Federal Register

9–22–04 Wednesday
Vol. 69 No. 183 Sept. 22, 2004

United States
Government
Printing Office
SUPERINTENDENT
OF DOCUMENTS
Washington, DC 20402

OFFICIAL BUSINESS
Penalty for Private Use, $300

PERIODICALS
Postage and Fees Paid
U.S. Government Printing Office
(ISSN 0097-6326)

Federal Register

9–22–04 Wednesday
Vol. 69 No. 183 Sept. 22, 2004

Pages 56665–56924

The **FEDERAL REGISTER** (ISSN 0097–6326) is published daily, Monday through Friday, except official holidays, by the Office of the Federal Register, National Archives and Records Administration, Washington, DC 20408, under the Federal Register Act (44 U.S.C. Ch. 15) and the regulations of the Administrative Committee of the Federal Register (1 CFR Ch. I). The Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 is the exclusive distributor of the official edition. Periodicals postage is paid at Washington, DC.

The **FEDERAL REGISTER** provides a uniform system for making available to the public regulations and legal notices issued by Federal agencies. These include Presidential proclamations and Executive Orders, Federal agency documents having general applicability and legal effect, documents required to be published by act of Congress, and other Federal agency documents of public interest.

Documents are on file for public inspection in the Office of the Federal Register the day before they are published, unless the issuing agency requests earlier filing. For a list of documents currently on file for public inspection, see *www.archives.gov*.

The seal of the National Archives and Records Administration authenticates the Federal Register as the official serial publication established under the Federal Register Act. Under 44 U.S.C. 1507, the contents of the **Federal Register** shall be judicially noticed.

The **Federal Register** is published in paper and on 24x microfiche. It is also available online at no charge as one of the databases on GPO Access, a service of the U.S. Government Printing Office.

The online edition of the **Federal Register** *www.gpoaccess.gov/nara*, available through GPO Access, is issued under the authority of the Administrative Committee of the Federal Register as the official legal equivalent of the paper and microfiche editions (44 U.S.C. 4101 and 1 CFR 5.10). It is updated by 6 a.m. each day the **Federal Register** is published and includes both text and graphics from Volume 59, Number 1 (January 2, 1994) forward.

For more information about GPO Access, contact the GPO Access User Support Team, call toll free 1-888-293-6498; DC area 202-512-1530; fax at 202-512-1262; or via email at *gpoaccess@gpo.gov*. The Support Team is available between 7:00 a.m. and 9:00 p.m. Eastern Time, Monday–Friday, except official holidays.

The annual subscription price for the **Federal Register** paper edition is $749 plus postage, or $808, plus postage, for a combined **Federal Register, Federal Register** Index and List of CFR Sections Affected (LSA) subscription; the microfiche edition of the **Federal Register** including the **Federal Register** Index and LSA is $165, plus postage. Six month subscriptions are available for one-half the annual rate. The prevailing postal rates will be applied to orders according to the delivery method requested. The price of a single copy of the daily **Federal Register,** including postage, is based on the number of pages: $11 for an issue containing less than 200 pages; $22 for an issue containing 200 to 400 pages; and $33 for an issue containing more than 400 pages. Single issues of the microfiche edition may be purchased for $3 per copy, including postage. Remit check or money order, made payable to the Superintendent of Documents, or charge to your GPO Deposit Account, VISA, MasterCard, American Express, or Discover. Mail to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250-7954; or call toll free 1-866-512-1800, DC area 202-512-1800; or go to the U.S. Government Online Bookstore site, see *bookstore.gpo.gov*.

There are no restrictions on the republication of material appearing in the **Federal Register.**

How To Cite This Publication: Use the volume number and the page number. Example: 69 FR 12345.

Postmaster: Send address changes to the Superintendent of Documents, Federal Register, U.S. Government Printing Office, Washington DC 20402, along with the entire mailing label from the last issue received.

Printed on recycled paper.

SUBSCRIPTIONS AND COPIES

PUBLIC

Subscriptions:

Paper or fiche	**202–512–1800**
Assistance with public subscriptions	**202–512–1806**
General online information	**202–512–1530; 1–888–293–6498**

Single copies/back copies:

Paper or fiche	**202–512–1800**
Assistance with public single copies	**1–866–512–1800 (Toll-Free)**

FEDERAL AGENCIES

Subscriptions:

Paper or fiche	**202–741–6005**
Assistance with Federal agency subscriptions	**202–741–6005**

Contents

Federal Register

Vol. 69, No. 183

Wednesday, September 22, 2004

Agricultural Marketing Service
RULES
Onions grown in—
Idaho and Oregon; import regulations, 56667–56672
PROPOSED RULES
Milk marketing orders:
Central, 56725–56730

Agriculture Department
See Agricultural Marketing Service
See Food Safety and Inspection Service
See Forest Service
NOTICES
Reports and guidance documents; availability, etc.:
Farm Service Agency; county committee elections; uniform guidelines, 56742

Arts and Humanities, National Foundation
See National Foundation on the Arts and the Humanities

Coast Guard
RULES
Ports and waterways safety:
Atlantic Ocean, Chesapeake and Delaware Canal, Delaware Bay, Delaware River, et al.; security zone, 56695–56697
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 56782–56783

Commerce Department
See Foreign-Trade Zones Board
See Industry and Security Bureau
See International Trade Administration
See National Institute of Standards and Technology
See National Oceanic and Atmospheric Administration

Committee for the Implementation of Textile Agreements
NOTICES
Textile and apparel categories:
Quota and visa requirements—
Beneficiary ATPDEA countries; apparel articles; duty- and quota-free import limitations, 56748
Beneficiary Sub-Saharan African countries; apparel articles; duty- and quota-free import limitations, 56747–56748

Commodity Futures Trading Commission
NOTICES
Meetings; Sunshine Act, 56748

Corporation for National and Community Service
RULES
Foster Grandparent Program and Retired and Senior Volunteer Program; correction, 56718–56719

Defense Department
See Navy Department

Employment and Training Administration
NOTICES
Adjustment assistance:
Ace Products, Inc., et al., 56787
Candor Hosiery Mills, Inc., 56787
Crystal Springs Apparel, LLC, 56787–56788
Down River, LLC, 56788
Federal Mogul Corp., 56788
Johnson Controls, Inc., 56788
Major League, Inc., 56788–56789
Marshall Erdman, 56789
Parametric Technology Corp., 56789–56790
TI Automotive, 56790

Energy Department
See Energy Information Administration
See Federal Energy Regulatory Commission
NOTICES
Meetings:
DOE/NSF Nuclear Science Advisory Committee, 56749

Energy Information Administration
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 56749–56750

Environmental Protection Agency
RULES
Air programs:
Ambient air quality standards, national—
8-hour ozone standard; designated nonattainment areas reclassified, 56697–56711
Pesticides; tolerances in food, animal feeds, and raw agricultural commodities:
Tribenuron methyl, 56711–56718
NOTICES
Agency information collection activities; proposals, submissions, and approvals; comment request, 56754–56755
Air programs:
Stratospheric ozone protection—
Methyl bromide; critical use stock availability, 56756
Pesticide programs:
Risk assessments—
Rodenticides, 56756–56758
Tolerance reassessment decisions—
Desmedipham, 56758–56760
Water pollution control:
National Pollutant Discharge Elimination System—
Southern California; offshore oil and gas exploration, development and production operations; general permit, 56761–56764

Executive Office of the President
See Presidential Documents

Federal Accounting Standards Advisory Board
NOTICES
Meetings:
2005 schedule, 56764

Federal Aviation Administration
RULES
Airworthiness directives:
Bombardier, 56682–56683
Empresa Brasileira de Aeronautica, S.A. (EMBRAER), 56676–56679

McDonnell Douglas, 56680–56682
Robinson Helicopter Co., 56688–56690
Rolls-Royce plc, 56683–56688
Airworthiness standards:
Special conditions—
Dassault Model Mystere-Falcon and Model Fan Jet Falcon airplanes; various series, 56672–56674
Lockheed Martin Corp. Model 1329-23A, -23-D, -23E, and 1329-25 airplanes, 56674–56676
Class D and E airspace, 56690–56692
PROPOSED RULES
Airworthiness directives:
Empresa Brasileira de Aeronautica S.A. (EMBRAER), 56735–56738
General Electric Co., 56730–56733
New Piper Aircraft, Inc., 56733–56735
NOTICES
Environmental statements; record of decision:
Toledo Express Airport, OH, 56817
Exemption petitions; summary and disposition, 56817
Meetings:
Aviation Rulemaking Advisory Committee, 56817–56818
Government/Industry Aeronautical Charting Forum, 56818

Federal Communications Commission
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 56764–56765

Federal Energy Regulatory Commission
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 56750–56751
Electric rate and corporate regulation filings, 56752–56753
Hydroelectric applications, 56753
Meetings:
Energy Northwest; site visit, 56754
Applications, hearings, determinations, etc.:
National Fuel Gas Supply Corp., 56751
Pine Needle LNG Co., LLC, 56751–56752
Trunkline Gas Co., LLC, 56752

Federal Highway Administration
NOTICES
Engineering and traffic operations:
Laboratory Accreditation Program; construction materials testing; quality assurance requirements, 56818–56819

Federal Railroad Administration
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 56819–56820
Exemption petitions, etc.:
Canadian Pacific Railway, 56820–56821
Traffic control systems; discontinuance or modification:
Burlington Northern & Santa Fe Railway, 56821

Federal Reserve System
NOTICES
Banks and bank holding companies:
Formations, acquisitions, and mergers, 56765–56766

Federal Trade Commission
NOTICES
Prohibited trade practices:
General Electric Co., 56766–56769

Financial Management Service
See Fiscal Service

Fiscal Service
NOTICES
Surety companies acceptable on Federal bonds:
National Union Fire Insurance Co. of Pittsburgh et al.; correction, 56821

Fish and Wildlife Service
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 56783–56784
Environmental statements; notice of intent:
Marin Islands National Wildlife Refuge, CA; meeting, 56784–56785

Food and Drug Administration
PROPOSED RULES
Food for human consumption:
Salmonella; shell egg producers to implement prevention measures, 56823–56906
NOTICES
Meetings:
Blood Products Advisory Committee, 56770
Measuring the Effectiveness of the Nation's Foodservice and Retail Food Protection System, 56770–56771
Transmissible Spongiform Encephalopathies Advisory Committee, 56771
Reports and guidance documents; availability, etc.:
Occurrence of Foodborne Illness Risk Factors Within Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types; 2004 report, 56771–56772

Food Safety and Inspection Service
NOTICES
Reports and guidance documents; availability, etc.:
Post-lethality exposed ready-to-eat products; production information, 56742–56743

Foreign-Trade Zones Board
NOTICES
Applications, hearings, determinations, etc.:
Tennessee
Sofix Corp.; black colorformer chemicals manufacturing facility, 56744–56745

Forest Service
NOTICES
Environmental statements; notice of intent:
Sierra National Forest, CA, 56743–56744

General Services Administration
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 56769

Health and Human Services Department
See Food and Drug Administration
See Health Resources and Services Administration

Health Resources and Services Administration
NOTICES
Agency information collection activities; proposals, submissions, and approvals; comment request, 56772–56773

Grant and cooperative agreement awards:
African American infant mortality reduction initiative; various States, 56773
National Vaccine Injury Compensation Program:
Petitions received; list, 56773–56781

Homeland Security Department
See Coast Guard
NOTICES
Privacy Act:
Systems of records, 56781–56782

Industry and Security Bureau
RULES
Export administration regulations:
Entity list—
India; entity removed and license review policy revised; clarification, 56693–56695

Interior Department
See Fish and Wildlife Service
See Land Management Bureau
See Surface Mining Reclamation and Enforcement Office

International Trade Administration
PROPOSED RULES
Antidumping and countervailing duties:
Certification of factual information during proceedings, 56738–56741
NOTICES
Antidumping and countervailing duties:
Administrative review requests, 56745–56746
Applications, hearings, determinations, etc.:
North Carolina State University, 56746
University of—
Colorado Medical School, 56746

Labor Department
See Employment and Training Administration
See Mine Safety and Health Administration
See Occupational Safety and Health Administration

Land Management Bureau
NOTICES
Recreation management restrictions, etc.:
Imperial Sand Dunes Recreation Area, CA; special recreation permit fees payment; supplementary rules, 56785–56787

Mine Safety and Health Administration
NOTICES
Petitions for safety standard modifications; summary of affirmative decisions:, 56790–56794
Safety standard petitions:
Brooks Run Mining Co., LLC, et al., 56794–56795

National Foundation on the Arts and the Humanities
NOTICES
Meetings:
Humanities Panel, 56796–56797

National Institute of Standards and Technology
NOTICES
Meetings:
Information Security and Privacy Advisory Board, 56746–56747

National Oceanic and Atmospheric Administration
RULES
Fishery conservation and management:
Atlantic highly migratory species—
Atlantic shark, 56719–56720
PROPOSED RULES
Fishery conservation and management:
Atlantic highly migratory species—
Atlantic shark, 56741

National Science Foundation
NOTICES
Meetings; Sunshine Act, 56797

Navy Department
NOTICES
Inventions, Government-owned; availability for licensing, 56748–56749

Nuclear Regulatory Commission
NOTICES
Agency information collection activities; proposals, submissions, and approvals; request for comment, 56797
Environmental statements; availability, etc.:
Surmodics, Inc., 56799
Meetings:
Reactor Safeguards Advisory Committee, 56799–56801
Meetings; Sunshine Act, 56801
Applications, hearings, determinations, etc.:
Entergy Nuclear Vermont Yankee, LLC, et al., 56797–56798
Nuclear Management Co., LLC, 56798
Tennessee Valley Authority, 56798–56799

Occupational Safety and Health Administration
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 56795–56796

Personnel Management Office
PROPOSED RULES
Pay under General Schedule:
Locality pay areas; adjustments, 56721–56725

Presidential Documents
EXECUTIVE ORDERS
Libya; termination of emergency declared in Executive Order 12543 (EO 13357), 56665–56666
ADMINISTRATIVE ORDERS
Terrorism; continuation of national emergency with respect to persons who commit, threaten to commit, or support (Notice of September 21, 2004), 56921–56923

Public Debt Bureau
See Fiscal Service

Securities and Exchange Commission
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 56801–56802
Investment Company Act of 1940:
Atlas Assets, Inc., et al., 56802–56804
Joint industry plan:
Pacific Exchange, Inc., et al., 56804–56806
Securities:
National Association of Securities Dealers, Inc.; reporting requirements exemption, 56806–56808

Self-regulatory organizations; proposed rule changes:
Depository Trust Co., 56808–56809
Fixed Income Clearing Corp., 56809–56811
National Association of Securities Dealers, Inc., 56811–56812
National Securities Clearing Corp., 56812–56813
Pacific Exchange, Inc., 56813–56816

Surface Mining Reclamation and Enforcement Office
PROPOSED RULES
Abandoned mine land reclamation:
Coal production fees and fee allocation, republication, 56907–56920

Textile Agreements Implementation Committee
See Committee for the Implementation of Textile Agreements

Transportation Department
See Federal Aviation Administration
See Federal Highway Administration
See Federal Railroad Administration
RULES
Economic regulations:
Passenger baggage liability; minimum limit, 56692–56693
NOTICES
Aviation proceedings:
Agreements filed; weekly receipts, 56816
Certificates of public convenience and necessity and foreign air carrier permits; weekly applications, 56816

Treasury Department
See Fiscal Service

Separate Parts In This Issue

Part II
Health and Human Services Department, Food and Drug Administration, 56823–56906

Part III
Interior Department, Surface Mining Reclamation and Enforcement Office, 56907–56920

Part IV
Executive Office of the President, Presidential Documents, 56921–56923

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

Executive Orders:
13224 (See Notice of September 21, 2004) 56665
13357 56665

Administrative Orders:
Notices
Notice of September 21, 2004 56923

5 CFR

Proposed Rules:
531 56721

7 CFR
958 56667
980 56667

Proposed Rules:
1032 56725

14 CFR
25 (2 documents) 56672, 56674
39 (6 documents) 56676, 56680, 56682, 56683, 56687, 56688
71 56690
254 56692

Proposed Rules:
39 (3 documents) 56730, 56733, 56735

15 CFR
744 56693

19 CFR

Proposed Rules:
351 56738

21 CFR

Proposed Rules:
16 56824
118 56824

30 CFR

Proposed Rules:
870 56908
872 56908

33 CFR
165 56695

40 CFR
81 56697
180 56711

45 CFR
2552 56718
2553 56718

50 CFR
635 56719

Proposed Rules:
635 56741

Federal Register
Vol. 69, No. 183
Wednesday, September 22, 2004

Presidential Documents

Title 3—

The President

Executive Order 13357 of September 20, 2004

Termination of Emergency Declared in Executive Order 12543 With Respect to the Policies and Actions of the Government of Libya and Revocation of Related Executive Orders

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*) (IEEPA), the National Emergencies Act (50 U.S.C. 1601 *et seq.*) (NEA), section 5 of the United Nations Participation Act, as amended (22 U.S.C. 287c) (UNPA), sections 504 and 505 of the International Security and Development Cooperation Act (22 U.S.C. 2349aa–8 and 2349aa–9), section 40106 of title 49, United States Code, and section 301 of title 3, United States Code,

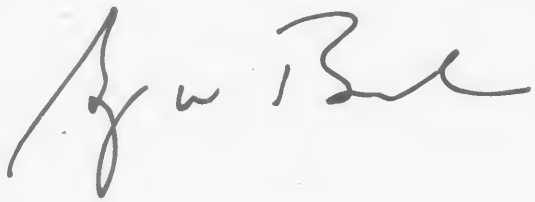
I, GEORGE W. BUSH, President of the United States of America, find that the situation that gave rise to the declaration of a national emergency in Executive Order 12543 of January 7, 1986, with respect to the policies and actions of the Government of Libya, and that led to the steps taken in that order and in Executive Order 12544 of January 8, 1986, and Executive Order 12801 of April 15, 1992, has been significantly altered by Libya's commitments and actions to eliminate its weapons of mass destruction programs and its Missile Technology Control Regime (MTCR) -class missiles, and by other developments. Accordingly, I hereby terminate the national emergency declared in Executive Order 12543, and revoke that Executive Order, Executive Order 12544, and Executive Order 12801. I also hereby revoke Executive Order 12538 of November 15, 1985, and further order:

Section 1. Pursuant to section 202(a) of the NEA (50 U.S.C. 1622(a)), termination of the national emergency declared in Executive Order 12543 with respect to the policies and actions of the Government of Libya shall not affect any action taken or proceeding pending not finally concluded or determined as of the effective date of this order, any action or proceeding based on any act committed prior to such date, or any rights or duties that matured or penalties that were incurred prior to such date.

Sec. 2. This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, instrumentalities, or entities, its officers or employees, or any other person.

