning the content of an application, together with the forms you must submit, are in the application package for this program.

Notice of Intent to Apply: The Department will be able to develop a more efficient process for reviewing grant applications if it has a better understanding of the number of entities that intend to apply for funding under this competition. Therefore, the Secretary strongly encourages each potential applicant to notify the Department by sending a short e-mail message indicating the applicant's intent to submit an application for funding. The e-mail need not include information regarding the content of the proposed application, only the

applicant's intent to submit it. This e-mail notification should be sent to Diane Austin at *artsdemo@ed.gov.*

Applicants that fail to provide this e-mail notification may still apply for funding.

Page Limit for Program Narrative: The program narrative (Part III of the application) is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. Applicants are strongly encouraged to limit Part III to the equivalent of no more than 30 single-sided, double-spaced pages printed in 12-font type or larger.

The suggested page limit does not apply to Part I, the cover sheet; Part II, the budget section, including the narrative budget justification; Part IV, the assurances and certifications; or the one-page abstract, the competitive preference priority, the absolute priority, curriculum vitae, or bibliography of literature cited. However, you must include all of the program narrative in Part III.

3. *Submission Dates and Times:*

Applications Available: February 6, 2006.

Deadline for Notice of Intent To Apply: March 8, 2006.

Deadline for Transmittal of Applications: April 7, 2006.

Applications for grants under this competition must be submitted electronically using the Grants.gov Apply site (Grants.gov). For information (including dates and times) about how to submit your application electronically or by mail or hand delivery if you qualify for an exception to the electronic submission requirement, please refer to section IV. 6. *Other Submission Requirements in this notice.*

We do not consider an application that does not comply with the deadline requirements.

Deadline for Intergovernmental Review: June 6, 2006.

4. *Intergovernmental Review:* This competition is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this competition.

5. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

6. *Other Submission Requirements:* Applications for grants under this competition must be submitted electronically unless you qualify for an exception to this requirement in accordance with the instructions in this section.

a. Electronic Submission of Applications

Applications for grants under the AEMDD program—CFDA Number 84.351D—must be submitted electronically using the Grants.gov Apply site at: *http://www.grants.gov.* Through this site, you will be able to download a copy of the application package, complete it offline, and then upload and submit your application. You may not e-mail an electronic copy of a grant application to us.

We will reject your application if you submit it in paper format unless, as described elsewhere in this section, you qualify for one of the exceptions to the electronic submission requirement and submit, no later than two weeks before the application deadline date, a written statement to the Department that you qualify for one of these exceptions. Further information regarding calculation of the date that is two weeks before the application deadline date is provided later in this section under *Exception to Electronic Submission Requirement.*

You may access the electronic grant application for the AEMDD program at: *http://www.grants.gov.* You must search for the downloadable application package for this program by the CFDA number. Do not include the CFDA number's alpha suffix in your search.

Please note the following:

- When you enter the Grants.gov site, you will find information about submitting an application electronically through the site, as well as the hours of operation.
- Applications received by Grants.gov are time and date stamped. Your application must be fully uploaded and submitted, and must be date/time stamped by the Grants.gov system no later than 4:30 p.m., Washington, DC time, on the application deadline date. Except as otherwise noted in this section, we will not consider your application if it is date/time stamped by the Grants.gov system later than 4:30 p.m., Washington, DC time, on the application deadline date. When we retrieve your application from Grants.gov, we will notify you if we are rejecting your application because it was date/time stamped by the Grants.gov system after 4:30 p.m., Washington, DC time, on the application deadline date.
- The amount of time it can take to upload an application will vary depending on a variety of factors including the size of the application and the speed of your Internet connection. Therefore, we strongly recommend that you do not wait until the application deadline date to begin the submission process through Grants.gov.
- You should review and follow the Education Submission Procedures for submitting an application through Grants.gov that are included in the application package for this program to ensure that you submit your application in a timely manner to the Grants.gov system. You can also find the Education Submission Procedures pertaining to Grants.gov at *http://eGrants.ed.gov/help/GrantsgovSubmissionProcedures.pdf.*
- To submit your application via Grants.gov, you must complete all of the steps in the Grants.gov registration process (see *http://www.Grants.gov/GetStarted*). These steps include (1) registering your organization, (2) registering yourself as an Authorized Organization Representative (AOR), and (3) getting authorized as an AOR by your organization. Details on these steps are outlined in the Grants.gov 3-Step Registration Guide (see *http://www.grants.gov/assets/GrantsgovCoBrandBrochure8X11.pdf*). You also must provide on your application the same D-U-N-S Number used with this registration. Please note that the registration process may take five or more business days to complete, and you must have completed all registration steps to allow you to successfully submit an application via Grants.gov.
- You will not receive additional point value because you submit your application in electronic format, nor will we penalize you if you qualify for an exception to the electronic submission requirement, as described elsewhere in this section, and submit your application in paper format.
- You must submit all documents electronically, including all information typically included on the Application for Federal Education Assistance (ED 424), Budget Information—Non-Construction Programs (ED 524), and all necessary assurances and certifications. You must attach any narrative sections of your application as files in a .DOC (document), .RTF (rich text), or .PDF (Portable Document) format. If you upload a file type other than the three file types specified above or submit a password protected file, we will not review that material.
- Your electronic application must comply with any page limit requirements described in this notice.
- After you electronically submit your application, you will receive an automatic acknowledgment from Grants.gov that contains a Grants.gov

tracking number. The Department will retrieve your application from Grants.gov and send you a second confirmation by e-mail that will include a PR/Award number (an ED-specified identifying number unique to your application).