Sec. 3. (a) This order is effective at 12:01 a.m. eastern daylight time on September 21, 2004.

(b) This order shall be transmitted to the Congress and published in the **Federal Register**.



THE WHITE HOUSE,
September 20, 2004.

[FR Doc. 04–21411
Filed 9–21–04; 8:45 am]
Billing code 3195–01–P

Rules and Regulations

Federal Register
Vol. 69, No. 183
Wednesday, September 22, 2004

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Parts 958 and 980

[Docket No. FV04–958–1 IFR]

Onions Grown in Certain Designated Counties in Idaho and Malheur County, Oregon; Relaxation of Handling and Import Regulations

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Interim final rule with request for comments.

SUMMARY: This rule relaxes the size requirement for pearl onions, relaxes the minimum grade and size requirements for cipolline onion varieties, and updates the regulatory text concerning certain reporting requirements for onions handled under the Idaho-Eastern Oregon onion marketing order. The marketing order regulates the handling of onions grown in Idaho and Eastern Oregon and is administered locally by the Idaho Eastern-Oregon Onion Committee (Committee). This rule also relaxes the requirements for pearl and cipolline onions under the import regulations as required by section 8e of the Agricultural Marketing Agreement Act of 1937. Specifically, this rule changes the definition of pearl onions to mean onions 2 inches in diameter or less, establishes a relaxed minimum grade of U.S. No. 2 and relaxed minimum diameter of 1½ inches for cipolline onions, and adds clarification and specificity to the reporting requirements for onions handled for peeling, chopping, or slicing. The changes are intended to facilitate the marketing of onions handled under the marketing order, improve producer returns, and bring the section 8e import regulation into conformity with the marketing order.

DATES: Effective: September 23, 2004; comments received by November 22, 2004 will be considered prior to issuance of a final rule.

ADDRESSES: Interested persons are invited to submit written comments concerning this rule. Comments must be sent to the Docket Clerk, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue SW., STOP 0237, Washington, DC 20250–0237; Fax: (202) 720–8938; E-mail: *moab.docketclerk@usda.gov;* or Internet: *http://www.regulations.gov.* All comments should reference the docket number and the date and page number of this issue of the **Federal Register** and will be made available for public inspection in the Office of the Docket Clerk during regular business hours, or can be viewed at: *http://www.ams.usda.gov/fv/moab.html.*

FOR FURTHER INFORMATION CONTACT: Robert J. Curry, Northwest Marketing Field Office, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 1220 SW. Third Avenue, suite 385, Portland, Oregon 97204; telephone: (503) 326–2724, Fax: (503) 326–7440; or George Kelhart, Technical Advisor, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue SW., STOP 0237, Washington, DC 20250–0237; telephone: (202) 720–2491, Fax: (202) 720–8938.

Small businesses may request information on complying with this regulation by contacting Jay Guerber, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue SW., STOP 0237, Washington, DC 20250–0237; telephone: (202) 720–2491, Fax: (202) 720–8938, or E-mail: *Jay.Guerber@usda.gov.*

SUPPLEMENTARY INFORMATION: This rule is issued under Marketing Agreement No. 130 and Marketing Order No. 958, both as amended (7 CFR part 958), regulating the handling of onions grown in certain designated counties in Idaho, and Malheur County, Oregon, hereinafter referred to as the "order." The order is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the "Act."

This rule is also issued under section 8e of the Act, which provides that whenever certain specified commodities, including onions, are regulated under a Federal marketing order, imports of these commodities into the United States are prohibited unless they meet the same or comparable grade, size, quality, or maturity requirements as those in effect for the domestically produced commodities.

The Department of Agriculture (USDA) is issuing this rule in conformance with Executive Order 12866.

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule is not intended to have retroactive effect. This rule will not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under § 608c(15)(A) of the Act, any handler subject to an order may file with USDA a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. A handler is afforded the opportunity for a hearing on the petition. After the hearing USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA's ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

There are no administrative procedures which must be exhausted prior to any judicial challenge to the provisions of import regulations issued under section 8e of the Act.

This rule relaxes handling regulations for pearl and cipolline onions produced in certain designated counties in Idaho, and Malheur County Oregon, by redefining pearl onions to mean onions 2 inches in diameter or less, and by establishing a relaxed minimum grade of U.S. No. 2 and a relaxed minimum diameter of 1½ inches for cipolline onion varieties. As provided under section 8e of the Act, these changes also apply to all imported pearl and cipolline onions. This rule also adds clarification and specificity to the

reporting requirements by updating § 958.328(d) for onions handled for peeling, chopping, or slicing to reflect current form provisions. These changes were unanimously recommended by the Committee on April 1, 2004, and are intended to facilitate the marketing of Idaho-Eastern Oregon onions and improve producer returns.

Sections 958.51 and 958.52 of the order authorize the Committee to recommend, and the USDA to issue, grade, size, quality, pack, and container regulations for any variety or varieties of onions grown in the production area. Section 958.53 authorizes the issuance of special regulations to facilitate the handling of pearl onions as well as other special purpose shipments. Section 958.65 authorizes the Committee to collect information from handlers. Regulations specific to the handling of onions produced in the regulated production area are contained in § 958.328 of the order's handling regulations, whereas relevant import regulations are contained in § 980.117 and § 980.501 of the vegetable import regulations.

Pearl onions and cipolline onions are small, specialty onions with end uses in both the fresh market (raw and cooked) and processed market. Although there are relatively few pearl onions and cipolline onions produced in the Northwest, increased producer interest in both types of onions, as well as changes in customer preferences, encouraged this Committee recommendation.

Pearl onions are defined, in part, in both the order and the import regulations as onions that are produced using specific cultural practices that limit growth and are inspected and certified as measuring no larger than the maximum designated size. Factors that can limit growth, and subsequently final bulb size, include the variety, plant density, depth planted, photoperiod, and temperature. Pearl onions are mild flavored white, red, or yellow skinned onions generally ranging in size from about ¾ inch to less than 2 inches in diameter.

Although pearl onions must be inspected and certified as measuring no larger than the maximum size designated under the order, they have been exempt from the minimum grade, size, and maturity requirements of the order since 1985. In order to be eligible for this exemption, the onions must be no greater than the stated maximum size limit. Although exempt from the grade, size, and maturity requirements, shipments of pearl onions are subject to administrative assessments.

Due to previous changes in handling, marketing, and buyer preferences, the defined maximum diameter of pearl onions was changed from 1½ inches to 1¾ inches in 1990 (55 FR 27825). Similarly, due to ongoing changes in handling, marketing, and buyer preferences, this rule further relaxes the size requirements by increasing the defined maximum diameter of pearl onions to 2 inches.

The pearl onion market is a minor segment of the onion market served by the Idaho-Eastern Oregon production area. As such, the Committee continues to believe that pearl onions do not compete directly with most of the onions produced in this area and that the current exemption from size, grade, and maturity requirements should continue.

Due to changing dynamics in the cultural and handling practices in this region, as well as buyer and consumer preferences, this relaxation in requirements will help facilitate the efficient movement of pearl onions into fresh market channels and may also enhance producer returns.

Cipolline onions—also known as Borettana onions—are traditional Italian onions that are relatively small and button shaped, and include white, red, and yellow varieties. As noted earlier, cipolline (pronounced chip-ah-LEE-nee) onions have constituted a very small percentage of the onions produced and marketed in the order's regulated production area in the past. However, due to an increase in cipolline onion production, and a growing consumer interest in this specialty onion, the order's grade and size requirements were beginning to adversely affect the handling and marketing of cipolline onions.

Under the order, white, red, and yellow onion varieties handled for the fresh market have varying minimum grade and size requirements. Specifically, white varieties must meet a minimum grade of U.S. No. 1, 1 inch minimum to 2 inches maximum or at least 1½ inches minimum, whereas red varieties must meet a minimum grade of U.S. No. 2 and a minimum diameter of 1½ inches. The most prevalent onions packed in the Idaho-Eastern Oregon production area, yellow onion varieties, must meet a minimum grade of U.S. No. 2 and measure 3 inches or larger in diameter, or, if packed to U.S. No. 1 grade, they may have a minimum measurement of 1¾ inches in diameter. Prior to this change, cipolline onions were handled, graded, and inspected in accordance with the different order requirements for white, red, and yellow onion varieties.

Cipolline onions, however, range in size from about 1 inch in diameter to about 3 inches in diameter, with prevalence found in the 2-inch to 3-inch sizes. Since most of the cipolline onions produced in this area are yellow, U.S. No. 2 grade cipolline onions would have difficulty meeting the three-inch minimum size requirement. Following a review of the cultural practices, supply situation, and demand characteristics for cipolline onions, the Committee determined that the marketing of all cipolline onion varieties would be enhanced if handlers were held to a minimum grade of U.S. No. 2 and a minimum size of 1½inches in diameter—the same minimum requirements for all Idaho-Eastern Oregon red varieties.

This rule, by establishing a minimum grade and size for all cipolline onion varieties distinct from the prevalent white, red, and yellow varieties, will help ensure that marketable cipolline onions meet the minimum requirements of the order. While the requirements in place prior to this action allowed for the shipment of white cipolline onions that graded U.S. No. 1, 1-inch minimum to 2-inches maximum, no such shipments were ever made from the production area. Therefore, this change in the minimum grade and size requirements is not expected to impact the shipment of white cipolline onions.

As mentioned earlier, section 8e of the Act provides that when certain domestically produced commodities, including onions, are regulated under a Federal marketing order, imports of that commodity must meet the same or comparable grade, size, quality, and maturity requirements. Section 8e also provides that whenever two or more marketing orders regulating the same commodity produced in different areas of the United States are concurrently in effect, a determination must be made as to which of the areas produces the commodity in most direct competition with the imported commodity. Imports must meet the requirements established for that particular area.

Grade, size, quality, and maturity regulations have been issued regularly under both Marketing Order No. 958 and Marketing Order No. 959, which regulates the handling of onions produced in South Texas, since the marketing orders were established. The import regulations specify that import requirements for onions are to be based on the seasonal categories of onions produced in both marketing order areas. In that regard, imported onions must meet the requirements of the Idaho-Eastern Oregon onion marketing order during the period June 5 through March

9 and the South Texas onion marketing order during the period March 10 through June 4 of each season. Pearl and cipolline onions are not currently produced in South Texas. However, they are produced and marketed in limited quantities through out the year under the Idaho-Eastern Oregon onion marketing order. Therefore, the requirements for imported pearl and cipolline onions should be based upon the requirements established under Marketing Order No. 958 for the entire year.

As a consequence, this action changes § 980.117(a)(1) and (2) and (b)(1) of the onion import regulations by determining that imports of pearl and cipolline onions during the entire year are in most direct competition with the marketing of onions produced under Marketing Order No. 958 and changes § 980.117(h) and (i) by redefining pearl onions to mean onions produced using specific cultural practices that limit growth to 2 inches or less in diameter. Accordingly, all cipolline onions imported must be U.S. No. 2 grade or better and measure 1½ inches or more in diameter, and pearl onions cannot be larger than 2 inches in diameter.

This rule also clarifies certain handler reporting requirements. Under the handling regulations, onions that are inspected and certified as meeting the grade, size, maturity, and pack requirements of the order and are subsequently peeled, chopped, or sliced for fresh market within the production area may be handled without reinspection. Section 958.328(d) provides reporting procedures for the handling of such previously inspected onions for peeling, chopping, or slicing.

The Committee uses Form FV–37, Rehandling of Onions Report, to collect information from handlers specific to onions handled under this section. These reporting requirements are in place primarily to ensure handler compliance with the order's provisions. This rule adds clarification and specificity to the regulations by updating § 958.328(d) to reflect current Form FV–37 provisions. The change is expected to minimize handler errors in completing the form and help ensure timely submission of the completed form to the Committee.

This form has been approved previously by the Office of Management and Budget (OMB) under OMB Number 0581–0178, Vegetable and Specialty Crops. This action will not impact the information collection burden hours currently approved by OMB for this form.

Initial Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA), the Agricultural Marketing Service (AMS) has considered the economic impact of this action on small entities. Accordingly, AMS has prepared this initial regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and the rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf. Thus, both statutes have small entity orientation and compatibility.

Import regulations issued under the Act are based on those established under Federal marketing orders which regulate the handling of domestically produced products.

There are approximately 42 handlers of Idaho-Eastern Oregon onions who are subject to regulation under the order and approximately 190 onion producers in the regulated area. In addition, based on the most recent information available, approximately 472 importers of onions are subject to import regulations and may be affected by this rule. Small agricultural service firms are defined by the Small Business Administration (13 CFR 121.201) as those having annual receipts of less than $5,000,000, and small agricultural producers are defined as those having annual receipts of less than $750,000.

Based on its assessment records, the Committee estimates that about 39 of the 42 handlers ship less than $5,000,000 worth of onions on an annual basis. In addition, based on the acreage (20,600), production (12,000,000 cwt), and total producer revenue ($130,768,000) reported by the National Agricultural Statistics Service for 2003, and the current number of onion producers (190), the average annual gross producer revenue is approximately $688,252. Thus, the majority of the onion handlers and the onion producers in this industry may be classified as small entities. Although it is not known how many importers of onions may be classified as small entities, we believe that many of the 472 importers can be classified as such. There are two firms involved in altering onions under the order and both firms can be classified as small entities.

This rule relaxes the size requirement for pearl onions, relaxes the minimum grade and size requirements for cipolline onions, and clarifies certain reporting requirements for onions handled under the Idaho-Eastern Oregon onion marketing order. Authority for this action is contained in §§ 958.51, 958.52, 958.53, and 958.65 of the order. This rule—unanimously recommended by the Committee at its April 1, 2004, meeting—changes § 958.328(h) by redefining pearl onions to mean onions produced using specific cultural practices that limit growth to the same general size as boilers and picklers (as defined in the U.S. Standards for Grades of Onions), and that have been inspected and certified as measuring 2 inches in diameter or less. In addition, this rule changes § 958.328(a)(2) by adding cipolline onions to the minimum grade and size requirements established for red onion varieties: U.S. No. 2 grade or better and 1½ inch diameter or larger.

Under authority in section 8e of the Act, this rule also changes § 980.117(a)(1) and (2), and (b)(1), of the onion import regulations by determining that imports of pearl and cipolline onions are in most direct competition during the entire year with the marketing of onions produced under Marketing Order No. 958 and changes § 980.117(h) and (i) by redefining pearl onions to mean onions produced using specific cultural practices that limit growth to 2 inches in diameter or less. Although not specifically referenced in the text of § 980.117, this rule also relaxes the minimum grade and size for imported cipolline onions to U.S. No. 2 grade and 1½ inches in diameter.

Finally, this rule updates § 958.328(d) to reflect the current form used for onions handled for peeling, chopping, or slicing. This action is intended to facilitate the handling and marketing of pearl and cipolline onions, increase producer returns, and help minimize errors in completing Form FV–37 concerning the handling of onions for peeling, chopping, or slicing, and to help ensure timely submission of the form to the Committee.

According to the Committee, there is currently one producer and one handler of pearl and cipolline onions in the regulated production area, and, as such, statistics relating to the production and marketing of pearl and cipolline onions in the Idaho-Eastern Oregon onion production area cannot be made available. The quantity of such specialty onions, however, would be minor in relation to the prevalent large, globular shaped Spanish-type onion produced in the production area. Regarding pearl and cipolline onions produced elsewhere in the United States or imported into the United States: statistical information is available

grouped by dry bulb type onions, green onions, or onion sets and is generally unavailable by variety, size, or color. However, the U.S. Department of Commerce does track the quantity of pearl onions imported into the United States with a maximum diameter of .39 inches. In 2003, for example, approximately 211 hundredweight of pearl onions (less than or equal to .39 inches in diameter) were imported—in diminishing order—from Chile, Spain, China, Mexico, and India. In comparison, most onions imported into the U.S. are produced in Mexico, Canada, Peru, and Chile. Currently, there are no government statistics on the domestic production or importation of cipolline onions.

Regarding the impact of this rule on affected entities, relaxing the size requirement for pearl onions and the grade and size requirement for cipolline onions is expected to benefit handlers, importers, and producers. With the change in the definition of pearl onions to include onions as large as 2 inches in diameter, a potentially greater quantity of onions will pass inspection and thus be certified under the order's pearl onion exemption provisions. Similarly, by relaxing the minimum grade and size requirements for cipolline onions, a greater quantity of these onions should meet the order's handling regulations. This could translate into an increased market for cipolline onions and greater returns for handlers, importers, and producers. While the requirements in place prior to this action allowed for the shipment of white cipolline onions that graded U.S. No. 1, 1-inch minimum to 2 inches maximum, no such shipments were ever made. Therefore, this action is not expected to impact the shipment of white cipolline onions.

The clarification of reporting requirements for peeled, chopped, and sliced onions will have the tangible effect of providing more clearly understood instructions to handlers who are required to complete Form FV–37.

The Committee considered several alternatives to the relaxation in handling regulations for pearl and cipolline onions. The Committee initiated this action due to a request from the Idaho-Eastern Oregon onion industry's single pearl and cipolline onion producer and handler for an all-inclusive exemption from the requirements of the order. A special subcommittee was formed to study the request. The initial request was an exemption for an entire specialty product line, which included onion sets, pearl onions, boiler onions, prepack onions, cipolline onions, and shallots. The requester's main contention with the order is that none of his onions fit the profile of the Idaho-Eastern Oregon onion industry's foremost product, the large, globular shaped and mild Spanish-type onion. In addition, the requester was of the view that the Committee's promotion efforts—a major budgetary item for the Committee—does not benefit him as a producer and marketer of the small specialty onions. The requester also stated that the cost to him in complying with the order—in administrative assessments and inspection fees—is too high when considering his benefits from the order.

The subcommittee noted that onion sets and shallots do not need to be considered for further exemptions since neither is regulated under the marketing order. In addition, the subcommittee determined that boiler and prepacker size onions should not be exempt from the handling regulations since both are produced throughout the regulated production area. Various members of the subcommittee were of the view that the marketing of out-of-grade and off-size boiler and prepacker onions would have a negative impact on the marketing of all Idaho-Eastern Oregon onions.

Further, as noted earlier in this document, pearl onions have been exempt from the minimum grade, size, and maturity requirements of § 958.328 for several years. The subcommittee determined that an increase in the maximum size for pearl onions would facilitate the handling and marketing of these onions. The subcommittee considered increasing the maximum size under the pearl onion definition from 1⅞ inches to as much as 2¾ inches in diameter. This was rejected, however, because this would permit handlers to ship these onions exempt from the quality requirements in competition with larger sized onions subject to such requirements. The subcommittee also rejected consideration of an exemption from the current assessment and inspection requirements for pearl onions as being detrimental to the program. Pearl onions are inspected under the order to assure that they do not exceed the maximum diameter permitted.