• We may request that you provide us original signatures on forms at a later date.

Application Deadline Date Extension in Case of Technical Issues with the Grants.gov System: If you are prevented from electronically submitting your application on the application deadline date because of technical problems with the Grants.gov system, we will grant you an extension until 4:30 p.m., Washington, DC time, the following business day to enable you to transmit your application electronically, or by hand delivery. You also may mail your application by following the mailing instructions as described elsewhere in this notice. If you submit an application after 4:30 p.m., Washington, DC time, on the deadline date, please contact the person listed elsewhere in this notice under **FOR FURTHER INFORMATION CONTACT**, and provide an explanation of the technical problem you experienced with Grants.gov, along with the Grants.gov Support Desk Case Number (if available). We will accept your application if we can confirm that a technical problem occurred with the Grants.gov system and that that problem affected your ability to submit your application by 4:30 p.m., Washington, DC time, on the application deadline date. The Department will contact you after a determination is made on whether your application will be accepted.

Note: Extensions referred to in this section apply only to the unavailability of or technical problems with the Grants.gov system. We will not grant you an extension if you failed to fully register to submit your application to Grants.gov before the deadline date and time or if the technical problem you experienced is unrelated to the Grants.gov system.

Exception to Electronic Submission Requirement: You qualify for an exception to the electronic submission requirement, and may submit your application in paper format, if you are unable to submit an application through the Grants.gov system because—

• You do not have access to the Internet; or

• You do not have the capacity to upload large documents to the Grants.gov system; *and*

• No later than two weeks before the application deadline date (14 calendar days or, if the fourteenth calendar day before the application deadline date falls on a Federal holiday, the next business day following the Federal holiday), you mail or fax a written statement to the Department, explaining which of the two grounds for an exception prevent you from using the Internet to submit your application. If you mail your written statement to the Department, it must be postmarked no later than two weeks before the application deadline date. If you fax your written statement to the Department, we must receive the faxed statement no later than two weeks before the application deadline date.

Address and mail or fax your statement to: Diane Austin, U.S. Department of Education, 400 Maryland Avenue, SW., room 4W210, Washington, DC 20202–5950. FAX: (202) 205–5630.

Your paper application must be submitted in accordance with the mail or hand delivery instructions described in this notice.

b. Submission of Paper Applications by Mail

If you qualify for an exception to the electronic submission requirement, you may mail (through the U.S. Postal Service or a commercial carrier), your application to the Department. You must mail the original and two copies of your application, on or before the application deadline date, to the Department at the applicable following address:

By mail through the U.S. Postal Service: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.351D), 400 Maryland Avenue, SW., Washington, DC 20202–4260; or,

By mail through a commercial carrier: U.S. Department of Education, Application Control Center—Stop 4260, Attention: (CFDA Number 84.351D), 7100 Old Landover Road, Landover, MD 20785–1506.

Regardless of which address you use, you must show proof of mailing consisting of one of the following:

(1) A legibly dated U.S. Postal Service postmark,

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service,

(3) A dated shipping label, invoice, or receipt from a commercial carrier, or

(4) Any other proof of mailing acceptable to the Secretary of the U.S. Department of Education.

If you mail your application through the U.S. Postal Service, we do not accept either of the following as proof of mailing:

(1) A private metered postmark, or

(2) A mail receipt that is not dated by the U.S. Postal Service.

If your application is postmarked after the application deadline date, we will not consider your application.

Note: The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, you should check with your local post office.

c. Submission of Paper Applications by Hand Delivery

If you qualify for an exception to the electronic submission requirement, you (or a courier service) may deliver your paper application to the Department by hand. You must deliver the original and two copies of your application by hand, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.351D), 550 12th Street, SW., Room 7041, Potomac Center Plaza, Washington, DC 20202–4260.

The Application Control Center accepts hand deliveries daily between 8 a.m. and 4:30 p.m., Washington, DC time, except Saturdays, Sundays and Federal holidays.

Note for Mail or Hand Delivery of Paper Applications: If you mail or hand deliver your application to the Department:

(1) You must indicate on the envelope and—if not provided by the Department—in Item 4 of the Application for Federal Education Assistance (ED 424) the CFDA number—and suffix letter, if any—of the competition under which you are submitting your application.

(2) The Application Control Center will mail a grant application receipt acknowledgment to you. If you do not receive the grant application receipt acknowledgment within 15 business days from the application deadline date, you should call the U.S. Department of Education Application Control Center at (202) 245–6288.

V. Application Review Information

Selection Criteria: The selection criteria for this competition are from section 75.210 of EDGAR. The maximum score for all the selection criteria is 100 points. The maximum score for each criterion is indicated in parentheses. Each criterion also includes the factors that the reviewers will consider in determining how well an application meets the criterion. The **Note** following selection criterion (e) is guidance to help applicants in preparing their applications, and are not required by statute or regulations. The criteria are as follows:

(a) *Need for project* (10 points). The Secretary considers the need for the proposed project. In determining the

need for the project the Secretary considers the following factors:

(1) The extent to which the proposed project will provide services or otherwise address the needs of students at risk of educational failure.

(2) The extent to which specific gaps or weaknesses in services, infrastructure, or opportunities have been identified and will be addressed by the proposed project, including the nature and magnitude of those gaps or weaknesses.

(b) *Significance* (20 points). The Secretary considers the significance of the proposed project. In determining the significance of the proposed project, the Secretary considers the following factors:

(1) The importance or magnitude of the results or outcomes likely to be attained by the proposed project, especially improvements in teaching and student achievement.

(2) The likely utility of the products (such as information, materials, processes, or techniques) that will result from the proposed project, including the potential for their being used effectively in a variety of other settings.

(3) The potential replicability of the proposed project or strategies, including, as appropriate, the potential for implementation in a variety of settings.

(4) The extent to which the results of the proposed project are to be disseminated in ways that will enable others to use the information or strategies.

(c) *Quality of the project design* (35 points). The Secretary considers the quality of the design of the proposed project. In determining the quality of the design of the proposed project, the Secretary considers the following factors:

(1) The extent to which the design of the proposed project reflects up-to-date knowledge from research and effective practice.

(2) The extent to which the proposed project is part of a comprehensive effort to improve teaching and learning and support rigorous academic standards for students.

(3) The extent to which the design for implementing and evaluating the proposed project will result in information to guide possible replication of project activities or strategies, including information about the effectiveness of the approach or strategies employed by the project.

(4) The extent to which the proposed project is designed to build capacity and yield results that will extend beyond the period of Federal financial assistance.

(d) *Quality of the management plan* (15 points). The Secretary considers the quality of the management plan for the proposed project. In determining the quality of the management plan for the proposed project, the Secretary considers the following factors:

(1) The adequacy of the management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks.

(2) The extent to which the time commitments of the project director and principal investigator and other key project personnel are appropriate and adequate to meet the objectives of the proposed project.

(3) The adequacy of procedures for ensuring feedback and continuous improvement in the operation of the proposed project.

(e) *Quality of the project evaluation* (20 points). The Secretary considers the quality of the evaluation to be conducted of the proposed project. In determining the quality of the evaluation, the Secretary considers the following factors:

(1) The extent to which the methods of evaluation are thorough, feasible, and appropriate to the goals, objectives, and outcomes of the proposed project.

(2) The extent to which the methods of evaluation will provide performance feedback and permit periodic assessment of progress toward achieving intended outcomes.

(3) The extent to which the evaluation will provide guidance about effective strategies suitable for replication or testing in other settings.

Note: A strong evaluation plan should be included in the application narrative and should be used, as appropriate, to shape the development of the project from the beginning of the grant period. The plan should include benchmarks to monitor progress toward specific project objectives and also outcome measures to assess the impact on teaching and learning or other important outcomes for project participants. More specifically, the plan should identify the individual and/or organization that has agreed to serve as evaluator for the project and describe the qualifications of that evaluator. The plan should describe the evaluation design, indicating: (1) What types of data will be collected; (2) when various types of data will be collected; (3) what methods will be used; (4) what instruments will be developed and when; (5) how the data will be analyzed; (6) when reports of results and outcomes will be available; and (7) how the applicant will use the information collected through the evaluation to monitor progress of the funded project and to provide accountability information both about success at the initial site and about effective strategies for replication in other settings. Applicants are encouraged to devote an appropriate level of resources to project evaluation.

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN). We may also notify you informally.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Grant Administration:* Applicants should budget for a three-day meeting for project directors to be held in Washington, DC.

4. *Reporting:* At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multi-year award, you must submit an annual performance report that provides the most current performance and financial expenditure information as specified by the Secretary in 34 CFR 75.118. For specific requirements on grantee reporting, please go to: *http://www.ed.gov/fund/grant/apply/appforms/appforms.html* and review the links on that Web page specifically associated with ED Form 524B.

5. *Performance Measures:* In response to the Government Performance and Results Act (GPRA), the Department has established the following performance measure for assessing the effectiveness of the AEMDD program: the percentage of students participating in arts models programs who demonstrate higher achievement than those in control or comparison groups. Grantees funded under this competition will be expected to collect and report to the Department data on the numbers of these students applicable to their project.

VII. Agency Contact

For Further Information Contact: Diane Austin, U.S. Department of Education, 400 Maryland Avenue, SW., Room 4W210, Washington, DC 20202–

5950. Telephone: (202) 260–1280 or by e-mail: *artsdemo@ed.gov*.

If you use a telecommunications device for the deaf (TDD), you may call the Federal Relay Service (FRS) at 1–800–877–8339.

Individuals with disabilities may obtain this document in an alternative format (e.g., Braille, large print, audiotape, or computer diskette) on request to the program contact person listed in this section.

VIII. Other Information

Electronic Access to This Document: You may view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at the following site: *http://www.ed.gov/news/fedregister*.

To use PDF you must have Adobe Acrobat Reader, which is available free at this site. If you have questions about using PDF, call the U.S. Government Printing Office (GPO), toll free, at 1–888–293–6498; or in the Washington, DC area at (202) 512–1530.

Note: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: *http://www.gpoaccess.gov/nara/index.html*.

Dated: February 1, 2006.

Christopher J. Doherty,

Acting Assistant Deputy Secretary, Office of Innovation and Improvement.

[FR Doc. 06–1076 Filed 2–3–06; 8:45 am]

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Federal Register

Vol. 71, No. 24

Monday, February 6, 2006

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The United States Government Manual	741–6000
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FEDERAL REGISTER PAGES AND DATE, FEBRUARY

CFR PARTS AFFECTED DURING FEBRUARY

At the end of each month, the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

REMINDERS

The items in this list were editorially compiled as an aid to Federal Register users. Inclusion or exclusion from this list has no legal significance.