Finally, the subcommittee considered various exemption and regulatory options in regard to cipolline onions. A complete exemption from the order was rejected since the subcommittee considered the cipolline onions as being a competitive product to the prevalent onion varieties produced and marketed under the order. Consideration was also given to establishing a different regulatory scheme for the county in which the cipolline onions are produced. This was not considered a viable option due to administrative concerns and the fact cipolline onions can be produced anywhere within the production area.

The Committee, based on the subcommittee's consideration of the issue, determined that pearl and cipolline onions are promoted through the order's generic promotion efforts since a major component of these efforts are coupled to the Idaho-Eastern Oregon onion logo. In this regard, the Committee feels that all handlers within the regulated production area benefit from the order.

This rule will not impose any additional reporting or recordkeeping requirements on either small or large onion handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies. In addition, USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this rule.

The Committee's meeting was widely publicized throughout the Idaho-Eastern Oregon onion industry and all interested persons were invited to attend the meeting and participate in Committee deliberations. Like all Committee meetings, the April 1, 2004, meeting was a public meeting and all entities, both large and small, were able to express their views on this issue.

Also, as indicated earlier, the subcommittee appointed to consider this matter met on February 25, 2004, and discussed this issue in detail. That meeting was also a public meeting and both large and small entities were able to participate and express their views. Finally, interested persons are invited to submit information on the regulatory and informational impacts of this action on small businesses.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: *http://www.ams.usda.gov/fv/moab.html*. Any questions about the compliance guide should be sent to Jay Guerber at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

This rule invites comments on a change to the handling regulations prescribed under the Idaho-Eastern Oregon onion marketing order and the onion import regulations. Any comments received will be considered prior to finalization of this rule.

After consideration of all relevant material presented, including the Committee's recommendation, and

other information, it is found that this interim final rule, as hereinafter set forth, will tend to effectuate the declared policy of the Act.

In accordance with section 8e of the Act, the United States Trade Representative has concurred with the issuance of this rule.

Pursuant to 5 U.S.C. 553, it is also found and determined upon good cause that it is impracticable, unnecessary, and contrary to the public interest to give preliminary notice prior to putting this rule into effect and that good cause exists for not postponing the effective date of this rule until 30 days after publication in the **Federal Register** because: (1) Handlers will begin shipping onions for the 2004–2005 season in August and to ensure maximum benefit to the industry, this relaxation should be in effect as soon as possible; (2) the Committee unanimously recommended these changes at a public meeting and interested parties had an opportunity to provide input; and (3) this rule provides a 60-day comment period and any comments received will be considered prior to finalization of this rule.

List of Subjects

7 CFR Part 958

Marketing agreements, Onions, Reporting and recordkeeping requirements.

7 CFR Part 980

Food grades and standards, Imports, Marketing agreements, Onions, Potatoes, Tomatoes.

■ For the reasons set forth in the preamble, 7 CFR parts 958 and 980 are amended as follows:

■ 1. The authority citation for 7 CFR parts 958 and 980 continues to read as follows:

Authority: 7 U.S.C. 601–674.

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

■ 2. In § 958.328, paragraphs (a)(1) and (2), paragraph (d), and paragraph (h), are revised to read as follows:

§ 958.328 Handling regulation.

* * * * *

(a) *Grade and size requirements—(1) White varieties (except cipolline (Borettana) varieties).* Shall be either:

(i) U.S. No. 1, 1 inch minimum to 2 inches maximum diameter; or

(ii) U.S. No. 1, at least 1½ inches minimum diameter. However, neither of these two categories of onions may be commingled in the same bag or other container.

(2) *Cipolline (Borettana) varieties and red varieties.* U.S. No. 2 or better grade, at least 1½ inches minimum diameter.

* * * * *

(d) *Onions for peeling, chopping, or slicing.* Onions that have been inspected and certified as meeting the requirements of paragraphs (a) and (b) of this section and that are subsequently peeled, chopped, or sliced for fresh market within the production area may be handled without reinspection subject to the following:

(1) Each handler making shipments of onions for altering by peeling, chopping, or slicing must, within 15 days of delivery of the onions, provide the committee with a copy of the original inspection certificate verifying that minimum marketing order requirements have been met. Furthermore, each handler of onions for peeling, chopping, or slicing must, within 15 days of delivery of the onions, provide the handler responsible for alteration of the onions and the committee the following information on forms provided by the committee:

(i) Business name, address, telephone number, signature and the date the form was signed;

(ii) The date the onions were delivered to the handler responsible for alteration of the onions by peeling, chopping, or slicing;

(iii) Information specific to the delivery of such onions to that handler (*e.g.*, rail car number, truck license number, or "from storage" if both handlers are the same entity);

(iv) Inspection certificate number;

(v) The hundredweight of onions delivered for alteration;

(vi) Such other information that may be required by the committee.

(2) Each handler responsible for alteration of onions for peeling, chopping, or slicing must, within 15 days of alteration of the onions, provide the handler and the committee the following information on forms provided by the committee:

(i) Business name, address, telephone number, signature and the date the form was signed;

(ii) The date the onions were altered by peeling, chopping, or slicing;

(iii) The hundredweight of onions after alteration;

(iv) Such other information that may be required by the committee.

Handlers who peel, chop, or slice onions produced outside the production area must provide the committee with documentation showing that the onions so prepared were produced outside the production area.

* * * * *

(h) *Definitions.* The terms "U.S. No. 1", "U.S. Commercial," and "U.S. No. 2" have the same meaning as defined in the United States Standards for Grades of Onions (Other than Bermuda Granex-Grano and Creole Types), as amended (7 CFR 51.2830 through 51.2854), or the United States Standards for Grades of Bermuda-Granex-Grano Type Onions (7 CFR 51.3195 through 51.3209), as amended, whichever is applicable to the particular variety, or variations thereof specified in this section. The term "braided red onions" means onions of red varieties with tops braided (interlaced). "Pearl onions" means onions produced using specific cultural practices that limit growth to the same general size as boilers and picklers (defined in the United States Standards specified in this paragraph), and that have been inspected and certified as measuring 2 inches in diameter or less. The term "moderately cured" means the onions are mature and are more nearly well cured than fairly well cured. Other terms used in this section have the same meaning as when used in Marketing Agreement No. 130 and this part.

PART 980—VEGETABLES; IMPORT REGULATIONS

■ 3. In § 980.117, paragraphs (a)(2), (b)(1) and (2), (h), and (i) are revised to read as follows:

§ 980.117 Import regulations; onions.

(a) * * *

(2) Therefore, it is hereby determined that: Imports of onions during the June 5 through March 9 period, and the entire year for imports of pearl and cipolline varieties of onions, are in most direct competition with the marketing of onions produced in designated counties of Idaho and Malheur County, Oregon, covered by Marketing Order No. 958, as amended (7 CFR Part 958) and during the March 10 through June 4 period the marketing of imported onions, not including pearl or cipolline varieties of onions, is in most direct competition with onions produced in designated counties in South Texas covered by Marketing Order No. 959, as amended (7 CFR part 959).

(b) * * *

(1) During the period June 5 through March 9 of each marketing year, and the entire year for pearl and cipolline onions, whenever onions grown in designated counties in Idaho and Malheur County, Oregon, are regulated under Marketing Order No. 958, imported onions shall comply with the

grade, size, quality, and maturity requirements imposed under that order.

(2) During the period March 10 through June 4 of each marketing year, whenever onions grown in designated counties in South Texas are regulated under Marketing Order No. 959, imported onions, not including pearl and cipolline onions, shall comply with the grade, size, quality, and maturity requirements imposed under that order.

* * * * *

(h) *Definitions.* For the purpose of this section, *Onions* means all varieties of *Allium cepa* marketed dry, except dehydrated, canned, or frozen onions, pickling onions in brine, onion sets, green onions, or braided red onions. The term *U.S. No. 2* has the same meaning as set forth in the United States Standards for Grades of Bermuda-Granex-Grano Type Onions (7 CFR 2851.3195 through 2851.3209), the United States Standards for Grades of Creole Onions (7 CFR 2851.3955 through 2851.3970), or the United States Standards for Grades of Onions Other Than Bermuda-Granex-Grano and Creole Types (7 CFR 2851.2830 through 2851.2854), whichever is applicable to the particular variety, and variations thereof specified in this section. The term *moderately cured* means the onions are mature and are more nearly well cured than fairly well cured. *Importation* means release from the custody of U.S. Customs and Border Protection. The term *pearl onions* means onions produced using specific cultural practices that limit growth to 2 inches in diameter or less.

(i) *Exemptions.* The grade, size, quality and maturity requirements of this section shall not be applicable to onions imported for processing, livestock feed, charity, or relief, and pearl onions, onion sets (plantings), braided red onions, and minimum quantity shipments of 110 pounds, but such onions shall be subject to the safeguard provisions in § 980.501. Processing includes canning, freezing, dehydration, extraction (juice) and pickling in brine. Processing does not include fresh chop, fresh cut, convenience food or other pre-packaged salad operations. Pearl onions must be inspected for size prior to entry into the United States.

Dated: September 16, 2004.

Kenneth C. Clayton,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 04–21238 Filed 9–21–04; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. NM289, Special Conditions No. 25–272–SC]

Special Conditions: Dassault Model Mystere-Falcon 20–C5, 20–D5, 20–E5, and 20–F5 Series and Dassault Model Fan Jet Falcon Series C, D, E, F, and G Airplanes; High Intensity Radiated Fields (HIRF)

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions; request for comments.

SUMMARY: These special conditions are issued for Dassault Model Mystere-Falcon 20–C5, 20–D5, 20–E5, and 20–F5 series and Dassault Model Fan Jet Falcon series C, D, E, F, and G airplanes modified by Genesis3 Engineering. These modified airplanes will have novel and unusual design features when compared to the state of technology envisioned in the airworthiness standards for transport category airplanes. The modification incorporates the installation of an Innovative Solutions & Support (IS&S) Dual Air Data Display Unit (ADDU) and an Air Data Sensor Unit (ADS). The applicable airworthiness regulations do not contain adequate or appropriate safety standards for the protection of these systems from the effects of high-intensity radiated fields (HIRF). These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that provided by the existing airworthiness standards.

DATES: The effective date of these special conditions is September 13, 2004. Comments must be received on or before October 22, 2004.

ADDRESSES: Comments on these special conditions may be mailed in duplicate to: Federal Aviation Administration, Transport Airplane Directorate, Attn: Rules Docket (ANM–113), Docket No. NM289, 1601 Lind Avenue, SW., Renton, Washington, 98055–4056; or delivered in duplicate to the Transport Airplane Directorate at the above address. All comments must be marked: Docket No. NM289.

FOR FURTHER INFORMATION CONTACT: Mr. Greg Dunn, FAA, Airplane and Flight Crew Interface Branch, ANM–111, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue, SW., Renton, Washington, 98055–4056; telephone (425) 227–2799; facsimile (425) 227–1320.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA has determined that notice and opportunity for prior public comment is impracticable because these procedures would significantly delay certification, and thus delivery, of the affected airplanes. In addition, the substance of these special conditions has been subject to the public comment process in several prior instances with no substantive comments received. The FAA therefore finds that good cause exists for making these special conditions effective upon issuance; however, the FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. The most helpful comments reference a specific portion of the special conditions, explain the reason for any recommended change, and include supporting data. We ask that you send us two copies of written comments.

We will file in the docket all comments we receive, as well as a report summarizing each substantive public contact with FAA personnel concerning these special conditions. The docket is available for public inspection before and after the comment closing date. If you wish to review the docket in person, go to the address in the **ADDRESSES** section of this preamble between 7:30 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

We will consider all comments we receive on or before the closing date for comments. We will consider comments filed late if it is possible to do so without incurring expense or delay. We may change these special conditions based on the comments we receive.

If you want the FAA to acknowledge receipt of your comments on these special conditions, include with your comments a pre-addressed, stamped postcard on which the docket number appears. We will stamp the date on the postcard and mail it back to you.

Background

On March 29, 2004, Genesis3 Engineering, Woodland Park, Colorado, applied to the FAA, Denver Aircraft Certification Office, for a supplemental type certificate (STC) to modify Dassault Model Mystere-Falcon 20–C5, 20–D5, 20–E5, and 20–F5 series and Dassault Model Fan Jet Falcon series C, D, E, F, and G airplanes. The Dassault Model Mystere-Falcon 20–C5, 20–D5, 20–E5, and 20–F5 series and Dassault Model Fan Jet Falcon series C, D, E, F, and G airplanes are small transport category

airplanes powered by two turbofan engines, with a maximum takeoff weight of 32,000 pounds. These airplanes operate with a 2-pilot crew and can hold up to 10 passengers. They are currently approved under Type Certificate No. A7EU.

The proposed modification incorporates the installation of an Innovative Solutions & Support (IS&S) Dual Air Data Display Unit (ADDU) and an Air Data Sensor Unit (ADS). The information these units display is flight critical. The avionics/electronics and electrical systems to be installed in this airplane have the potential to be vulnerable to high-intensity radiated fields (HIRF) external to the airplane.

Type Certification Basis

Under the provisions of 14 CFR 21.101, Amendment 21–69, Genesis3 Engineering must show that the Dassault Model Mystere-Falcon 20–C5, 20–D5, 20–E5, and 20–F5 series and Dassault Model Fan Jet Falcon series C, D, E, F, and G airplanes, as changed, continue to meet the applicable provisions of the regulations incorporated by reference in Type Certificate No. A7EU, or the applicable regulations in effect on the date of application for the change. The regulations incorporated by reference in the type certificate are commonly referred to as the "original type certification basis."

The original type certification basis for the Dassault Model Mystere-Falcon 20–C5, 20–D5, 20–E5, and 20–F5 series and Dassault Model Fan Jet Falcon series C, D, E, F, and G includes Civil Air Regulations (CAR) 4b, as amended by amendment 4b–1 through 4b–12, Special Regulation SR–422B, and provisions of 14 CFR part 25 Amendment 25–4, in lieu of CAR 4b.350 (e) and (f).

If the Administrator finds that the applicable airworthiness regulations (*i.e.*, CAR 4b, as amended) do not contain adequate or appropriate safety standards for the modified Dassault Model Mystere-Falcon 20–C5, 20–D5, 20–E5, and 20–F5 series and Dassault Model Fan Jet Falcon series C, D, E, F, and G airplanes because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

In addition to the applicable airworthiness regulations and special conditions, the Dassault Model Mystere-Falcon 20–C5, 20–D5, 20–E5, and 20–F5 series and Dassault Model Fan Jet Falcon series C, D, E, F, and G airplanes must comply with the fuel vent and exhaust emission requirements of 14 CFR part 34 and the noise certification requirements of 14 CFR part 36.

Special conditions, as defined in 14 CFR 11.19, are issued in accordance with § 11.38 and become part of the type certification basis in accordance with § 21.101(b)(2).

Special conditions are initially applicable to the model for which they are issued. Should Genesis3 Engineering apply at a later date for a supplemental type certificate to modify any other model included on Type Certificate No. A7EU to incorporate the same or similar novel or unusual design feature, these special conditions would also apply to the other model under the provisions of § 21.101(a)(1).

Novel or Unusual Design Features

As noted earlier, the modified Dassault Model Mystere-Falcon 20–C5, 20–D5, 20–E5, and 20–F5 series and Dassault Model Fan Jet Falcon series C, D, E, F, and G airplanes will incorporate an Innovative Solutions & Support (IS&S) Dual Air Data Display Unit (ADDU) and an Air Data Sensor Unit (ADS) that will perform critical functions. These systems may be vulnerable to high-intensity radiated fields external to the airplane. The current airworthiness standards of part 25 do not contain adequate or appropriate safety standards for the protection of this equipment from the adverse effects of HIRF. Accordingly, this system is considered to be a novel or unusual design feature.

Discussion

There is no specific regulation that addresses protection requirements for electrical and electronic systems from HIRF. Increased power levels from ground-based radio transmitters and the growing use of sensitive avionics/electronics and electrical systems to command and control airplanes have made it necessary to provide adequate protection.

To ensure that a level of safety is achieved equivalent to that intended by the regulations incorporated by reference, special conditions are needed for the Dassault Model Mystere-Falcon 20–C5, 20–D5, 20–E5, and 20–F5 series and Dassault Model Fan Jet Falcon series C, D, E, F, and G airplanes modified by Genesis3 Engineering. These special conditions require that new avionics/electronics and electrical systems that perform critical functions be designed and installed to preclude component damage and interruption of function due to both the direct and indirect effects of HIRF.

High-Intensity Radiated Fields (HIRF)

With the trend toward increased power levels from ground-based transmitters, and the advent of space and satellite communications, coupled with electronic command and control of the airplane, the immunity of critical digital avionics/electronics and electrical systems to HIRF must be established.

It is not possible to precisely define the HIRF to which the airplane will be exposed in service. There is also uncertainty concerning the effectiveness of airframe shielding for HIRF. Furthermore, coupling of electromagnetic energy to cockpit-installed equipment through the cockpit window apertures is undefined. Based on surveys and analysis of existing HIRF emitters, an adequate level of protection exists when compliance with the HIRF protection special condition is shown with either paragraph 1 or 2 below:

1. A minimum threat of 100 volts rms (root-mean-square) per meter electric field strength from 10 KHz to 18 GHz.

a. The threat must be applied to the system elements and their associated wiring harnesses without the benefit of airframe shielding.

b. Demonstration of this level of protection is established through system tests and analysis.

2. A threat external to the airframe of the field strengths identified in the following table for the frequency ranges indicated. Both peak and average field strength components from the table are to be demonstrated.

Frequency	Field strength (volts per meter)	
	Peak	Average
10 kHz–100 kHz	50	50
100 kHz–500 kHz	50	50
500 kHz–2 MHz	50	50
2 MHz–30 MHz	100	100
30 MHz–70 MHz	50	50
70 MHz–100 MHz	50	50
100 MHz–200 MHz	100	100
200 MHz–400 MHz	100	100
400 MHz–700 MHz	700	50
700 MHz–1 GHz	700	100
1 GHz–2 GHz	2000	200
2GHz–4 GHz	3000	200
4 GHz–6 GHz	3000	200
6 GHz–8 GHz	1000	200
8 GHz–12 GHz	3000	300
12 GHz–18 GHz	2000	200
18 GHz–40 GHz	600	200

The field strengths are expressed in terms of peak of the root-mean-square (rms) over the complete modulation period.

The threat levels identified above are the result of an FAA review of existing studies on the subject of HIRF, in light of the ongoing work of the Electromagnetic Effects Harmonization Working Group of the Aviation Rulemaking Advisory Committee.

Applicability

As discussed above, these special conditions are applicable to Dassault Model Mystere-Falcon 20–C5, 20–D5, 20–E5, and 20–F5 series and Dassault Model Fan Jet Falcon series C, D, E, F, and G airplanes. Should Genesis3 Engineering apply at a later date for a supplemental type certificate to modify any other model included on Type Certificate No. A7EU, to incorporate the same or similar novel or unusual design features, these special conditions would apply to that model as well as under the provisions of 14 CFR 21.101(a)(1).