RULES GOING INTO EFFECT FEBRUARY 6, 2006

COMMERCE DEPARTMENT
National Oceanic and Atmospheric Administration
Endangered and threatened species:
West Coast steelhead; 10 distinct population segments; published 1-5-06
Ocean and coastal resource management:
Coastal Zone Management Act; Federal consistency process; published 1-5-06

ENVIRONMENTAL PROTECTION AGENCY
Air pollution control; new motor vehicles and engines:
Evaporative emissions, dynamometer regulations, and vehicle labeling; technical amendments; published 12-8-05
Air quality implementation plans; approval and promulgation; various States; air quality planning purposes; designation of areas:
Indiana; published 1-5-06
Air quality implementation plans; approval and promulgation; various States:
Texas; published 12-7-05

HEALTH AND HUMAN SERVICES DEPARTMENT
Food and Drug Administration
Organization, functions, and authority delegations:
Departmental Appeals Board; address change; technical amendment; published 2-6-06

LABOR DEPARTMENT
Federal Contract Compliance Programs Office
Contractors and subcontractors obligations:
Gender, race, and ethnicity information collection requirements; Internet applicants; published 10-7-05

SECURITIES AND EXCHANGE COMMISSION
Electronic Data Gathering, Analysis, and Retrieval System (EDGAR):
Filer Manual; revisions; published 2-2-06

TRANSPORTATION DEPARTMENT
Federal Aviation Administration
Airworthiness directives:
Burkhardt Grob Luft-Und Raumfahrt GmbH & Co KG; published 12-28-05

COMMENTS DUE NEXT WEEK

AGRICULTURE DEPARTMENT
Agricultural Marketing Service
Egg, poultry, and rabbit products; inspection and grading:
Administrative requirements; update; comments due by 2-13-06; published 1-13-06 [FR E6-00258]

AGRICULTURE DEPARTMENT
Animal and Plant Health Inspection Service
Plant-related quarantine, domestic:
Karnal bunt; comments due by 2-13-06; published 12-13-05 [FR 05-23995]
Plant-related quarantine, foreign:
Nursery stock; comments due by 2-13-06; published 12-15-05 [FR 05-24031]

COMMERCE DEPARTMENT
National Oceanic and Atmospheric Administration
International fisheries regulations:
West Coast States and Western Pacific fisheries—
Pacific halibut catch sharing plan; comments due by 2-14-06; published 1-30-06 [FR E6-01113]

COMMODITY FUTURES TRADING COMMISSION
Commodity Exchange Act:
Market and large trader reporting; amendments; comments due by 2-13-06; published 12-15-05 [FR 05-23977]

DEFENSE DEPARTMENT
Sexually explicit material; sale or rental on DoD property; comments due by 2-17-06; published 12-19-05 [FR 05-24160]

ENVIRONMENTAL PROTECTION AGENCY
Air pollution control; new motor vehicles and engines:
Light-duty vehicles, light-duty trucks, and heavy-duty vehicles; emission durability procedures; comments due by 2-16-06; published 1-17-06 [FR 06-00073]
Air pollution; standards of performance for new stationary sources:
Electric generating units; emissions test; comments due by 2-17-06; published 10-20-05 [FR 05-20983]
Hearing; comments due by 2-17-06; published 11-22-05 [FR 05-23087]
Air programs:
Fine particulate matter and ozone; interstate transport control measures
Supplemental reconsideration notice; comments due by 2-16-06; published 12-29-05 [FR 05-24609]
Fuel and fuel additives—
Reformulated and conventional gasoline including butane blenders and attest engagements; standards and requirements modifications; comments due by 2-13-06; published 12-15-05 [FR 05-23806]
Reformulated and conventional gasoline including butane blenders and attest engagements; standards and requirements modifications; comments due by 2-13-06; published 12-15-05 [FR 05-23807]
Air programs; State authority delegations:
Various States; comments due by 2-16-06; published 1-17-06 [FR 06-00381]
Air quality implementation plans:
Preparation, adoption, and submittal—
Volatile organic compounds; emissions reductions in ozone nonattainment and maintenance areas; comments, data, and information request; comments due by 2-16-06; published 12-20-05 [FR 05-24260]
Air quality implementation plans; approval and promulgation; various States:
Maryland; comments due by 2-13-06; published 1-12-06 [FR E6-00221]
Wisconsin; comments due by 2-13-06; published 1-12-06 [FR E6-00227]
Pesticide, food, and feed additive petitions:
Syngenta Crop Protection, Inc.; comments due by 2-14-06; published 12-16-05 [FR 05-24097]
Pesticides; tolerances in food, animal feeds, and raw agricultural commodities:
Bifenazate; comments due by 2-14-06; published 12-16-05 [FR 05-24137]

FARM CREDIT ADMINISTRATION
Farm credit system:
Federal Agricultural Mortgage Corporation, disclosure and reporting requirements; risk-based capital requirements; revision; comments due by 2-15-06; published 11-17-05 [FR 05-22730]

FEDERAL COMMUNICATIONS COMMISSION
Television broadcasting:
Cable Television Consumer Protection and Competition Act—
Multichannel video programming distributor marketplace; local franchising process; comments due by 2-13-06; published 12-14-05 [FR 05-24029]

FEDERAL RETIREMENT THRIFT INVESTMENT BOARD
Thrift Savings Plan:
Death benefits; comments due by 2-13-06; published 1-12-06 [FR E6-00207]