Conclusion

This action affects only certain novel or unusual design features on Dassault Model Mystere-Falcon 20–C5, 20–D5, 20–E5, and 20–F5 series and Dassault Model Fan Jet Falcon series C, D, E, F, and G airplanes. It is not a rule of general applicability and affects only the applicant who applied to the FAA for approval of these features on the airplane.

The substance of these special conditions has been subjected to the notice and comment procedure in several prior instances and has been derived without substantive change from those previously issued. Because a delay would significantly affect the certification of the airplane, which is imminent, the FAA has determined that prior public notice and comment are unnecessary and impracticable, and good cause exists for adopting these special conditions upon issuance. The FAA is requesting comments to allow interested persons to submit views that may not have been submitted in response to the prior opportunities for comment described above.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and record keeping requirements.

■ The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701, 44702, 44704.

The Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the supplemental type certification basis for the Dassault Model Mystere-Falcon 20–C5, 20–D5, 20–E5, and 20–F5 series and Dassault Model Fan Jet Falcon series C, D, E, F, and G modified by Genesis3 Engineering:

1. *Protection from Unwanted Effects of High-Intensity Radiated Fields (HIRF).* Each electrical and electronic system that performs critical functions must be designed and installed to ensure that the operation and operational capability of these systems to perform critical functions are not adversely affected when the airplane is exposed to high intensity radiated fields.

2. For the purpose of these special conditions, the following definition applies: *Critical Functions:* Functions whose failure would contribute to or cause a failure condition that would prevent the continued safe flight and landing of the airplane.

Issued in Renton, Washington, on September 13, 2004.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04–21224 Filed 9–21–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. NM288; Special Conditions No. 25–271–SC]

Special Conditions: Lockheed Martin Corporation Model 1329–23A, –23D, –23E, and 1329–25 Airplanes; High-Intensity Radiated Fields (HIRF)

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions; request for comments.

SUMMARY: These special conditions are issued for Lockheed Martin Corporation Model 1329–23A, –23D, –23E and 1329–25 airplanes modified by Garrett Aviation Services. These modified airplanes will have novel or unusual design features when compared to the state of technology envisioned in the airworthiness standards for transport category airplanes. The modification incorporates the installation of four Honeywell N1 Digital Electronic Engine Controls (DEEC) that perform critical functions. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for the protection of these systems from the effects of high-intensity-radiated fields (HIRF). These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: The effective date of these special conditions is September 13, 2004. Comments must be received on or before October 22, 2004.

ADDRESSES: Comments on these special conditions may be mailed in duplicate to: Federal Aviation Administration, Transport Airplane Directorate, Attn: Rules Docket (ANM–113), Docket No. NM288, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; or delivered in duplicate to the Transport Directorate at the above address. All comments must be marked *Docket No. NM288.*

FOR FURTHER INFORMATION CONTACT: Greg Dunn, FAA, Airplane and Flight Crew Interface Branch, ANM–111, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2799; facsimile (425) 227–1320.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA has determined that notice and opportunity for prior public comment is impracticable because these procedures would significantly delay certification of the airplane and thus delivery of the affected aircraft. In addition, the substance of these special conditions has been subject to the public comment process in several prior instances with no substantive comments received. The FAA therefore finds that good cause exists for making these special conditions effective upon issuance; however, the FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. The most helpful comments reference a specific portion of the special conditions, explain the reason for any recommended change, and include supporting data. We ask that you send us two copies of written comments.

We will file in the docket all comments we receive, as well as a report summarizing each substantive public contact with FAA personnel concerning these special conditions. The docket is available for public inspection before and after the comment closing date. If you wish to review the docket in person, go to the address in the **ADDRESSES** section of this preamble between 7:30 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

We will consider all comments we receive on or before the closing date for

comments. We will consider comments filed late if it is possible to do so without incurring expense or delay. We may change these special conditions based on the comments we receive.

If you want the FAA to acknowledge receipt of your comments on these special conditions, include with your comments a pre-addressed, stamped postcard on which the docket number appears. We will stamp the date on the postcard and mail it back to you.

Background

On December 4, 2003, Garrett Aviation Services, 1200 North Airport Drive, Capital Airport Springfield, IL 62707, applied for a supplemental type certificate (STC) to modify Lockheed Martin Corporation Model 1329–23A, –23D, –23E and 1329–25 airplanes. These models are currently approved under Type Certificate No. 2A15. They are transport category airplanes. The Lockheed Martin Corporation Model 1329–23A, –23D, –23E and 1329–25 airplanes are powered by four AiResearch TFE731–3–1F turbofan engines and have a maximum takeoff weight of 44,500 pounds. This airplane operates with a 2-pilot crew and can hold up to 10 passengers. The modification incorporates the installation of Honeywell N1 Digital Electronic Engine Controls (DEEC). The N1 Digital Electronic Engine Controls (DEEC) are a replacement for the existing analog electronic engine control (EEC) and also provide additional functional capability to the system. The digital avionics/electronics and electrical systems installed under this project in these airplanes have the potential to be vulnerable to high-intensity radiated fields (HIRF) external to the airplane.

Type Certification Basis

Under the provisions of 14 CFR 21.101, Garrett Aviation Services must show that the Lockheed Martin Corporation Model 1329–23A, –23D, –23E and 1329–25 airplanes, as changed, continue to meet the applicable provisions of the regulations incorporated by reference in Type Certificate No. 2A15, or the applicable regulations in effect on the date of application for the change. The regulations incorporated by reference in the type certificate are commonly referred to as the "original type certification basis." The certification basis for the Lockheed Martin Corporation Model 1329–23A, –23D, –23E and 1329–25 airplanes includes 14 CFR Part 25, dated February 1, 1964, as amended by Amendments 25–1 through 25–20, except for special conditions and exceptions noted in Type Certificate Data Sheet (TDCS) 2A15.

If the Administrator finds that the applicable airworthiness regulations (that is, 14 CFR part 25, as amended) do not contain adequate or appropriate safety standards for the Lockheed Martin Corporation Model 1329–23A, –23D, –23E and 1329–25 airplanes because of novel or unusual design features, special conditions are prescribed under the provisions of § 21.16.

In addition to the applicable airworthiness regulations and special conditions, the Lockheed Martin Corporation Model 1329–23A, –23D, –23E and 1329–25 airplanes must comply with the fuel vent and exhaust emission requirements of 14 CFR part 34 and the noise certification requirements of 14 CFR part 36.

Special conditions, as defined in 14 CFR 11.19, are issued in accordance with § 11.38 and become part of the type certification basis in accordance with § 21.101.

Special conditions are initially applicable to the model for which they are issued. Should Garrett Aviation Services apply at a later date for a supplemental type certificate to modify any other model included on Type Certificate No. 2A15 to incorporate the same or similar novel or unusual design features, these special conditions would also apply to the other model under the provisions of 14 CFR 21.101.

Novel or Unusual Design Features

The Lockheed Martin Corporation Model 1329–23A, –23D, –23E and 1329–25 airplanes modified by Garrett Aviation Services will incorporate Honeywell N1 Digital Electronic Engine Controls (DEEC) that will perform critical functions. These systems have the potential to be vulnerable to high-intensity radiated fields (HIRF) external to the airplane. The current airworthiness standards of part 25 do not contain adequate or appropriate safety standards for the protection of this equipment from the adverse effects of HIRF. Accordingly, these systems are considered to be novel or unusual design features.

Discussion

There is no specific regulation that addresses protection requirements for electrical and electronic systems from HIRF. Increased power levels from ground-based radio transmitters and the growing use of sensitive avionics/electronics and electrical systems to command and control airplanes have made it necessary to provide adequate protection.

To ensure that a level of safety is achieved equivalent to that intended by the regulations incorporated by reference, special conditions are needed for the Lockheed Martin Corporation Model 1329–23A, –23D, –23E and 1329–25 airplanes modified by Garrett Aviation Services. These special conditions require that new avionics/electronics and electrical systems that perform critical functions be designed and installed to preclude component damage and interruption of function due to both the direct and indirect effects of HIRF.

High-Intensity Radiated Fields (HIRF)

With the trend toward increased power levels from ground-based transmitters and the advent of space and satellite communications, coupled with electronic command and control of the airplane, the immunity of critical avionics/electronics and electrical systems to HIRF must be established.

It is not possible to precisely define the HIRF to which the airplane will be exposed in service. There is also uncertainty concerning the effectiveness of airframe shielding for HIRF. Furthermore, coupling of electromagnetic energy to cockpit-installed equipment through the cockpit window apertures is undefined. Based on surveys and analysis of existing HIRF emitters, an adequate level of protection exists when compliance with the HIRF protection special condition is shown with either paragraph 1, or 2 below:

1. A minimum threat of 100 volts rms (root-mean-square) per meter electric field strength from 10 KHz to 18 GHz.

a. The threat must be applied to the system elements and their associated wiring harnesses without the benefit of airframe shielding.

b. Demonstration of this level of protection is established through system tests and analysis.

2. A threat external to the airframe of the field strengths identified in the table below for the frequency ranges indicated. Both peak and average field strength components from the table are to be demonstrated.

Frequency	Field strength (volts per meter)	
	Peak	Average
10 kHz–100 kHz	50	50
100 kHz–500 kHz	50	50
500 kHz–2 MHz	50	50
2 MHz–30 MHz	100	100
30 MHz–70 MHz	50	50
70 MHz–100 MHz	50	50
100 MHz–200 MHz	100	100

Frequency	Field strength (volts per meter)	
	Peak	Average
200 MHz–400 MHz	100	100
400 MHz–700 MHz	700	50
700 MHz–1 GHz	700	100
1 GHz–2 GHz	2000	200
2 GHz–4 GHz	3000	200
4 GHz–6 GHz	3000	200
6 GHz–8 GHz	1000	200
8 GHz–12 GHz	3000	300
12 GHz–18 GHz	2000	200
18 GHz–40 GHz	600	200

The field strengths are expressed in terms of peak of the root-mean-square (rms) over the complete modulation period.

The threat levels identified above are the result of an FAA review of existing studies on the subject of HIRF, in light of the ongoing work of the Electromagnetic Effects Harmonization Working Group of the Aviation Rulemaking Advisory Committee.

Applicability

As discussed above, these special conditions are applicable to Lockheed Martin Corporation Model 1329–23A, –23D, –23E and 1329–25 airplanes modified by Garret Aviation Services. Should Garrett Aviation Services apply at a later date for a supplemental type certificate to modify any other model included on Type Certificate No. 2A15 to incorporate the same or similar novel or unusual design features, these special conditions would apply to that model as well under the provisions of § 21.101.

Conclusion

This action affects only certain novel or unusual design features on the Lockheed Martin Corporation Model 1329–23A, –23D, –23E and 1329–25 airplanes modified by Garrett Aviation Services. It is not a rule of general applicability and affects only the applicant who applied to the FAA for approval of these features on the airplane.

The substance of these special conditions has been subjected to the notice and comment period in several prior instances and has been derived without substantive change from those previously issued. Because a delay would significantly affect the certification of the airplane, which is imminent, the FAA has determined that prior public notice and comment are unnecessary and impracticable, and good cause exists for adopting these special conditions upon issuance. The FAA is requesting comments to allow interested persons to submit views that may not have been submitted in response to the prior opportunities for comment described above.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and record keeping requirements.

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701, 44702, 44704.

The Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the supplemental type certification basis for the Lockheed Martin Corporation Model 1329–23A, –23D, –23E and 1329–25 airplanes modified by Garrett Aviation Services.

1. *Protection from Unwanted Effects of High-Intensity Radiated Fields (HIRF).* Each electrical and electronic system that performs critical functions must be designed and installed to ensure that the operation and operational capability of these systems to perform critical functions are not adversely affected when the airplane is exposed to high-intensity radiated fields.

2. For the purpose of these special conditions, the following definition applies:

Critical Functions: Functions whose failure would contribute to or cause a failure condition that would prevent the continued safe flight and landing of the airplane.

Issued in Renton, Washington, on September 13, 2004.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04–21225 Filed 9–21–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2001–NM–292–AD; Amendment 39–13797; AD 2004–19–03]

RIN 2120–AA64

Airworthiness Directives; Empresa Brasileira de Aeronautica S.A. (EMBRAER) Model EMB–135 and EMB–145 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment supersedes an existing airworthiness directive (AD), applicable to certain EMBRAER Model EMB–135 and EMB–145 series airplanes, that currently requires revising the airplane flight manual and eventual disconnection of the precooler differential pressure switches. This amendment expands the applicability of the existing AD. This amendment also requires a one-time inspection of those additional airplanes to ensure the disconnection and insulation of the electrical connectors of certain precooler differential pressure switches located in the left and right pylons; and disconnection and insulation of the connectors, if necessary. The actions specified by this AD are intended to prevent incorrect operation of the precooler differential pressure switches, which could result in inappropriate automatic shutoff of the engine bleed valve, and consequent inability to restart a failed engine using cross-bleed from the other engine or possible failure of the anti-ice system. This action is also necessary to ensure that the flightcrew is advised of the procedures necessary to restart an engine in flight using the auxiliary power unit. This action is intended to address the identified unsafe condition.

DATES: Effective October 27, 2004.

The incorporation by reference of a certain publication, as listed in the regulations, is approved by the Director of the Federal Register as of October 27, 2004.

The incorporation by reference of a certain other publication, as listed in the regulations, was approved previously by the Director of the Federal Register as of July 3, 2000 (65 FR 39541, June 27, 2000).

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. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

FOR FURTHER INFORMATION CONTACT: Todd Thompson, Aerospace Engineer, International Branch, ANM–116, FAA, Transport Airplane Directorate, 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) by superseding AD 2000–13–02, amendment 39–11801 (65 FR 39541, June 27, 2000), which is applicable to certain EMBRAER Model EMB–135 and EMB–145 series airplanes, was published in the **Federal Register** on July 16, 2003 (68 FR 41973). The action proposed to require revising the airplane flight manual (AFM) and eventual disconnection of the precooler differential pressure switches. The action also proposed to expand the applicability of the existing AD. The action also proposed a one-time inspection of those additional airplanes to ensure the disconnection and insulation of the electrical connectors of certain precooler differential pressure switches located in the left and right pylons; and disconnection and insulation of the connectors, if necessary.

Comments

Interested persons have been afforded an opportunity to participate in the making of this amendment. Due consideration has been given to the comments received.

Request To Use Temporary Revision (TR) 55–3 to the AFM

One commenter, an operator, requests that the Abnormal Procedures Section and Limitations Section of TR 55–3 to the EMBRAER EMB–145 AFM, revised on July 2, 2003, be allowed as a form of compliance to the AFM text included in and required by the proposed AD. The commenter states that TR 55–3 complies with the intent of the text listed in the proposed AD, but the wording is not identical.

We agree with the intent of the commenter's request to revise this AD to allow additional acceptable text for the AFM revisions to the Abnormal Procedures and Limitations Sections. We have changed paragraphs (d) and (e) of this final rule to specify that statements approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA (Revision 56 to the EMBRAER EMB–145 AFM is one approved source of statements); or the AFM statements included in this AD; may be used. The contents of TR 55–3 have been incorporated into Revision 56 of the AFM and TR 55–3 is no longer available. A TR is only available until the AFM that the TR revises has been updated to include the contents of the TR.

Request To Delete Paragraphs (d) and (e) of the Proposed AD

One commenter, the airplane manufacturer, requests the deletion of paragraphs (d) and (e) of the AD. Paragraphs (d) and (e) require revisions to the Limitations Section and the Abnormal Procedures Section of the AFM within 24 hours after the effective date of the proposed AD. The commenter bases its request on the length of the FAA's rulemaking process to issue a supersedure AD (AD 2000–13–02) and on the average flight hours for the Model EMB–145 fleet. The commenter states that the 24-hour compliance time is too short and could significantly impact operators' flight operations. The commenter notes that paragraph (f) of the proposed AD has a compliance time of 100 flight hours. The commenter also states that, based on the fleet utilization of Model EMB–145 series airplanes, all affected airplanes will disconnect and insulate or remove the differential pressure switch in less than 20 calendar days after the effective date of the AD. The commenter notes that paragraph (f) directly addresses the unsafe condition. Furthermore, paragraph (f) states that "Following accomplishment of paragraph (f)(1), (f)(2), or (f)(3) of this AD, as applicable, the AFM revision required by paragraph (d) of this AD may be removed from the AFM."

We do not agree with the commenter's request to delete paragraphs (d) and (e) of this AD. As written, this AD addresses the unsafe condition with different actions having different compliance times. Paragraphs (d) and (e) of this AD require revising the AFM. Paragraph (f) of the AD requires doing a one-time general visual inspection of certain electrical connectors within 100 flight hours after the effective date of the AD. If the AFM revision is omitted, and an in-flight event occurs during the 100 flight hours after the effective date of the AD, the flightcrew may not be aware of the necessary procedures to restart an engine in flight using the auxiliary power unit. However, as discussed below in the "Changes to this Final Rule" paragraph, the compliance time for paragraphs (d) and (e) of this AD has been changed from within 24 hours after the effective date of this AD to within 14 days after the effective date of the AD.

Also, paragraphs (d), (e), and (f) of the AD are included under the "New Requirements of This AD" header and are applicable to airplanes having specific serial numbers that were not included in the applicability of AD 2000–13–02. The purpose of this AD is to expand the applicability of AD 2000–13–02 and require the currently required actions for the additional airplanes specified in paragraphs (d), (e), and (f) of this AD. Because the additional airplanes were not included in the applicability of AD 2000–13–02, they cannot be automatically included in paragraphs (a), (b), and (c) of this AD. (Adding new airplanes to the existing requirements would result in those airplanes being out of compliance as of the effective date of this AD.) Paragraphs (d) and (e) will not be deleted from this final rule.

Changes to This Final Rule

We have extended the compliance time in paragraphs (d) and (e) of this final rule. We have determined that these are non-emergency AFM revisions and that extending the compliance time for revising the AFM from 24 hours, as proposed, to 14 days will provide an acceptable level of safety.

We have also revised the cost impact section of this final rule to delete the new cost estimate for the disconnection of switches that was included in the proposed AD. We have determined that this is an "on-condition" action and that not all airplanes will be required to do this action.

Conclusion

After careful review of the available data, including the comments noted above, we have determined that air safety and the public interest require the adoption of the rule with the change described previously.

Change to Labor Rate Estimate

After the proposed AD was issued, we reviewed the figures we use to calculate the labor rate to do the required actions. To account for various inflationary costs in the airline industry, we find it appropriate to increase the labor rate used in these calculations from $60 per work hour to $65 per work hour. The economic impact information, below, has been revised to reflect this increase in the specified hourly labor rate.