HEALTH AND HUMAN SERVICES DEPARTMENT
Food and Drug Administration
Biological products:
Group A streptococcus; revocation of status; comments due by 2-15-06; published 12-2-05 [FR 05-23545]
Medical devices:
Obstetrical and gynecological devices—
Condom and condom with spermicidal lubricant; special control designation; comments due by 2-13-06; published 11-14-05 [FR 05-22611]

HOMELAND SECURITY DEPARTMENT
Coast Guard
Ports and waterways safety; regulated navigation areas,

LIST OF PUBLIC LAWS

This is a continuing list of public bills from the current session of Congress which have become Federal laws. It may be used in conjunction with "PLUS" (Public Laws Update Service) on 202–741–6043. This list is also available online at *http://www.archives.gov/federal-register/laws.html.*

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H.R. 4340/P.L. 109–169

United States-Bahrain Free Trade Agreement Implementation Act (Jan. 11, 2006; 119 Stat. 3581)

Last List January 12, 2006

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CFR CHECKLIST

This checklist, prepared by the Office of the Federal Register, is published weekly. It is arranged in the order of CFR titles, stock numbers, prices, and revision dates.

An asterisk (*) precedes each entry that has been issued since last week and which is now available for sale at the Government Printing Office.

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Title	Stock Number	Price	Revision Date
1	(869-056-00001-4)	5.00	Jan. 1, 2005
2	(869-056-00002-2)	5.00	Jan. 1, 2005
3 (2003 Compilation and Parts 100 and 101)	(869-056-00003-1)	35.00	[1] Jan. 1, 2005
4	(869-056-00004-9)	10.00	[4] Jan. 1, 2005
5 Parts:			
1-699	(869-056-00005-7)	60.00	Jan. 1, 2005
700-1199	(869-056-00006-5)	50.00	Jan. 1, 2005
1200-End	(869-056-00007-3)	61.00	Jan. 1, 2005
6	(869-056-00008-1)	10.50	Jan. 1, 2005
7 Parts:			
1-26	(869-056-00009-0)	44.00	Jan. 1, 2005
27-52	(869-056-00010-3)	49.00	Jan. 1, 2005
53-209	(869-056-00011-1)	37.00	Jan. 1, 2005
210-299	(869-056-00012-0)	62.00	Jan. 1, 2005
300-399	(869-056-00013-8)	46.00	Jan. 1, 2005
400-699	(869-056-00014-6)	42.00	Jan. 1, 2005
700-899	(869-056-00015-4)	43.00	Jan. 1, 2005
900-999	(869-056-00016-2)	60.00	Jan. 1, 2005
1000-1199	(869-056-00017-1)	22.00	Jan. 1, 2005
1200-1599	(869-056-00018-9)	61.00	Jan. 1, 2005
1600-1899	(869-056-00019-7)	64.00	Jan. 1, 2005
1900-1939	(869-056-00020-1)	31.00	Jan. 1, 2005
1940-1949	(869-056-00021-9)	50.00	Jan. 1, 2005
1950-1999	(869-056-00022-7)	46.00	Jan. 1, 2005
2000-End	(869-056-00023-5)	50.00	Jan. 1, 2005
8	(869-056-00024-3)	63.00	Jan. 1, 2005
9 Parts:			
1-199	(869-056-00025-1)	61.00	Jan. 1, 2005
200-End	(869-056-00026-0)	58.00	Jan. 1, 2005
10 Parts:			
1-50	(869-056-00027-8)	61.00	Jan. 1, 2005
51-199	(869-056-00028-6)	58.00	Jan. 1, 2005
200-499	(869-056-00029-4)	46.00	Jan. 1, 2005
500-End	(869-056-00030-8)	62.00	Jan. 1, 2005
11	(869-056-00031-6)	41.00	Jan. 1, 2005
12 Parts:			
1-199	(869-056-00032-4)	34.00	Jan. 1, 2005
200-219	(869-056-00033-2)	37.00	Jan. 1, 2005
220-299	(869-056-00034-1)	61.00	Jan. 1, 2005
300-499	(869-056-00035-9)	47.00	Jan. 1, 2005
500-599	(869-056-00036-7)	39.00	Jan. 1, 2005
600-899	(869-056-00037-5)	56.00	Jan. 1, 2005
900-End	(869-056-00038-3)	50.00	Jan. 1, 2005
13	(869-056-00039-1)	55.00	Jan. 1, 2005
14 Parts:			
1-59	(869-056-00040-5)	63.00	Jan. 1, 2005
60-139	(869-056-00041-3)	61.00	Jan. 1, 2005
140-199	(869-056-00042-1)	30.00	Jan. 1, 2005
200-1199	(869-056-00043-0)	50.00	Jan. 1, 2005
1200-End	(869-056-00044-8)	45.00	Jan. 1, 2005
15 Parts:			
0-299	(869-056-00045-6)	40.00	Jan. 1, 2005
300-799	(869-056-00046-4)	60.00	Jan. 1, 2005
800-End	(869-056-00047-2)	42.00	Jan. 1, 2005
16 Parts:			
0-999	(869-056-00048-1)	50.00	Jan. 1, 2005
1000-End	(869-056-00049-9)	60.00	Jan. 1, 2005
17 Parts:			
1-199	(869-056-00051-1)	50.00	Apr. 1, 2005
200-239	(869-056-00052-9)	58.00	Apr. 1, 2005
240-End	(869-056-00053-7)	62.00	Apr. 1, 2005
18 Parts:			
1-399	(869-056-00054-5)	62.00	Apr. 1, 2005
400-End	(869-056-00055-3)	26.00	[6] Apr. 1, 2005
19 Parts:			
1-140	(869-056-00056-1)	61.00	Apr. 1, 2005
141-199	(869-056-00057-0)	58.00	Apr. 1, 2005
200-End	(869-056-00058-8)	31.00	Apr. 1, 2005
20 Parts:			
1-399	(869-056-00059-6)	50.00	Apr. 1, 2005
400-499	(869-056-00060-0)	64.00	Apr. 1, 2005
500-End	(869-056-00061-8)	63.00	Apr. 1, 2005
21 Parts:			
1-99	(869-056-00062-6)	42.00	Apr. 1, 2005
100-169	(869-056-00063-4)	49.00	Apr. 1, 2005
170-199	(869-056-00064-2)	50.00	Apr. 1, 2005
200-299	(869-056-00065-1)	17.00	Apr. 1, 2005
300-499	(869-056-00066-9)	31.00	Apr. 1, 2005
500-599	(869-056-00067-7)	47.00	Apr. 1, 2005
600-799	(869-056-00068-5)	15.00	Apr. 1, 2005
800-1299	(869-056-00069-3)	58.00	Apr. 1, 2005
1300-End	(869-056-00070-7)	24.00	Apr. 1, 2005
22 Parts:			
1-299	(869-056-00071-5)	63.00	Apr. 1, 2005
300-End	(869-056-00072-3)	45.00	Apr. 1, 2005
23	(869-056-00073-1)	45.00	Apr. 1, 2005
24 Parts:			
0-199	(869-056-00074-0)	60.00	Apr. 1, 2005
200-499	(869-056-00074-0)	50.00	Apr. 1, 2005
500-699	(869-056-00076-6)	30.00	Apr. 1, 2005
700-1699	(869-056-00077-4)	61.00	Apr. 1, 2005
1700-End	(869-056-00078-2)	30.00	Apr. 1, 2005
25	(869-056-00079-1)	63.00	Apr. 1, 2005
26 Parts:			
§§ 1.0-1-1.60	(869-056-00080-4)	49.00	Apr. 1, 2005
§§ 1.61-1.169	(869-056-00081-2)	63.00	Apr. 1, 2005
§§ 1.170-1.300	(869-056-00082-1)	60.00	Apr. 1, 2005
§§ 1.301-1.400	(869-056-00083-9)	46.00	Apr. 1, 2005
§§ 1.401-1.440	(869-056-00084-7)	62.00	Apr. 1, 2005
§§ 1.441-1.500	(869-056-00085-5)	57.00	Apr. 1, 2005
§§ 1.501-1.640	(869-056-00086-3)	49.00	Apr. 1, 2005
§§ 1.641-1.850	(869-056-00087-1)	60.00	Apr. 1, 2005
§§ 1.851-1.907	(869-056-00088-0)	61.00	Apr. 1, 2005
§§ 1.908-1.1000	(869-056-00089-8)	60.00	Apr. 1, 2005
§§ 1.1001-1.1400	(869-056-00090-1)	61.00	Apr. 1, 2005
§§ 1.1401-1.1550	(869-056-00091-0)	55.00	Apr. 1, 2005
§§ 1.1551-End	(869-056-00092-8)	55.00	Apr. 1, 2005
2-29	(869-056-00093-6)	60.00	Apr. 1, 2005
30-39	(869-056-00094-4)	41.00	Apr. 1, 2005
40-49	(869-056-00095-2)	28.00	Apr. 1, 2005
50-299	(869-056-00096-1)	41.00	Apr. 1, 2005