Cost Impact

Approximately 365 Model EMB–135 and EMB–145 series airplanes of U.S. registry will be affected by this AD.

The AFM revision that is currently required by AD 2000–13–02 takes approximately 1 work hour per airplane to accomplish, at an average labor rate of $65 per work hour. Based on these figures, the cost impact of the currently required AFM revision is estimated to be $65 per airplane.

The disconnection of switches that is currently required by AD 2000–13–02

takes approximately 1 work hour per airplane to accomplish, at an average labor rate of $65 per work hour. Based on these figures, the cost impact of the currently required disconnection of switches is estimated to be $65 per airplane.

The new AFM revisions required by this new AD will take approximately 1 work hour per airplane to accomplish, at an average labor rate of $65 per work hour. Based on these figures, the cost impact of the new AFM revisions of this AD on U.S. operators is estimated to be $23,725, or $65 per airplane.

The new inspection required by this new AD will take approximately 1 work hour per airplane to accomplish, at an average labor rate of $65 per work hour. Based on these figures, the cost impact of the inspection on U.S. operators is estimated to be $23,725, or $65 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.

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 removing amendment 39–11801 (65 FR 39541, June 27, 2000), and by adding a new airworthiness directive (AD), amendment 39–13797, to read as follows:

2004–19–03 Empresa Brasileira De Aeronautica S.A. (EMBRAER): Amendment 39–13797. Docket 2001–NM–292–AD. Supersedes AD 2000–13–02, Amendment 39–11801.

Applicability: Model EMB–135 and EMB–145 series airplanes; as identified in EMBRAER Alert Service Bulletin 145–36–A018, Change 01, dated October 20, 2000; certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

To prevent incorrect operation of the precooler differential pressure switches, which could result in inappropriate automatic shutoff of the engine bleed valve, and consequent inability to perform engine cross-bleed restarts or possible failure of the anti-ice system; and to ensure that the flightcrew is advised of proper procedures to restart an engine in flight using the auxiliary power unit; accomplish the following:

Restatement of Requirements of AD 2000–13–02

Revision to Airplane Flight Manual (AFM): Limitations Section

(a) For airplanes identified in AD 2000–13–02, amendment 39–11801: Within 24 hours after July 3, 2000 (the effective date of AD 2000–13–02, amendment 39–11801), revise the Limitations Section of the AFM to include the following statements (this may be accomplished by inserting a copy of this AD into the AFM; following accomplishment of paragraph (c) of this AD, the revisions required by this paragraph may be removed from the AFM):

"THE APU MUST BE OPERATIVE FOR EVERY DEPARTURE. SINGLE BLEED OPERATION IN ICING CONDITIONS IS PROHIBITED."

Revision to AFM: Abnormal Procedures Section

(b) For airplanes identified in AD 2000–13–02, amendment 39–11801: Within 24 hours after July 3, 2000, replace the existing "ENGINE AIRSTART" procedure in the Abnormal Procedures Section of the AFM with the following procedures (this may be accomplished by inserting a copy of this AD into the AFM):

"ENGINE AIRSTART

Affected engine:
One Electric Fuel Pump (A or B)—ON
Ignition—AUTO
Start/Stop Selector—STOP
Engine Bleed—CLOSE
Thrust Lever—IDLE
Airspeed and Altitude—REFER TO AIRSTART ENVELOPE

Perform an assisted start or windmilling, as required.

CAUTION: IN ICING CONDITIONS USE CROSSBLEED START ONLY, TO AVOID LOSS OF ANTI-ICE SYSTEM PERFORMANCE.

Assisted Start

Crossbleed Start:
N2 (operating engine)—ABOVE 80%
Crossbleed—AUTO OR OPEN
Engine Bleed (operating engine)—OPEN
Start/Stop Selector—START, THEN RUN
Engine Indication—MONITOR

Check ITT and N2 rising. Observe limits. Check ignition and fuel flow indication at 10% N2.

APU bleed start:
APU—START
APU Bleed—OPEN
Crossbleed—AUTO
Engine Bleed (operating engine)—CLOSE
Start/Stop Selector—START, THEN RUN
Engine Indication—MONITOR

Check ITT and N2 rising. Observe limits. Check ignition and fuel flow indication at 10% N2.

Windmilling Start:

Airspeed—ABOVE 260 KIAS
Minimum N2—12%
Start/Stop Selector—START, THEN RUN
ITT and N2—MONITOR
NOTE:
Windmilling start will be slower than an assisted start.
Windmilling start with N2 above 30% and increasing, the loss of altitude may be minimized, by reducing airspeed.
Start will be faster if ITT is below 320 °C.

After Start:

Affected Engine Bleed—AS REQUIRED
Crossbleed—AUTO
APU Bleed—AS REQUIRED"

Disconnection of the Precooler Differential Pressure Switches

(c) For airplanes identified in AD 2000–13–02, amendment 39–11801: Within 100 flight hours after July 3, 2000, disconnect the

electrical connector from the precooler differential pressure switches in the left and right engine pylons, in accordance with EMBRAER Alert Service Bulletin 145–36–A018, dated April 14, 2000; or Change 01, dated October 20, 2000. Following accomplishment of this paragraph, the AFM revision required by paragraph (a) of this AD may be removed from the AFM.

New Requirements of This AD

Revision to AFM: Limitations Section

(d) For airplanes having serial numbers 145245, 145250 through 145255 inclusive, 145258 through 145262 inclusive, 145264 through 145324 inclusive, 145326, and 145327: Within 14 days after the effective date of this AD, revise the Limitations Section of the AFM to include statements approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA (Revision 56 to the EMBRAER EMB–145 AFM is one approved source of statements); or the following statements (this may be accomplished by inserting a copy of this AD into the AFM; following accomplishment of paragraph (f) of this AD, the revisions required by this paragraph may be removed from the AFM):

"THE APU MUST BE OPERATIVE FOR EVERY DEPARTURE. SINGLE BLEED OPERATION IN ICING CONDITIONS IS PROHIBITED."

Revision to AFM: Abnormal Procedures Section

(e) For airplanes having serial numbers 145245, 145250 through 145255 inclusive, 145258 through 145262 inclusive, 145264 through 145324 inclusive, 145326, and 145327: Within 14 days after the effective date of this AD, replace the existing "ENGINE AIRSTART" procedure in the Abnormal Procedures Section of the AFM with statements approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate (Revision 56 to the EMBRAER EMB–145 AFM is one approved source of statements); or the following procedures (this may be accomplished by inserting a copy of this AD into the AFM):

"ENGINE AIRSTART

Affected engine:
One Electric Fuel Pump (A or B)—ON
Ignition—AUTO
Start/Stop Selector—STOP
Engine Bleed—CLOSE
Thrust Lever—IDLE
Airspeed and Altitude—REFER TO AIRSTART ENVELOPE

Perform an assisted start or windmilling, as required.

CAUTION: IN ICING CONDITIONS USE CROSSBLEED START ONLY, TO AVOID LOSS OF ANTI-ICE SYSTEM PERFORMANCE.

Assisted Start:

Crossbleed Start:
N2 (operating engine)—ABOVE 80%
Crossbleed——AUTO OR OPEN
Engine Bleed (operating engine)—OPEN
Start/Stop Selector—START, THEN RUN
Engine Indication—MONITOR

Check ITT and N2 rising. Observe limits. Check ignition and fuel flow indication at 10% N2.

APU bleed start:
APU—START
APU Bleed—OPEN
Crossbleed—AUTO
Engine Bleed (operating engine)—CLOSE
Start/Stop Selector—START, THEN RUN
Engine Indication—MONITOR

Check ITT and N2 rising. Observe limits. Check ignition and fuel flow indication at 10% N2.

Windmilling Start

Airspeed—ABOVE 260 KIAS
Minimum N2—12%
Start/Stop Selector—START, THEN RUN
ITT and N2—MONITOR
NOTE:
Windmilling start will be slower than an assisted start.
Windmilling start with N2 above 30% and increasing, the loss of altitude may be minimized, by reducing airspeed.
Start will be faster if ITT is below 320 °C.

After Start:

Affected Engine Bleed—AS REQUIRED
Crossbleed—AUTO
APU Bleed—AS REQUIRED"

Inspection of Electrical Connectors and Follow-on Actions

(f) For airplanes having serial numbers 145245, 145250 through 145255 inclusive, 145258 through 145262 inclusive, 145264 through 145324 inclusive, 145326, and 145327: Within 100 flight hours after the effective date of this AD, perform a one-time general visual inspection to ensure that electrical connector P1904 located in the right pylon is insulated and disconnected from precooler differential pressure switch S0354, and to ensure that electrical connector P1904 or P2252 located in the left pylon is insulated and disconnected from precooler differential pressure switch S0355, per the Accomplishment Instructions of EMBRAER Alert Service Bulletin 145–36–A018, Change 01, dated October 20, 2000. Following accomplishment of paragraph (f)(1), (f)(2), or (f)(3) of this AD, as applicable, the AFM revision required by paragraph (d) of this AD may be removed from the AFM.

(1) If all connectors are disconnected and insulated, no further action is required by this paragraph.

(2) If any connector is connected to a precooler differential pressure switch, prior to further flight, disconnect and insulate the connector per the Accomplishment Instructions of the alert service bulletin.

(3) If any connector is disconnected from a precooler differential pressure switch, but is not insulated, prior to further flight, insulate the connector per the Accomplishment Instruction of the alert service bulletin.

Note 1: For the purposes of this AD, a general visual inspection is defined as: "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 enhance visual access to all exposed 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."

(g) Actions accomplished before the effective date of this AD, per the Accomplishment Instructions of EMBRAER Alert Service Bulletin 145–36–A018, dated April 14, 2000; or EMBRAER Service Bulletin 145–36–0018, dated November 5, 2002; are considered acceptable for compliance with the actions specified in paragraph (f) of this AD.

Alternative Methods of Compliance

(h) In accordance with 14 CFR 39.19, the Manager, International Branch, ANM–116, Transport Airplane Directorate, is authorized to approve alternative methods of compliance for this AD.

Incorporation by Reference

(i) Unless otherwise specified in this AD, the actions shall be done in accordance with EMBRAER Alert Service Bulletin 145–36–A018, dated April 14, 2000; and EMBRAER Alert Service Bulletin 145–36–A018, Change 01, dated October 20, 2000; as applicable.

(1) The incorporation by reference of EMBRAER Alert Service Bulletin 145–36–A018, Change 01, dated October 20, 2000; is approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

(2) The incorporation by reference of EMBRAER Alert Service Bulletin 145–36–A018, dated April 14, 2000; was approved previously by the Director of the Federal Register as of July 3, 2000 (65 FR 39541, June 27, 2000).

(3) Copies may be obtained from Empresa Brasileira de Aeronautica S.A. (EMBRAER), P.O. Box 343—CEP 12.225, Sao Jose dos Campos—SP, Brazil. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Note 2: The subject of this AD is addressed in Brazilian airworthiness directive 2000–04–01R2, dated May 28, 2001.

Effective Date

(j) This amendment becomes effective on October 27, 2004.

Issued in Renton, Washington, on September 9, 2004.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04–21050 Filed 9–21–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2003–NM–69–AD; Amendment 39–13799; AD 2004–19–05]

RIN 2120–AA64

Airworthiness Directives; McDonnell Douglas Model MD–11 and –11F Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment supersedes an existing airworthiness directive (AD), applicable to certain McDonnell Douglas Model MD–11 and MD–11F airplanes, that currently requires replacing terminal strips and supports above the main cabin area and avionics compartment with new strips and supports, as applicable. That AD also requires performing an inspection to detect arcing damage of the surrounding structure of the terminal strips and electrical cables in the avionics compartment, and repairing or replacing any damaged component with a new component. This amendment expands the applicability of the existing AD to include additional airplanes. For certain airplanes, this action also requires replacement of the terminal board for the applicable item numbers in the aft passenger compartment. The actions specified by this AD are intended to prevent electrical arcing caused by power feeder cable terminal lugs grounding against terminal strip support brackets, which could result in smoke and fire in the main cabin or avionics compartment. This action is intended to address the identified unsafe condition.

DATES: Effective October 27, 2004.

The incorporation by reference of a certain publication, as listed in the regulations, is approved by the Director of the Federal Register as of October 27, 2004.

The incorporation by reference of a certain other publication, as listed in the regulations, was approved previously by the Director of the Federal Register as of August 23, 2002 (67 FR 47647, July 19, 2002).

ADDRESSES: The service information referenced in this AD may be obtained from Boeing Commercial Airplanes, Long Beach Division, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Data and Service Management, Dept. C1–L5A (D800–0024). This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

FOR FURTHER INFORMATION CONTACT: Brett Portwood, Aerospace Engineer, Systems and Equipment Branch, ANM–130L, FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California 90712–4137; telephone (562) 627–5350; fax (562) 627–5210.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) by superseding AD 2002–14–09, amendment 39–12809 (67 FR 47647, July 19, 2002), which is applicable to certain McDonnell Douglas Model MD–11 and MD–11F airplanes, was published in the **Federal Register** on May 27, 2004 (69 FR 30245). The action proposed to expand the applicability of the existing AD to include additional airplanes. For certain airplanes, the action also proposed to require replacement of the terminal board for the applicable item numbers in the aft passenger compartment.

Comments

Interested persons have been afforded an opportunity to participate in the making of this amendment. No comments were submitted in response to the proposal or the FAA's determination of the cost to the public.

Conclusion

The FAA has determined that air safety and the public interest require the adoption of the rule as proposed.

Explanation of Change Made to Final Rule

Because the language in Note 2 of the proposed AD is regulatory in nature, that note has been included in paragraph (d) of this final rule.

Cost Impact

There are approximately 154 airplanes of the affected design in the worldwide fleet listed in Boeing Alert Service Bulletin MD11–24A178. The FAA estimates that 61 airplanes of U.S. registry will be affected by this AD. The cost estimate for those airplanes is as follows:

1. The actions that are currently required by AD 2002–14–09 and retained in this AD take approximately 3 or 4 work hours per airplane (depending on airplane configuration) to accomplish, at an average labor rate of $65 per work hour. Required parts cost approximately $1,142 per airplane. Based on these figures, the cost impact of the currently required actions on U.S. operators is estimated to be $1,337 or $1,420 per airplane (depending on airplane configuration).

2. For Group 3 and 4 airplanes identified in Boeing Alert Service Bulletin MD11–24A178, the new actions that are required in this AD action take approximately 4 (kit/part number SA11240178–3) or 5 (kit/part number SA11240178–5) work hours per airplane to accomplish, at an average labor rate of $65 per work hour. Required parts will cost approximately $3,031 (kit/part number SA11240178–3) or $617 per airplane (kit/part number SA11240178–5). Based on these figures, the cost impact of these new requirements of this AD on U.S. operators is estimated to be $3,291 (kit/part number SA11240178–3) or $942 (kit/part number SA11240178–5) per airplane.

There are approximately 103 airplanes of the affected design in the worldwide fleet listed in McDonnell Douglas Alert Service Bulletin MD11–24A177. The FAA estimates that 33 airplanes of U.S. registry will be affected by this AD.

For airplanes identified in Boeing Alert Service Bulletin MD11–24A177, the new replacement that is required in this AD action takes between 1 and 3 work hours per airplane to accomplish, at an average labor rate of $65 per work hour. Required parts will cost between $114 and $876 per airplane. Based on these figures, the cost impact of the new replacement requirements of this AD on U.S. operators is estimated to be between $5,907 and $35,343, or between $179 and $1,071 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.

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 removing amendment 39–12809 (67 FR 47647, July 19, 2002), and by adding a new airworthiness directive (AD), to read as follows:

2004–19–05 McDonnell Douglas: Amendment 39–13799. Docket 2003–NM–69–AD. Supersedes AD 2002–14–09, Amendment 39–12809.

Applicability: Model MD–11 and –11F airplanes, as listed in Boeing Alert Service Bulletin MD11–24A178, Revision 02, dated March 11, 2003, and McDonnell Douglas Alert Service Bulletin MD11–24A177, dated July 18, 2003; certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

To prevent electrical arcing caused by power feeder cable terminal lugs grounding against terminal strip support brackets, which could result in smoke and fire in the main cabin or avionics compartment, accomplish the following:

Certain Requirements of AD 2002–14–09, Amendment 39–12809

Replacement, Inspection, and Corrective Action If Necessary

(a) For airplanes listed in the effectivity of McDonnell Douglas Alert Service Bulletin MD11–24A178, Revision 01, dated December 17, 2001: Within 18 months after August 23, 2002 (the effective date of AD 2002–14–09, amendment 39–12809), do the actions specified in paragraphs (a)(1) and (a)(2) of this AD per the service bulletin.

(1) Replace the applicable terminal strips in the avionics compartment with new terminal strips (including inspecting wires for damage, repairing any damaged wire, and removing the nameplate); and

(2) Perform a general visual inspection to detect arcing damage of the surrounding structure of the terminal strips and electrical cables in the avionics compartment. If any damage is detected, before further flight, repair or replace any damaged component with a new component, per the service bulletin; except if the type of structural material of the surrounding structure that has been affected is not covered in the Structural Repair Manual, repair per a method approved by the Manager, Los Angeles Aircraft Certification Office (ACO), FAA.

Note 1: For the purposes of this AD, a general visual inspection is defined as "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 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."

(b) Accomplishment of the replacement, inspection, and corrective action, before the effective date of this AD, per McDonnell Douglas Alert Service Bulletin MD11–24A178, dated May 14, 2001, is considered acceptable for compliance with the applicable actions specified in paragraph (a) of this AD.

New Requirements of This AD

Replacement, Inspection, and Corrective Action If Necessary

(c) For Groups 3 and 4 airplanes listed in the effectivity of Boeing Alert Service Bulletin MD11–24A178, Revision 02, dated March 11, 2003: Within 18 months after the effective date of this AD, do the actions specified in paragraphs (c)(1) and (c)(2) of this AD per the Accomplishment Instructions of the service bulletin. Although the service bulletin specifies to report inspection findings to the airplane manufacturer, this AD does not include such a requirement.

(1) Replace the applicable terminal strips in the avionics compartment with new terminal strips (including inspecting wires for damage, repairing any damaged wire, and removing the nameplate); and

(2) Perform a general visual inspection to detect arcing damage of the surrounding structure of the terminal strips and electrical cables in the avionics compartment. If any damage is detected, before further flight, repair or replace any damaged component with a new component, per the service bulletin; except if the type of structural material of the surrounding structure that has been affected is not covered in the Structural Repair Manual, repair per a method approved by the Manager, Los Angeles ACO, FAA.

(d) For airplanes listed in McDonnell Douglas Alert Service Bulletin MD11–24A177, dated July 18, 2003: Within 18 months after the effective date of this AD, replace the terminal board for the applicable item numbers in the aft passenger compartment, per the Accomplishment Instructions of the service bulletin. Boeing Service Bulletin Information Notice MD11–24A177 IN 01, dated August 7, 2003, revises service kit numbers specified in paragraph 2.B., "Post-Warranty," of the service bulletin.

Alternative Methods of Compliance

(e)(1) In accordance with 14 CFR 39.19, the Manager, Los Angeles ACO, FAA, is authorized to approve alternative methods of compliance for this AD.

(2) Alternative methods of compliance, approved previously per AD 2002–14–09, amendment 39–12809, are approved as alternative methods of compliance with paragraph (a) of this AD.

Incorporation by Reference

(f) Unless otherwise specified in this AD, the actions shall be done in accordance with McDonnell Douglas Alert Service Bulletin MD11–24A178, Revision 01, dated December 17, 2001; Boeing Alert Service Bulletin MD11–24A178, Revision 02, excluding Appendix A, dated March 11, 2003; and McDonnell Douglas Alert Service Bulletin MD11–24A177, dated July 18, 2003, as revised by Boeing Service Bulletin Information Notice MD11–24A177 IN 01, dated August 7, 2003; as applicable.

(1) The incorporation by reference of Boeing Alert Service Bulletin MD11–24A178, Revision 02, excluding Appendix A, dated March 11, 2003; and McDonnell Douglas Alert Service Bulletin MD11–24A177, dated July 18, 2003, as revised by Boeing Service Bulletin Information Notice MD11–24A177 IN 01, dated August 7, 2003; as applicable; is approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

(2) The incorporation by reference of McDonnell Douglas Alert Service Bulletin MD11–24A178, Revision 01, dated December 17, 2001, was approved previously by the Director of the Federal Register as of August 23, 2002 (67 FR 47647, July 19, 2002).

(3) Copies may be obtained from Boeing Commercial Airplanes, Long Beach Division, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Data and Service Management, Dept. C1–L5A (D800–0024). Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California; or at the National Archives and Records Administration

(NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Effective Date

(g) This amendment becomes effective on October 27, 2004.

Issued in Renton, Washington, on September 13, 2004.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04–21175 Filed 9–21–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2003–NM–185–AD; Amendment 39–13801; AD 2004–19–07]

RIN 2120–AA64

Airworthiness Directives; Bombardier Model DHC–8–102 Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to certain Bombardier Model DHC–8–102 airplanes, that requires modification of the electrical power circuit. This action is necessary to prevent component failure in the radar indicator, resulting in an overcurrent condition and consequent overheating or burning of an internal component or the ribbon cable. This could lead to smoke in the cockpit, resulting in incapacitation of the flight crew and loss of control of the airplane. This action is intended to address the identified unsafe condition.

DATES: Effective October 27, 2004.

The incorporation by reference of a certain publication listed in the regulations is approved by the Director of the Federal Register as of October 27, 2004.

ADDRESSES: The service information referenced in this AD may be obtained from Bombardier, Inc., Bombardier Regional Aircraft Division, 123 Garratt Boulevard, Downsview, Ontario M3K 1Y5, Canada. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, New York Aircraft Certification Office (ACO), 1600 Stewart Ave., suite 410, Westbury, New York; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

FOR FURTHER INFORMATION CONTACT: Doug Wagner, Aerospace Engineer, Systems and Flight Test Branch, ANE–172, FAA, New York Aircraft Certification Office, 1600 Stewart Ave., suite 410, Westbury, New York 11590; telephone (516) 228–7306; fax (516) 794–5531.

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 Bombardier Model DHC–8–102 airplanes was published in the **Federal Register** on April 7, 2004 (69 FR 18306). That action proposed to require modification of the electrical power circuit.

Comments

Interested persons have been afforded an opportunity to participate in the making of this amendment. Due consideration has been given to the single comment received.

Request To Give Credit for Modification Using Alternate Service Information

The commenter, an operator, requests that a paragraph be added to the proposed AD giving credit for reconfiguring the circuit breaker wiring as specified in Allied Signal RDS–86 Weather Radar System Manual 006–05996–0005, Revision 5 or higher. The commenter states that it has operated the affected Model DHC–8–102 airplanes continually since 1986, and that the performance of the RDS–86 weather radar system made consultation with the airplane and equipment manufacturers necessary. In 1996, the commenter reconfigured certain circuit breakers for the weather radar system per the equipment manufacturer's recommendations. The commenter notes that the airplane manufacturer did not provide documentation for this change until 2002, when it issued Bombardier Modification Summary Package (ModSum) IS8Q3450000, Revision A, dated October 15, 2002, which the proposed AD references as the appropriate source of service information for the proposed requirements.

The FAA does not agree. It is important to maintain proper configuration of airplane wiring to ensure proper airplane maintenance by operators. The final rule requires modification of the power circuit per ModSum IS8Q3450000, Revision A. The ModSum identifies three installation configurations, and the ModSum installation instructions identify the correct interface buses to be modified and wires to be reconfigured. The Allied Signal RDS–86 Weather Radar System Manual shows only pin connections of the indicator and receiver/transmitter without any details of unique airplane interconnections. Such limited information provides no means of showing that appropriate wiring changes have been made and is insufficient to demonstrate that the unsafe condition has been addressed properly. We have not changed the final rule in this regard. However, under the provisions of paragraph (b) of the final rule, we may consider requests for approval of an alternative method of compliance if sufficient data are submitted to substantiate that such a design change would provide an acceptable level of safety.

Conclusion

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

Cost Impact

The FAA estimates that 48 airplanes of U.S. registry will be affected by this AD, that it will take between 3 work hours and 9 work hours per airplane to accomplish the required actions, and that the average labor rate is $65 per work hour. Required parts will cost approximately $150 per airplane. Based on these figures, the cost impact of the AD on U.S. operators is estimated to be between $16,560 and $35,280, or between $345 and $735 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.

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:

2004–19–07 Bombardier, Inc. (Formerly de Havilland, Inc.): Amendment 39–13801. Docket 2003–NM–185–AD.

Applicability: Model DHC–8–102 airplanes, serial numbers 023 through 392 inclusive; certificated in any category; equipped with an RDS86 Weather Radar System, excluding those airplanes equipped with option CR834CH00284.

Compliance: Required as indicated, unless accomplished previously.

To prevent component failure in the radar indicator, resulting in an overcurrent condition and consequent overheating or burning of an internal component or the ribbon cable, which could lead to smoke in the cockpit, resulting in incapacitation of the crew and loss of control of the airplane; accomplish the following:

Modification

(a) Within 12 months after the effective date of this AD, modify the electrical power circuit by accomplishing all the actions in the Accomplishment Instructions of Bombardier Modification Summary Package (ModSum) IS8Q3450000, Revision A, dated October 15, 2002; as applicable. Do the actions per the ModSum.

Alternative Methods of Compliance

(b) In accordance with 14 CFR 39.19, the Manager, New York Aircraft Certification Office (ACO), FAA, is authorized to approve alternative methods of compliance for this AD.

Incorporation by Reference

(c) The actions shall be done in accordance with Bombardier Modification Summary Package IS8Q3450000, Revision A, dated October 15, 2002. (The date of the Modification Summary Package only appears on the first page of the document.) 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. Copies may be obtained from Bombardier, Inc., Bombardier Regional Aircraft Division, 123 Garratt Boulevard, Downsview, Ontario M3K 1Y5, Canada. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, New York Aircraft Certification Office (ACO), 1600 Stewart Ave., suite 410, Westbury, New York; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Note 1: The subject of this AD is addressed in Canadian airworthiness directive CF–2003–13, effective June 20, 2003.

Effective Date

(d) This amendment becomes effective on October 27 2004.

Issued in Renton, Washington, on September 14, 2004.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04–21174 Filed 9–21–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2003–NE–57–AD; Amendment 39–13798; AD 2004–19–04]

RIN 2120–AA64

Airworthiness Directives; Rolls-Royce plc RB211–22B, RB211–524, and RB211–535 Series Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for Rolls-Royce plc (RR) RB211–22B, RB211–524, and RB211–535 series turbofan engines. This AD requires revising the Time Limits Manual for RR RB211–22B, RB211–524, and RB211–535 series turbofan engines. These revisions include required enhanced inspection of selected critical life-limited parts at each piece-part exposure. This AD results from the need to require enhanced inspection of selected critical life-limited parts of RB211–22B, RB211–524, and RB211–535 series turbofan engines. We are issuing this AD to prevent failure of critical life-limited rotating engine parts, which could result in an uncontained engine failure and damage to the airplane.

DATES: This AD becomes effective October 27, 2004.

ADDRESSES: You can get the service information identified in this AD from Rolls-Royce plc, P.O. Box 31, Derby, DE24 8BJ, United Kingdom; telephone: 011–44–1332–242424; fax: 011–44–1332–249936.

You may examine the AD docket at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA.

FOR FURTHER INFORMATION CONTACT: Christopher Spinney, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803–5299; telephone (781) 238–7175, fax (781) 238–7199.

SUPPLEMENTARY INFORMATION: The FAA proposed to amend 14 CFR part 39 with a proposed airworthiness directive (AD). The proposed AD applies to Rolls-Royce plc RB211–22B, RB211–524, and RB211–535 series turbofan engines. We published the proposed AD in the **Federal Register** on March 12, 2004 (69 FR 11821). That action proposed to require revisions to the Time Limits Manual for RR RB211–22B, RB211–524, and RB211–535 series turbofan engines to include required enhanced inspection of selected critical parts at each piece-part exposure.

Examining the AD Docket

You may examine the AD Docket (including any comments and service information), by appointment, between 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays. *See* **ADDRESSES** for the location.

Comments

We provided the public the opportunity to participate in the development of this AD. We received no

comments on the proposal or on the determination of the cost to the public.

Conclusion

We have carefully reviewed the available data and determined that air safety and the public interest require adopting the AD as proposed.

Costs of Compliance

There are about 882 RB211–22B and RB211–524 series engines and about 1,160 RB211–535 series engines of the affected design in the worldwide fleet. We estimate that 30 RB211–22B and RB211–524 series engines and 620 RB211–535 series engines installed on airplanes of U.S. registry will be affected by this AD. We also estimate that it will take about 75 work hours per engine to perform the inspections, and that the average labor rate is $65 per work hour. Since this is an added inspection requirement, included as part of the normal maintenance cycle, no additional part costs are involved. Based on these figures, the total cost impact of this AD on U.S. operators is estimated to be $3,169,000.

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 summary of the costs to comply with this AD and placed it in the AD Docket. You may get a copy of this summary by sending a request to us at the address listed under **ADDRESSES.** Include "AD Docket No. 2003–NE–57–AD" in your request.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, 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):

2004–19–04 Rolls-Royce plc: Docket No. 2003–NE–57–AD.

Effective Date

(a) This AD becomes effective October 27, 2004.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Rolls-Royce plc (RR) RB211–22B, RB211–524, and RB211–535 series turbofan engines. These engines are installed on, but not limited to, Boeing 747, 757, 767, Lockheed L–1011, and Tupolev Tu204 airplanes.

Unsafe Condition

(d) This AD results from the need to require enhanced inspection of selected critical life-limited parts of RB211–22B, RB211–524, and RB211–535 series turbofan engines. The actions specified in this AD are intended to prevent failure of critical life-limited rotating engine parts, which could result in an uncontained engine failure and damage to 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.

(f) Within the next 40 days after the effective date of this AD, revise the Time Limits Manual (TLM), and for air carrier operations revise the approved continuous airworthiness maintenance program, by adding the following text and the applicable table determined by engine model number:

"GROUP A PARTS MANDATORY INSPECTION

(1) Inspections referred to as 'Focus Inspect' in the applicable Engine Manual inspection Task are mandatory inspections for the components given below, when the conditions that follow are satisfied:

(i) When the component has been completely disassembled to piece-part level as given in the applicable disassembly procedures contained in the Engine Manual; and

(ii) The part has more than 100 recorded flight cycles in operation since the last piece-part inspection; or

(iii) The component removal was for damage or a cause directly related to its removal; or

(iv) Where serviceable used components, for which the inspection history is not fully known, are to be used again.

(2) The list of Group A Parts for RB211–22B engines is specified below:

Part nomenclature (RB211–22B series engines)	Part number	Inspected per overhaul manual task
Low Pressure Compressor Rotor Disc	All	72–31–12–200–006
Low Pressure Compressor Rotor Shaft	All	72–31–20–200–000
Intermediate Pressure Compressor Rotor Shaft Stages 1 to 5	All	72–32–31–200–000
Intermediate Pressure Compressor Rotor Shaft Stages 6 to 7	All	72–32–31–200–001
Intermediate Pressure Compressor Rotor Rear Stubshaft	All	72–33–31–200–000
High Pressure Compressor Rotor Stage 1 to 2 Disc Shaft	All	72–41–31–200–000
High Pressure Compressor Rotor Stage 3 Disc	All	72–41–31–200–001
High Pressure Compressor Rear Rotor Shaft Assembly	All	72–41–31–200–002
Compressor/Turbine Joint Flange Support Disc	All	72–41–31–200–003
High Pressure Turbine Disc	All	72–41–51–200–000
Intermediate Pressure Turbine Disc	All	72–51–31–200–000
Intermediate Pressure Turbine Shaft	All	72–51–33–200–000
Low Pressure Turbine Stage 1 Disc	All	72–51–61–200–000
Low Pressure Turbine Stage 2 Disc	All	72–51–61–200–001
Low Pressure Turbine Stage 3 Disc	All	72–51–61–200–002
Low Pressure Turbine Shaft	All	72–51–63–200–000

(3) The list of Group A Parts for RB211–535 series engines is specified below:

Part nomenclature (RB211–535 series engines)	Part number	Inspected per overhaul manual task
Low Pressure Compressor Rotor Disc	All	72–31–12–200–000
Low Pressure Compressor Rotor Shaft	All	72–31–20–200–000
Intermediate Pressure Compressor Rotor Shaft	All	72–32–31–200–001
Intermediate Pressure Compressor Rotor Rear Stubshaft	All	72–33–21–200–000
High Pressure Compressor Rotor Stage 1 & 2 Disc	All	72–41–31–200–000
High Pressure Compressor Rotor Stage 3 Disc	All	72–41–31–200–001
High Pressure Compressor Rear Rotor Shaft Assembly	All	72–41–31–200–002
Compressor/Turbine Joint Flange Support Disc (applicable to –535C only)	All	72–41–31–200–003
High Pressure Turbine Disc	All	72–41–51–200–000
Intermediate Pressure Turbine Rotor Disc	All	72–51–31–200–000
Intermediate Pressure Turbine Shaft	All	72–51–33–200–000
Low Pressure Turbine Stage 1 Disc	All	72–51–61–200–000
Low Pressure Turbine Stage 2 Disc	All	72–51–61–200–001
Low Pressure Turbine Stage 3 Disc	All	72–51–61–200–002
Low Pressure Turbine Shaft	All	72–51–63–200–000

(4) The list of Group A Parts for RB211–524B, –524B3, and –524B4 series engines is specified below:

Part nomenclature (RB211–524B, –524B3, and –524B4 series engines)	Part number	Inspected per overhaul manual task
Low Pressure Compressor Rotor Disc	All	[1] 72–31–12–200–05 [2] 72–31–12–200–013
Low Pressure Compressor Rotor Shaft	All	72–31–20–200–000
Intermediate Pressure Compressor Stage 1 Disc	All	72–32–31–200–000
Intermediate Pressure Compressor Stage 2 Disc	All	72–32–31–200–000
Intermediate Pressure Compressor Stage 3 Disc	All	72–32–31–200–000
Intermediate Pressure Compressor Stage 4 Disc	All	72–32–31–200–000
Intermediate Pressure Compressor Stage 5 Disc	All	72–32–31–200–001
Intermediate Pressure Compressor Rotor Shaft Stages 6 to 7	All	72–32–31–200–001
Intermediate Pressure Compressor Front Stubshaft Drive Cone	All	72–32–31–200–008
Intermediate Pressure Compressor Rotor Rear Stubshaft	All	72–33–21–200–010
High Pressure Compressor Rotor Stage 1 to 2 Disc	All	72–41–31–200–000
High Pressure Compressor Rotor Stage 3 Disc	All	72–41–31–200–001
High Pressure Compressor Rear Rotor Shaft Assembly	All	72–41–31–200–002
High Pressure Compressor/Turbine Joint Flange Support Disc	All	72–41–31–200–006
High Pressure Turbine Bearing Inner Race Support Panel	All	72–41–51–200–005
High Pressure Turbine Disc	All	72–41–51–200–019
High Pressure Turbine Conical Shaft	All	72–41–51–200–021
Intermediate Pressure Turbine Disc	All	72–51–31–200–003
Intermediate Pressure Turbine Shaft	All	72–51–33–200–005
Low Pressure Turbine Stage 1 Disc	All	[1] 72–51–61–200–000 [2] 72–51–61–200–007
Low Pressure Turbine Stage 2 Disc	All	[1] 72–51–61–200–001 [2] 72–51–61–200–008
Low Pressure Turbine Stage 3 Disc	All	[1] 72–51–61–200–002 [2] 72–51–61–200–009
Low Pressure Turbine Shaft	All	[1] 72–51–63–200–000 [2] 72–51–63–200–003

[1] (Configuration 1).
[2] (Configuration 2).