Title	Stock Number	Price	Revision Date
300–499	(869–056–00097–9)	61.00	Apr. 1, 2005
500–599	(869–056–00098–7)	12.00	[5]Apr. 1, 2005
600–End	(869–056–00099–5)	17.00	Apr. 1, 2005
27 Parts:			
1–199	(869–056–00100–2)	64.00	Apr. 1, 2005
200–End	(869–056–00101–1)	21.00	Apr. 1, 2005
28 Parts:			
0–42	(869–056–00102–9)	61.00	July 1, 2005
43–End	(869–056–00103–7)	60.00	July 1, 2005
29 Parts:			
0–99	(869–056–00104–5)	50.00	July 1, 2005
100–499	(869–056–00105–3)	23.00	July 1, 2005
500–899	(869–056–00106–1)	61.00	July 1, 2005
900–1899	(869–056–00107–0)	36.00	[7]July 1, 2005
1900–1910 (§§ 1900 to 1910.999)	(869–056–00108–8)	61.00	July 1, 2005
1910 (§§ 1910.1000 to end)	(869–056–00109–6)	58.00	July 1, 2005
1911–1925	(869–056–00110–0)	30.00	July 1, 2005
1926	(869–056–00111–8)	50.00	July 1, 2005
1927–End	(869–056–00112–6)	62.00	July 1, 2005
30 Parts:			
1–199	(869–056–00113–4)	57.00	July 1, 2005
200–699	(869–056–00114–2)	50.00	July 1, 2005
700–End	(869–056–00115–1)	58.00	July 1, 2005
31 Parts:			
0–199	(869–056–00116–9)	41.00	July 1, 2005
200–499	(869–056–00117–7)	33.00	July 1, 2005
500–End	(869–056–00118–5)	33.00	July 1, 2005
32 Parts:			
1–39, Vol. I		15.00	[2]July 1, 1984
1–39, Vol. II		19.00	[2]July 1, 1984
1–39, Vol. III		18.00	[2]July 1, 1984
1–190	(869–056–00119–3)	61.00	July 1, 2005
191–399	(869–056–00120–7)	63.00	July 1, 2005
400–629	(869–056–00121–5)	50.00	July 1, 2005
630–699	(869–056–00122–3)	37.00	July 1, 2005
700–799	(869–056–00123–1)	46.00	July 1, 2005
800–End	(869–056–00124–0)	47.00	July 1, 2005
33 Parts:			
1–124	(869–056–00125–8)	57.00	July 1, 2005
125–199	(869–056–00126–6)	61.00	July 1, 2005
200–End	(869–056–00127–4)	57.00	July 1, 2005
34 Parts:			
1–299	(869–056–00128–2)	50.00	July 1, 2005
300–399	(869–056–00129–1)	40.00	[7]July 1, 2005
400–End & 35	(869–056–00130–4)	61.00	July 1, 2005
36 Parts:			
1–199	(869–056–00131–2)	37.00	July 1, 2005
200–299	(869–056–00132–1)	37.00	July 1, 2005
300–End	(869–056–00133–9)	61.00	July 1, 2005
37	(869–056–00134–7)	58.00	July 1, 2005
38 Parts:			
0–17	(869–056–00135–5)	60.00	July 1, 2005
18–End	(869–056–00136–3)	62.00	July 1, 2005
39	(869–056–00139–1)	42.00	July 1, 2005
40 Parts:			
1–49	(869–056–00138–0)	60.00	July 1, 2005
50–51	(869–056–00139–8)	45.00	July 1, 2005
52 (52.01–52.1018)	(869–056–00140–1)	60.00	July 1, 2005
52 (52.1019–End)	(869–056–00141–0)	61.00	July 1, 2005
53–59	(869–056–00142–8)	31.00	July 1, 2005
60 (60.1–End)	(869–056–00143–6)	58.00	July 1, 2005
60 (Apps)	(869–056–00144–4)	57.00	July 1, 2005
61–62	(869–056–00145–2)	45.00	July 1, 2005
63 (63.1–63.599)	(869–056–00146–1)	58.00	July 1, 2005
63 (63.600–63.1199)	(869–056–00147–9)	50.00	July 1, 2005
63 (63.1200–63.1439)	(869–056–00148–7)	50.00	July 1, 2005
63 (63.1440–63.6175)	(869–056–00149–5)	32.00	July 1, 2005
63 (63.6580–63.8830)	(869–056–00150–9)	32.00	July 1, 2005
63 (63.8980–End)	(869–056–00151–7)	35.00	[7]July 1, 2005
64–71	(869–056–00152–5)	29.00	July 1, 2005
72–80	(869–056–00153–5)	62.00	July 1, 2005
81–85	(869–056–00154–1)	60.00	July 1, 2005
86 (86.1–86.599–99)	(869–056–00155–0)	58.00	July 1, 2005
86 (86.600–1–End)	(869–056–00156–8)	50.00	July 1, 2005
87–99	(869–056–00157–6)	60.00	July 1, 2005
100–135	(869–056–00158–4)	45.00	July 1, 2005
136–149	(869–056–00159–2)	61.00	July 1, 2005
150–189	(869–056–00160–6)	50.00	July 1, 2005
190–259	(869–056–00161–4)	39.00	July 1, 2005
260–265	(869–056–00162–2)	50.00	July 1, 2005
266–299	(869–056–00163–1)	50.00	July 1, 2005
300–399	(869–056–00164–9)	42.00	July 1, 2005
400–424	(869–056–00165–7)	56.00	[8]July 1, 2005
425–699	(869–056–00166–5)	61.00	July 1, 2005
700–789	(869–056–00167–3)	61.00	July 1, 2005
790–End	(869–056–00168–1)	61.00	July 1, 2005
41 Chapters:			
1, 1–1 to 1–10		13.00	[3]July 1, 1984
1, 1–11 to Appendix, 2 (2 Reserved)		13.00	[3]July 1, 1984
3–6		14.00	[3]July 1, 1984
7		6.00	[3]July 1, 1984
8		4.50	[3]July 1, 1984
9		13.00	[3]July 1, 1984
10–17		9.50	[3]July 1, 1984
18, Vol. I, Parts 1–5		13.00	[3]July 1, 1984
18, Vol. II, Parts 6–19		13.00	[3]July 1, 1984
18, Vol. III, Parts 20–52		13.00	[3]July 1, 1984
19–100		13.00	[3]July 1, 1984
1–100	(869–056–00169–0)	24.00	July 1, 2005
101	(869–056–00170–3)	21.00	July 1, 2005
102–200	(869–056–00171–1)	56.00	July 1, 2005
201–End	(869–056–00172–0)	24.00	July 1, 2005
42 Parts:			
1–399	(869–056–00173–8)	61.00	Oct. 1, 2005
400–429	(869–056–00174–6)	63.00	Oct. 1, 2005
430–End	(869–056–00175–4)	64.00	Oct. 1, 2005
43 Parts:			
1–999	(869–056–00176–2)	56.00	Oct. 1, 2005
1000–end	(869–056–00177–1)	62.00	Oct. 1, 2005
44	(869–056–00178–9)	50.00	Oct. 1, 2005
45 Parts:			
1–199	(869–056–00179–7)	60.00	Oct. 1, 2005
200–499	(869–056–00180–1)	34.00	Oct. 1, 2005
500–1199	(869–056–00171–9)	56.00	Oct. 1, 2005
1200–End	(869–056–00182–7)	61.00	Oct. 1, 2005
46 Parts:			
1–40	(869–056–00183–5)	46.00	Oct. 1, 2005
41–69	(869–056–00184–3)	39.00	[9]Oct. 1, 2005
70–89	(869–056–00185–1)	14.00	[9]Oct. 1, 2005
90–139	(869–056–00186–0)	44.00	Oct. 1, 2005
140–155	(869–056–00187–8)	25.00	Oct. 1, 2005
156–165	(869–056–00188–6)	34.00	[9]Oct. 1, 2005
166–199	(869–056–00189–4)	46.00	Oct. 1, 2005
200–499	(869–056–00190–8)	40.00	Oct. 1, 2005
500–End	(869–056–00191–6)	25.00	Oct. 1, 2005
47 Parts:			
0–19	(869–056–00192–4)	61.00	Oct. 1, 2005
20–39	(869–056–00193–2)	46.00	Oct. 1, 2005
40–69	(869–056–00194–1)	40.00	Oct. 1, 2005
70–79	(869–056–00195–9)	61.00	Oct. 1, 2005
80–End	(869–056–00196–7)	61.00	Oct. 1, 2005
48 Chapters:			
1 (Parts 1–51)	(869–056–00197–5)	63.00	Oct. 1, 2005
1 (Parts 52–99)	(869–056–00198–3)	49.00	Oct. 1, 2005
2 (Parts 201–299)	(869–056–00199–1)	50.00	Oct. 1, 2005
3–6	(869–056–00200–9)	34.00	Oct. 1, 2005
7–14	(869–056–00201–7)	56.00	Oct. 1, 2005
15–28	(869–056–00202–5)	47.00	Oct. 1, 2005

Title	Stock Number	Price	Revision Date
29–End	(869–056–00203–3)	47.00	Oct. 1, 2005
49 Parts:			
1–99	(869–056–00204–1)	60.00	Oct. 1, 2005
100–185	(869–056–00205–0)	63.00	Oct. 1, 2005
186–199	(869–056–00206–8)	23.00	Oct. 1, 2005
200–299	(869–056–00207–6)	32.00	Oct. 1, 2005
300–399	(869–056–00208–4)	32.00	Oct. 1, 2005
400–599	(869–056–00209–2)	64.00	Oct. 1, 2005
600–999	(869–056–00210–6)	19.00	Oct. 1, 2005
1000–1199	(869–056–00211–4)	28.00	Oct. 1, 2005
1200–End	(869–056–00212–2)	34.00	Oct. 1, 2005
50 Parts:			
1–16	(869–056–00213–1)	11.00	Oct. 1, 2005
17.1–17.95(b)	(869–056–00214–9)	32.00	Oct. 1, 2005
17.95(c)–end	(869–056–00215–7)	32.00	Oct. 1, 2005
17.96–17.99(h)	(869–056–00215–7)	61.00	Oct. 1, 2005
17.99(i)–end and 17.100–end	(869–056–00217–3)	47.00	Oct. 1, 2005
18–199	(869–056–00218–1)	50.00	Oct. 1, 2005
200–599	(869–056–00218–1)	45.00	Oct. 1, 2005
600–End	(869–056–00219–0)	62.00	Oct. 1, 2005
CFR Index and Findings Aids	(869–056–00050–2)	62.00	Jan. 1, 2005
Complete 2006 CFR set		1,398.00	2006
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Subscription (mailed as issued)		332.00	2006
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Complete set (one-time mailing)		325.00	2005
Complete set (one-time mailing)		325.00	2004