(5) The list of Group A Parts for RB211–524B2, –524C2, and –524D4 series engines is specified below:

Part nomenclature (RB211–524B2, –524C2, and –524D4 series engines)	Part number	Inspected per overhaul manual task
Low Pressure Compressor Rotor Disc	All	72–31–12–200–013
Low Pressure Compressor Rotor Shaft	All	72–31–20–200–000
Intermediate Pressure Compressor Stage 1 Disc	All	72–32–31–200–000
Intermediate Pressure Compressor Stage 2 Disc	All	72–32–31–200–000
Intermediate Pressure Compressor Stage 3 Disc	All	72–32–31–200–000
Intermediate Pressure Compressor Stage 4 Disc	All	72–32–31–200–000

Part nomenclature (RB211–524B2, –524C2, and –524D4 series engines)	Part number	Inspected per overhaul manual task
Intermediate Pressure Compressor Stage 5 Disc	All	72–32–31–200–001
Intermediate Pressure Compressor Rotor Shaft Stages 6 to 7	All	72–32–31–200–001
Intermediate Pressure Compressor Front Stubshaft Drive Cone	All	72–32–31–200–008
Intermediate Pressure Compressor Rotor Rear Stubshaft	All	72–33–21–200–010
High Pressure Compressor Rotor Stage 1 to 2 Disc	All	72–41–31–200–000
High Pressure Compressor Rotor Stage 3 Disc	All	72–41–31–200–001
High Pressure Compressor Rear Rotor Shaft Assembly	All	72–41–31–200–002
High Pressure Compressor/Turbine Joint Flange Support Disc	All	72–41–31–200–006
High Pressure Turbine Bearing Inner Race Support Panel	All	72–41–51–200–005
High Pressure Turbine Disc	All	72–41–51–200–019
High Pressure Turbine Conical Shaft	All	72–41–51–200–021
Intermediate Pressure Turbine Rotor Disc	All	72–51–31–200–003
Intermediate Pressure Turbine Shaft	All	72–51–33–200–005
Low Pressure Turbine Stage 1 Disc	All	72–51–61–200–007
Low Pressure Turbine Stage 2 Disc	All	72–51–61–200–008
Low Pressure Turbine Stage 3 Disc	All	72–51–61–200–009
Low Pressure Turbine Shaft	All	72–51–63–200–003

(6) The list of Group A Parts for RB211–524G and –524H series engines is specified below:

Part nomenclature (RB211–524G and –524H series engines)	Part number	Inspected per overhaul manual task
Low Pressure Compressor Rotor Disc	All	72–31–12–200–000
Low Pressure Compressor Rotor Shaft	All	72–31–20–200–000
Intermediate Pressure Compressor Stage 1 Disc	All	72–32–31–200–000
Intermediate Pressure Compressor Stage 2 Disc	All	72–32–31–200–000
Intermediate Pressure Compressor Stage 3 Disc	All	72–32–31–200–000
Intermediate Pressure Compressor Stage 4 Disc	All	72–32–31–200–000
Intermediate Pressure Compressor Stage 5 Disc	All	72–32–31–200–000
Intermediate Pressure Compressor Rotor Shaft Stages 6 to 7	All	72–32–31–200–001
Intermediate Pressure Compressor Front Stubshaft Drive Cone	All	72–32–31–200–008
Intermediate Pressure Compressor Rotor Rear Stubshaft	All	72–33–21–200–010
High Pressure Compressor Rotor Stage 1 to 2 Disc	All	[1] 72–41–31–200–000
High Pressure Compressor Rotor Stage 3 Disc	All	[1] 72–41–31–200–001
High Pressure Compressor Rear Rotor Shaft Assembly	All	[1] 72–41–31–200–002
Compressor/Turbine Joint Flange Support Disc	All	[1] 72–41–31–200–003
High Pressure Compressor Rotor Shaft Assembly	All	[2] 72–41–31–200–014
High Pressure Turbine Disc	All	[1] 72–41–51–200–010 [2] 72–41–51–200–024
Intermediate Pressure Turbine Disc	All	72–51–31–200–003
Intermediate Pressure Turbine Shaft	All	72–51–33–200–005
Low Pressure Turbine Stage 1 Disc	All	72–51–61–200–007
Low Pressure Turbine Stage 2 Disc	All	72–51–61–200–008
Low Pressure Turbine Stage 3 Disc	All	72–51–61–200–009
Low Pressure Turbine Shaft	All	72–51–63–200–003"

[1] (Configuration 1).
[2] (Configuration 2).

Alternative Methods of Compliance

(g) You must perform these mandatory inspections using the TLM and the applicable Engine Manual unless you receive approval to use an alternative method of compliance under paragraph (h) of this AD. Section 43.16 of the Federal Aviation Regulations (14 CFR 43.16) may not be used to approve alternative methods of compliance or adjustments to the times in which these inspections must be performed.

(h) The Manager, Engine Certification Office, has the authority to approve alternative methods of compliance for this AD if requested using the procedures found in 14 CFR 39.19.

Maintaining Records of the Mandatory Inspections

(i) You have met the requirements of this AD by using a TLM changed as specified in paragraph (f) of this AD, and, for air carriers operating under part 121 of the Federal Aviation Regulations (14 CFR part 121), by modifying your continuous airworthiness maintenance plan to reflect those changes. You must maintain records of the mandatory inspections that result from those changes to the TLM according to the regulations governing your operation. You do not need to record each piece-part inspection as compliance to this AD. For air carriers operating under part 121, you may use either the system established to comply with section 121.369 or use an alternative system that your principal inspector has accepted if that alternative system:

(1) Includes a method for preserving and retrieving the records of the inspections resulting from this AD; and

(2) Meets the requirements of § 121.369(c); and

(3) Maintains the records either indefinitely or until the work is repeated.

(j) These record keeping requirements apply only to the records used to document the mandatory inspections required as a result of revising the Time Limits Manual as specified in paragraph (f) of this AD, and do not alter or amend the record keeping requirements for any other AD or regulatory requirement.

Material Incorporated by Reference

(k) None.

Related Information

(l) Civil Aviation Authority (CAA) airworthiness directives No. G–2003–0006, dated September 18, 2003, No. G–2003–0009, dated September 19, 2003, and No. G–2003–0007, dated September 18, 2003 also address the subject of this AD.

Issued in Burlington, Massachusetts, on September 10, 2004.

Francis A. Favara,

Acting Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 04–21173 Filed 9–21–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2003–NE–54–AD; Amendment 39–13802; AD 2004–19–08]

RIN 2120–AA64

Airworthiness Directives; Rolls-Royce plc RB211 Trent 800 Series Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for Rolls-Royce plc (RR) RB211 Trent 800 series turbofan engines. This AD requires revising the Time Limits Manual for RR RB211 Trent 800 series turbofan engines. These revisions include required enhanced inspection of selected critical life-limited parts at each piece-part exposure. This AD results from the need to require enhanced inspection of selected critical life-limited parts of RB211 Trent 800 series turbofan engines. We are issuing this AD to prevent failure of critical life-limited rotating engine parts, which could result in an uncontained engine failure and damage to the airplane.

DATES: This AD becomes effective October 27, 2004.

ADDRESSES: You can get the service information identified in this AD from Rolls-Royce plc, P.O. Box 31, Derby, DE24 8BJ, United Kingdom; telephone: 011–44–1332–242424; fax: 011–44–1332–249936.

You may examine the AD docket at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA.

FOR FURTHER INFORMATION CONTACT: Christopher Spinney, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803–5299; telephone (781) 238–7175, fax (781) 238–7199.

SUPPLEMENTARY INFORMATION: The FAA proposed to amend 14 CFR part 39 with a proposed AD. The proposed AD applies to RR RB211 Trent 800 series turbofan engines. We published the proposed AD in the **Federal Register** on March 4, 2004 (69 FR 10179). That action proposed to require revising the Time Limits Manual for RR RB211 Trent 800 series turbofan engines to include required enhanced inspection of selected critical life-limited parts at each piece-part exposure.

Examining the AD Docket

You may examine the AD Docket (including any comments and service information), by appointment, between 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays. See **ADDRESSES** for the location.

Comments

We provided the public the opportunity to participate in the development of this AD. We received no comments on the proposal or on the determination of the cost to the public.

Conclusion

We have carefully reviewed the available data and determined that air safety and the public interest require adopting the AD as proposed.

Costs of Compliance

There are about 350 engines of the affected design in the worldwide fleet. We estimate that 90 engines installed on airplanes of U.S. registry are affected by this AD. We also estimate that it will take about 75 work hours per engine to perform the inspections, and that the average labor rate is $65 per work hour. Since this is an added inspection requirement, included as part of the normal maintenance cycle, no additional part costs are involved. Based on these figures, the total cost impact of the AD on U.S. operators is estimated to be $438,750.

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 summary of the costs to comply with this AD and placed it in the AD Docket. You may get a copy of this summary by sending a request to us at the address listed under **ADDRESSES.** Include "AD Docket No. 2003–NE–54–AD" in your request.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, 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):

2004–19–08 Rolls-Royce plc: Amendment 39–13802. Docket No. 2003–NE–54–AD.

Effective Date

(a) This AD becomes effective October 27, 2004.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Rolls-Royce plc (RR) RB211 Trent 800 series turbofan engines. These engines are installed on, but not limited to, Boeing 777 airplanes.

Unsafe Condition

(d) This AD results from the need to require enhanced inspection of selected critical life-limited parts of RB211 Trent 800 series turbofan engines. The actions specified in this AD are intended to prevent critical life-limited rotating engine part failure, which could result in an uncontained engine failure and damage to 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.

(f) Within the next 40 days after the effective date of this AD, revise the Time

Limits Manual (TLM), and for air carrier operations revise the approved continuous airworthiness maintenance program, by adding the following:

"GROUP A PARTS MANDATORY INSPECTION

(1) Inspections referred to as 'Focus Inspect' in the applicable Engine Manual inspection Task are mandatory inspections for the components given below, when the conditions that follow are satisfied:

(i) When the component has been completely disassembled to piece-part level as given in the applicable disassembly procedures contained in the Engine Manual; and

(ii) The part has more than 100 recorded flight cycles in operation since the last piece-part inspection. or

(iii) The component removal was for damage or a cause directly related to its removal; or

(iv) Where serviceable used components, for which the inspection history is not fully known, are to be used again.

(2) The list of Group A Parts is specified below:

Part nomenclature	Part number	Inspected per overhaul manual task
Low Pressure Compressor Rotor Disc	All	72–31–16–200–801
Low Pressure Compressor Rotor Shaft	All	72–31–20–200–801
Intermediate Pressure Compressor Rotor Shaft	All	72–32–31–200–801
Intermediate Pressure Rear Shaft	All	72–33–21–200–801
High Pressure Compressor Stage 1 to 4 Rotor Discs Shaft	All	72–41–31–200–801
High Pressure Compressor Stage 5 & 6 Discs and Cone	All	72–41–31–200–802
High Pressure Turbine Rotor Disc	All	72–41–51–200–801
Intermediate Pressure Turbine Rotor Disc	All	72–51–31–200–801
Intermediate Pressure Turbine Rotor Shaft	All	72–51–33–200–801
Low Pressure Turbine Stage 1 Rotor Disc	All	72–52–31–200–801
Low Pressure Turbine Stage 2 Rotor Disc	All	72–52–31–200–802
Low Pressure Turbine Stage 3 Rotor Disc	All	72–52–31–200–803
Low Pressure Turbine Stage 4 Rotor Disc	All	72–52–31–200–804
Low Pressure Turbine Stage 5 Rotor Disc	All	72–52–31–200–805
Low Pressure Turbine Rotor Shaft	All	72–52–33–200–801"

Alternative Methods of Compliance

(g) You must perform these mandatory inspections using the TLM and the applicable Engine Manual unless you receive approval to use an alternative method of compliance under paragraph (h) of this AD. Section 43.16 of the Federal Aviation Regulations (14 CFR 43.16) may not be used to approve alternative methods of compliance or adjustments to the times in which these inspections must be performed.

(h) The Manager, Engine Certification Office, has the authority to approve alternative methods of compliance for this AD if requested using the procedures found in 14 CFR 39.19.

Maintaining Records of the Mandatory Inspections

(i) You have met the requirements of this AD by using a TLM changed as specified in paragraph (f) of this AD, and, for air carriers operating under part 121 of the Federal Aviation Regulations (14 CFR part 121), by modifying your continuous airworthiness maintenance plan to reflect those changes. You must maintain records of the mandatory inspections that result from those changes to the TLM according to the regulations governing your operation. You do not need to record each piece-part inspection as compliance to this AD. For air carriers operating under part 121, you may use either the system established to comply with section 121.369 or use an alternative system that your principal maintenance inspector has accepted if that alternative system:

(1) Includes a method for preserving and retrieving the records of the inspections resulting from this AD; and

(2) Meets the requirements of section 121.369(c); and

(3) Maintains the records either indefinitely or until the work is repeated.

(j) These record keeping requirements apply only to the records used to document the mandatory inspections required as a result of revising the Time Limits Manual as specified in paragraph (f) of this AD, and do not alter or amend the record keeping requirements for any other AD or regulatory requirement.

Material Incorporated by Reference

(k) None.

Related Information

(l) Civil Aviation Authority (CAA) airworthiness directive No. G–2003–0003, dated November 25, 2003, also addresses the subject of this AD.

Issued in Burlington, Massachusetts, on September 15, 2004.

Jay J. Pardee,

Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 04–21270 Filed 9–21–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2004–SW–15–AD; Amendment 39–13803; AD 2004–19–09]

RIN 2120–AA64

Airworthiness Directives; Robinson Helicopter Company Model R22–Series Helicopters

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment supersedes an existing emergency airworthiness directive (AD) for the Robinson Helicopter Company (Robinson) Model R22, R22 Alpha, R22 Beta, and R22 Mariner helicopters, that currently requires track-and-balancing certain main rotor blades (blades), replacing blades, and determining the age of each blade and revising the component history card or equivalent maintenance record. This amendment requires the same actions, but changes the applicability and adds clarifying language. It also prohibits the issuance of special flight permits, which the existing AD allows. This amendment is prompted by the need to clarify the existing AD language. The actions specified by this AD are intended to prevent a fatigue crack, blade failure, and subsequent loss of control of the helicopter.

DATES: Effective October 7, 2004.

Comments for inclusion in the Rules Docket must be received on or before November 22, 2004.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Office of the Regional Counsel, Southwest Region, Attention: Rules Docket No. 2004–SW–15–AD, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137. You may also send comments electronically to the Rules Docket at the following address: *9-asw-adcomments@faa.gov.*

FOR FURTHER INFORMATION CONTACT: Fred Guerin, Aviation Safety Engineer, FAA, Los Angeles Aircraft Certification Office, Airframe Branch, 3960 Paramount Blvd., Lakewood, California 90712, telephone (562) 627–5232, fax (562) 627–5210.

SUPPLEMENTARY INFORMATION: On March 18, 2004, the FAA issued emergency AD 2004–06–52, Docket 2004–SW–01–AD, to require:

- Within 10 hours time-in-service (TIS) or 30 days, whichever occurs first, track-and-balancing blades that are 5 years old or have 1,000 hours TIS;
- Replacing the blades with airworthy blades before further flight if an abnormal increase in vibration occurs within 5 hours TIS after the last track-and-balance;
- Within 10 hours TIS or 30 days, whichever occurs first, for helicopters with blades, part number (P/N) A016–1, replacing the blades with airworthy blades other than blades, P/N A016–1, on or before reaching 2,000 hours TIS;
- Within 10 hours TIS or 30 days, whichever occurs first, for helicopters with blades, P/N A016–2, replacing the blades with airworthy blades other than blades, P/N A016–1, on or before reaching 2,200 hours TIS or 10 years, whichever occurs first; and
- Within 10 hours TIS or 30 days, whichever occurs first, determining the age of each blade and revising the component history card or equivalent maintenance record for blades, P/N A016–2, by adding a 10-year retirement life to the current 2,200 hours TIS retirement life.

That action was prompted by two accidents that occurred in Australia and Israel that were attributed to failure of a blade. Investigation revealed that corrosion from water penetration initiated a fatigue crack in a blade. Information from the accident investigations revealed that the cracked blades manifested an increase in helicopter vibration. Following a track-and-balance of the blades, the vibrations would go back to normal for a short time and then slowly increase again until blade failure occurred. That condition, if not corrected, could result in a fatigue crack, blade failure, and subsequent loss of control of the helicopter.

Since issuing that AD, several commenters have called regarding the following issues:

- The AD does not include the start date for determining the age of the blades on Model R22 helicopters that have been overhauled by the manufacturer since these helicopters are returned to the owner with new blades, but only have a "return-to-service tag". The FAA agrees, and has included specific instructions for overhauled helicopters in this AD.
- Paragraph (d) of the emergency AD is unclear and has been interpreted by some to mean that all Model R22 helicopters with blades, P/N A016–2, installed, are grounded within 10 hours TIS or 30 days. While the FAA does not understand this interpretation, we have reworded the paragraph in this AD in an attempt to make it clearer. These blades must be replaced with airworthy blades on or before reaching their retirement life.
- Are the R22 Model Beta II and HP helicopters affected by the AD since they are not specifically listed in the Applicability section of the AD? The R22 Model Beta II and HP helicopters are commercial names for the R22 Beta and R22 and are not shown on the helicopter's type certificate. The required identification plate for each helicopter must contain the Model designation. These data plate model numbers are the ones listed in the type certificate and, as appropriate, in our ADs. However, the applicability statement has been restated in terms of the Model R22-series helicopters with blades, P/N A0126–1 or A016–2, installed. Our intent was and is to include in the applicability ALL Model R–22 helicopters with the affected blades installed, regardless of their commercial designation.
- "Yellow tags" are issued for any return to service of a part, whether new or not; does any "yellow tag" constitute the start of the calendar life of the blade? The AD has been reworded to clarify that only "yellow tags" delivered with the blade when new may be used to start the calendar life of the blade.

These changes justify issuing this superseding AD instead of publishing Emergency AD 2004–06–52 as a Final Rule in the **Federal Register**.

Since an unsafe condition has been identified that is likely to exist or develop on other Robinson Model R22 helicopters of the same type design, this AD supersedes AD 2004–06–52 to require:

- Within 10 hours TIS or 30 days, whichever occurs first, tracking-and-balancing blades, P/N A016–2, that are 5 or more years old, or have 1,000 or more hours TIS;
- Replacing the blades with airworthy blades, P/N A016–2, before further flight if an abnormal increase in vibration occurs within 5 hours TIS after the last track-and-balance;
- Within 10 hours TIS or 30 days, whichever occurs first, for helicopters with blades, P/N A016–1, replacing the blades with airworthy blades, P/N A016–2 or A016–4;
- Within 10 hours TIS or 30 days, whichever occurs first, for helicopters with blades, P/N A016–2, replacing the blades with airworthy blades on or before reaching 2,200 hours TIS or 10 years, whichever occurs first; and
- Within 10 hours TIS or 30 days, whichever occurs first, determining the age of each blade and revising the component history card or equivalent maintenance record for blades, P/N A016–2, by adding a 10-year retirement life to the current 2,200 hours TIS retirement life.

The short compliance time involved is required because the previously described critical unsafe condition can adversely affect the controllability and structural integrity of the helicopter. Therefore, the previously stated actions are required within a short timeframe and this AD must be issued immediately.

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

The FAA estimates that this AD will affect 923 helicopters of U.S. registry. Track-and-balancing the blades, revising the component history card and maintenance manual, determining the age of each blade, and replacing blades, if necessary, will take approximately 11 work hours per helicopter to accomplish at an average labor rate of $65 per work hour. Required parts will cost approximately $25,000 (for 2 blades) per helicopter. Based on these figures, we estimate the total cost impact of the AD on U.S. operators to be $7,584,945, assuming that most blades currently in service reach the TIS retirement life before reaching the calendar retirement life, and that at most, 277 helicopters will need their blades replaced.

Comments Invited

Although this action is in the form of a final rule that involves requirements affecting flight safety and, thus, was not preceded by notice and an opportunity for public comment, comments are invited on this rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted in triplicate to the address specified under the caption **ADDRESSES.** All communications received on or before the closing date for comments will be considered, and this rule may be

amended in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of the AD action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this AD will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. 2004–SW–15–AD." The postcard will be date stamped and returned to the commenter.

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.