[1] Because Title 3 is an annual compilation, this volume and all previous volumes should be retained as a permanent reference source.

[2] The July 1, 1985 edition of 32 CFR Parts 1–189 contains a note only for Parts 1–39 inclusive. For the full text of the Defense Acquisition Regulations in Parts 1–39, consult the three CFR volumes issued as of July 1, 1984, containing those parts.

[3] The July 1, 1985 edition of 41 CFR Chapters 1–100 contains a note only for Chapters 1 to 49 inclusive. For the full text of procurement regulations in Chapters 1 to 49, consult the eleven CFR volumes issued as of July 1, 1984 containing those chapters.

[4] No amendments to this volume were promulgated during the period January 1, 2004, through January 1, 2005. The CFR volume issued as of January 1, 2004 should be retained.

[5] No amendments to this volume were promulgated during the period April 1, 2000, through April 1, 2005. The CFR volume issued as of April 1, 2000 should be retained.

[6] No amendments to this volume were promulgated during the period April 1, 2004, through April 1, 2005. The CFR volume issued as of April 1, 2004 should be retained.

[7] No amendments to this volume were promulgated during the period July 1, 2004, through July 1, 2005. The CFR volume issued as of July 1, 2004 should be retained.

[8] No amendments to this volume were promulgated during the period July 1, 2004, through July 1, 2005. The CFR volume issued as of July 1, 2003 should be retained.

[9] No amendments to this volume were promulgated during the period October 1, 2004, through October 1, 2005. The CFR volume issued as of October 1, 2004 should be retained.

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