The FAA has determined that this regulation is an emergency regulation that must be issued immediately to correct an unsafe condition in aircraft, and that it is not a "significant regulatory action" under Executive Order 12866. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket. A copy of it, if filed, 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, 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 a new airworthiness directive (AD), Amendment 39–13803, to read as follows:

2004–19–09 Robinson Helicopter Company: Amendment 39–13803. Docket No. 2004–SW–15–AD. Supersedes Emergency AD 2004–06–52, Docket No. 2004–SW–01–AD.

Applicability: Model R22-series helicopters, with a main rotor blade (blade), part number (P/N) A016–1 or A016–2, installed, certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

To prevent a fatigue crack, blade failure, and subsequent loss of control of the helicopter, accomplish the following:

(a) Within 10 hours time-in-service (TIS) or 30 days, whichever occurs first, for helicopters with blades, P/N A016–2, that are 5 or more years old, or have 1,000 or more hours TIS, track-and-balance the blades. If an abnormal increase in vibration occurs within 5 hours TIS after the last track and balance, before further flight, replace the blades with airworthy blades, P/N A016–2, that are less than 10 years old and have less than 2,200 hours TIS, or airworthy blades, P/N A016–4, that are less than 12 years old and have less than 2,200 hours TIS.

(b) Within 10 hours TIS or 30 days, whichever occurs first, for helicopters with blades, P/N A016–1, replace the blades with airworthy blades, P/N A016–2 or A016–4.

(c) Within 10 hours TIS or 30 days, whichever occurs first, determine the age of each blade:

(1) For a zero-hour TIS (new) blade delivered with an Airworthiness Approval tag, the time begins on the date stated on that tag. For a blade older than 9 years that predates the use of the Airworthiness Approval tag and was delivered as a new blade with a "yellow tag," the time begins on the date stated on that tag. Any subsequent yellow tag issued for a blade after the blade was placed into service is not valid for determining the original manufacture date.

(2) For a new blade that has neither an Airworthiness Approval tag nor a yellow tag because it was delivered on a factory-new helicopter, the time begins on the date stated on the original Airworthiness Certificate as documented in the aircraft maintenance records.

(3) For a new blade installed on an overhauled helicopter, the time begins on the date the helicopter was returned to service after overhaul as documented in the aircraft logbook or work report.

(4) For all other blades, the time begins on the date of manufacture. This date can be obtained from the manufacturer by providing them the serial number and part number.

(d) Within 10 hours TIS or 30 days, whichever occurs first, for helicopters with blades, P/N A016–2, replace the blades with airworthy blades on or before reaching 2,200 hours TIS or 10 years, whichever occurs first.

(e) Within 10 hours TIS or 30 days, whichever occurs first, revise the component history card or equivalent maintenance record for blades, P/N A016–2, by adding a 10-year retirement life to the current 2,200 hours TIS retirement life.

(f) Revise the Airworthiness Limitations section of the applicable maintenance manual by adding a new retirement life of 10 years to the current 2,200 hours TIS retirement life for blades, P/N A016–2.

Note: Robinson Model R22 Maintenance Manual, dated January 16, 2004, contains the revised Airworthiness Limitations section.

(g) To request a different method of compliance or a different compliance time for this AD, follow the procedures in 14 CFR 39.19. Contact the Los Angeles Aircraft Certification Office, Transport Airplane Directorate, FAA, for information about previously approved alternative methods of compliance.

(h) Special flight permits will not be issued.

(i) This amendment becomes effective on October 7, 2004.

Issued in Fort Worth, Texas, on September 16, 2004.

David A. Downey,

Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 04–21269 Filed 9–21–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2004–18819; Airspace Docket No. 04–ACE–45]

Modification of Class D Airspace; and Modification of Class E Airspace; Grand Island, NE

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Direct final rule; request for comments.

SUMMARY: This action amends title 14 Code of Federal Regulations, part 71 (14 CFR part 71) by revising Class D and Class E airspace areas at Grand Island, NE. A review of the controlled airspace areas at Grand Island, NE revealed they do not reflect the current Central Nebraska Regional Airport airport reference point (ARP). The review also identified discrepancies in the legal descriptions for the Grand Island, NE Class E airspace areas. These airspace areas are modified to conform to FAA Orders.

The intended effect of this rule is to provide controlled airspace of

appropriate dimensions to protect aircraft departing from and executing Standard Instrument Approach Procedures (SIAPs) to Central Nebraska Regional Airport. It also corrects discrepancies in the legal descriptions of Grand Island, NE Class E airspace areas and brings the airspace areas and legal descriptions into compliance with FAA Orders.

DATES: This direct final rule is effective on 0901 UTC, January 20, 2005. Comments for inclusion in the Rules Docket must be received on or before October 26, 2004.

ADDRESSES: Send comments on this proposal to the Docket Management System, U.S. Department of Transportation, Room Plaza 401, 400 Seventh Street, SW., Washington, DC 20590–0001. You must identify the docket number FAA–2004–18819/ Airspace Docket No. 04–ACE–45, at the beginning of your comments. You may also submit comments on the Internet at *http://dms.dot.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Office (telephone 1–800–647–5527) is on the plaza level of the Department of Transportation NASSIF Building at the above address.

FOR FURTHER INFORMATION CONTACT: Brenda Mumper, Air Traffic Division, Airspace Branch, ACE–520A, DOT Regional Headquarters Building, Federal Aviation Administration, 901 Locust, Kansas City, MO 64106; telephone: (816) 329–2524.

SUPPLEMENTARY INFORMATION: This amendment to 14 CFR part 71 modifies the Class D airspace area, the Class E airspace area designated as a surface area, the Class E airspace area designated as an extension to the Class D airspace area and the Class E airspace area extending upward from 700 feet above the surface at Grand Island, NE. An examination of controlled airspace for Grand Island, NE revealed that the Central Nebraska Regional Airport ARP used in the legal descriptions for all airspace areas is incorrect. The location of the Grand Island collocated very high frequency omni-directional radio range and tactical air navigational aid (VORTAC) used in the Class E airspace area designated as an extension to the class D airspace area legal description is incorrect.

The dimensions of the Class E airspace area designated as an extension to the Class D airspace area do not comply with airspace requirements as set forth in FAA Order 7400.2E, Procedures for Handling Airspace Matters. The widths of the extensions in this airspace area are decreased from 2.6 miles to 2.4 miles, the lengths are decreased from 7.4 miles to 7 miles from the Grand Island VORTAC and the centerline of the northwest extension is corrected from the Grand Island VORTAC 294° radial to the 291° radial.

The south extension to the Class E airspace area extending upward from 700 feet above the surface is no longer required. Dimensions of the northwest and north extensions, after being brought into compliance with FAA Order 7400.2E, are identical to those in the Class E airspace area designated as an extension to the Class D airspace area. Therefore, extensions to the Class E airspace area extending upward from 700 feet above the surface are deleted from the legal description.

These modifications provide controlled airspace of appropriate dimensions to protect aircraft departing from and executing SIAPs to Central Nebraska Regional Airport and bring the legal descriptions of the Grand Island, NE Class D and Class E airspace areas into compliance with FAA Order 7400.2E. Class D airspace areas are published in Paragraph 5000 of FAA Order 7400.9M, dated August 30, 2004, and effective September 16, 2004, which is incorporated by reference in 14 CFR 71.1. Class E airspace areas designated as surface areas, Class E airspace areas designated as an extension to a Class D airspace area and Class E airspace area extending upward from 700 feet or more above the surface of the earth are published in Paragraphs 6002, 6004 and 6005 respectively of the same FAA Order. The Class D and Class E airspace designations listed in this document will be published subsequently in the Order.

The Direct Final Rule Procedure

The FAA anticipates that this regulation will not result in adverse or negative comment and, therefore, is issuing it as a direct final rule. Previous actions of this nature have not been controversial and have not resulted in adverse comments or objections. Unless a written adverse or negative comment, or a written notice of intent to submit an adverse or negative comment is received within the comment period, the regulation will become effective on the date specified above. After the close of the comment period, the FAA will publish a document in the **Federal Register** indicating that no adverse or negative comments were received and confirming the date on which the final rule will become effective. If the FAA does receive, within the comment period, an adverse or negative comment, or written notice of intent to submit such a comment, a document withdrawing the direct final rule will be published in the **Federal Register**, and a notice of proposed rulemaking may be published with a new comment period.

Comments Invited

Interested parties are invited to participate in this rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide a factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. FAA–2004–18819/Airspace Docket No. 04–ACE–45." The postcard will be date/time stamped and returned to the commenter.

Agency Findings

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.

The FAA has determined that this regulation is noncontroversial and unlikely to result in adverse or negative comments. For the reasons discussed in the preamble, I certify that this regulation (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, 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.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

■ Accordingly, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

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

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9M, dated August 30, 2004, and effective September 16, 2004, is amended as follows:

Paragraph 5000 Class D Airspace.

* * * * *

ACE NE D Grand Island, NE

Grand Island, Central Nebraska Regional Airport, NE
(Lat. 40°58′03″ N., long. 98°18′35″ W.)

That airspace extending upward from the surface to and including 4,300 feet MSL within a 4.4-mile radius of Central Nebraska Regional Airport. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility directory.

* * * * *

Paragraph 6002 Class E Airspace Designated as Surface Areas.

* * * * *

ACE NE E2 Grand Island, NE

Grand Island, Central Nebraska Regional Airport, NE
(Lat. 40°58′03″ N., long. 98°18′35″ W.)

Within a 4.4-mile radius of Central Nebraska Regional Airport. This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility directory.

* * * * *

Paragraph 6004 Class E Airspace Designated as an Extension to a Class D or Class E Surface Area.

* * * * *

ACE NE E4 Grand Island, NE

Grand Island, Central Nebraska Regional Airport, NE
(Lat. 40°58′03″ N., long. 98°18′35″ W.)
Grand Island VORTAC
(Lat. 40°59′03″ N., long. 98°18′53″ W.)

That airspace extending upward from the surface within 2.4 miles each side of the Grand Island VORTAC 291° radial extending from the 4.4-mile radius of Central Nebraska Regional Airport to 7 miles northwest of the VORTAC and within 2.4 miles each side of the Grand Island VORTAC 360° radial extending from the 4.4-mile radius of the airport to 7 miles north of the VORTAC.

* * * * *

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

ACE NE E5 Grand Island, NE

Grand Island, Central Nebraska Regional Airport, NE
(Lat. 40°58′03″ N., long. 98°18′35″ W.)
Grand Island, VORTAC
(Lat. 40°59′03″ N., long. 98°18′53″ W.)

The airspace extending upward from 700 feet above the surface within a 6.9-mile radius of Central Nebraska Regional.

* * * * *

Issued in Kansas City, MO, on September 9, 2004.

Paul J. Sheridan,

Acting Manager, Air Traffic Division, Central Region.

[FR Doc. 04–21226 Filed 9–21–04; 8:45 am]
BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

14 CFR Part 254

RIN 2105–AD42

Passenger Baggage Liability

AGENCY: Department of Transportation (DOT), Office of the Secretary (OST)

ACTION: Final rule.

SUMMARY: In accordance with the provisions of 14 CFR 254.6, this final rule revises the minimum limit on domestic baggage liability applicable to air carriers to reflect inflation since December 1999, the date of the most recent revision to the rule. Section 254.6 requires that the Department revise periodically the limit to reflect any changes in the Consumer Price Index during the interim. The rule adjusts the minimum limit of liability from the current amount of $2,500 to $2,800, taking into account the changes in price level over a period of approximately four years.

DATES: *Effective Date:* This rule is effective on October 22, 2004.

FOR FURTHER INFORMATION CONTACT: Nicholas Lowry, Senior Attorney, Office of Aviation Enforcement and Proceedings (C–70), Department of Transportation, 400 Seventh St., SW., Washington, DC 20590; (202) 366–9351.

SUPPLEMENTARY INFORMATION:

I. Background

Part 254 of the Department's rules, 14 CFR part 254, establishes minimum baggage liability limits applicable to domestic air service, currently $2,500 per passenger. Provisions of 14 CFR 254.6 require that the Department periodically review the minimum limit of liability prescribed in part 254 in light of changes in the Consumer Price Index for Urban Consumers and directs the Department to revise the limit of liability to reflect changes in the price index that have occurred in the interim. Section 254.6 prescribes the use of a specific formula to calculate the revised minimum liability amount when making these periodic adjustments. Applying the formula to changes occurring between December 1999 and July 2004, the appropriate inflation adjustment is $2,500 × 189.4/168.3, or $2,813.42. The provision requires us to round the adjustment to the nearest $100, or to $2,800.

II. Waiver of Rulemaking Procedural Requirements

With this final rule, we are waiving the usual notice of proposed rulemaking and public comment procedures set forth in the Administrative Procedure Act (APA) (5 U.S.C. 553). The APA allows agencies to dispense with such procedures on finding of good cause when they are impracticable, unnecessary or contrary to the public interest. We have determined that under 5 U.S.C. 553(b)(3)(B) good cause exists for dispensing with the notice of proposed rulemaking and public comment procedures for this rule. This rulemaking is required by the terms of 14 CFR 254.6, as most recently amended in December 1999 (64 FR 70575, December 17, 1999). Accordingly, we believe prior comment is unnecessary and contrary to the public interest, and we are issuing this revision as a final rule.

Although this final rule will become effective in 30 days, the Department will defer enforcement of the notice provision in the revised rule, as it pertains to written notice of the new limit, for a reasonable period to allow carriers to replace or correct their current paper ticket stock and envelopes so as to provide proper written notice of the increased minimum liability limit without imposing an undue burden. Carriers are, however, subject to enforcement action from the date of issuance of this final rule if they otherwise fail to provide proper notice of the $2,800 liability limit or fail to apply the new limit, as appropriate.

III. Regulatory Impact Statement

Executive Order 12866

This final rule has been evaluated in accordance with the existing policies and procedures and is considered not significant under both Executive Order 12866 and DOT Regulatory Policies and Procedures. The rule is exempt from review by the Office of Management and Budget (OMB) in accordance with the provisions of Executive Order 12866, because its provisions are required by current regulatory language, without interpretation.

Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 (5 U.S.C. 601–612) requires an assessment of the impact of the proposed and final rule on small entities unless the agency certifies that the proposed regulation will have no significant economic impact on small entities. This revision of 14 CFR part 254 provides for a minimal increase in the amount of the minimum baggage liability limit that air carriers may incur in cases of lost or damaged baggage. It will pose minor additional costs only in those instances in which carriers lose or damage baggage, or delay delivering baggage to the traveler, and it affects only carriers operating large aircraft or those small carriers interlining with such carriers. As a result, many operations of small entities, such as air taxis and commuter air carriers, are not covered by the rule. Accordingly, we certify that this action will not have a significant economic impact on a substantial number of small entities.

Paperwork Reduction Act

This final rule imposes no new reporting or recordkeeping requirements necessitating clearance by OMB.

List of Subjects in 14 CFR Part 254

Administrative practice and procedure, Air carriers, Consumer protection, Department of Transportation.

■ Accordingly, the Department of Transportation revises 14 CFR part 254, *Domestic Baggage Liability*, to read as follows:

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

Authority: 49 U.S.C. 40113, 41501, 41501, 41504, 41510, 41702 and 41707.

■ 2. Section 254.4 is revised to read as follows:

§ 254.4 Carrier liability.

On any flight segment using large aircraft, or on any flight segment that is included on the same ticket as another flight segment that uses large aircraft, an air carrier shall not limit its liability for provable direct or consequential damages resulting from the disappearance of, damage to, or delay in delivery of a passenger's personal property, including baggage, in its custody to an amount less than $2,800 for each passenger.

■ 3. Section 254.5 is revised to read as follows:

§ 254.5 Notice requirement.

In any flight segment using large aircraft, or on any flight segment that is included on the same ticket as another flight segment that uses large aircraft, an air carrier shall provide to passengers, by conspicuous written material included on or with its ticket, either:

(a) Notice of any monetary limitation on its baggage liability to passengers; or

(b) The following notice: "Federal rules require any limit on an airline's baggage liability to be at least $2,800 per passenger."

Issued in Washington, DC on September 8, 2004.

Norman Y. Mineta,

Secretary of Transportation.

[FR Doc. 04–21247 Filed 9–21–04; 8:45 am]

BILLING CODE 4910–62–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Part 744

[Docket No. 040713207–4207–01]

RIN 0694–AD13

India: Removal of Indian Entity and Revision in License Review Policy for Certain Indian Entities; and a Clarification

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Final rule.

SUMMARY: On January 12, 2004, President George W. Bush announced the Next Steps in Strategic Partnership (NSSP) with India. The proposed cooperation outlined in the NSSP will progress through a series of reciprocal steps that build on each other, including steps related to enhancing cooperation in peaceful uses of space technology and steps to create the appropriate environment for successful high technology commerce. This rule implements three initial steps the United States has agreed to take under the NSSP. These steps are: To remove the Indian Space Research Organization (ISRO) Headquarters, Bangalore from the Department of Commerce Entity List; to remove the export license requirements for items subject to the Export Administration Regulations (EAR) having a classification of EAR99 or a classification where the third through fifth digits of the Export Commodity Classification Number (ECCN) are "999", *e.g.* XX999, for the seven (7) ISRO subsidiaries listed on the Entity List; and establish a presumption of approval for all items *not* controlled for nuclear proliferation reasons going to the "balance of plant" portion of Indian nuclear facilities subject to International Atomic Energy Agency safeguards (Rajasthan 1 & 2 and Tarapur 1 & 2).

This rule also makes one clarification in order to make clear the longstanding interpretation that information regarding the Entity List published in the **Federal Register** is intended to inform the public, not simply to inform exporters.

DATES: This rule is effective September 22, 2004.

ADDRESSES: Although this is a final rule, comments are welcome and should be addressed to Sharron Cook, Office of Exporter Services, Bureau of Industry and Security, Department of Commerce, PO Box 273, Washington, DC 20044, e-mailed to: *scook@bis.doc.gov* or faxed to (202) 482–3355.

Comments regarding the collections of information associated with this rule, including suggestions for reducing the burden, should be sent to OMB Desk Officer, New Executive Office Building, Washington, DC 20503—Attention: David Rostker; and to the Office of Administration, Bureau of Industry and Security, Department of Commerce, 14th and Pennsylvania Avenue, NW., Room 6883, Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Eileen M. Albanese, Office of Exporter Services, Bureau of Industry and Security, Telephone: (202) 482–0436.

SUPPLEMENTARY INFORMATION:

Background

In November 2001, Indian Prime Minister Vajpayee and President Bush committed India and the United States to a strategic partnership. Since then, the two countries have strengthened bilateral cooperation significantly in several areas. On January 12, 2004, the two leaders announced the next steps in implementing a shared vision to expand cooperation, deepen the ties of commerce and friendship between the two nations, and increase stability in Asia and beyond.

The proposed cooperation will progress through a series of reciprocal steps that will build on each other. It

will include expanded engagement on nuclear regulatory and safety issues and missile defense, ways to enhance cooperation in peaceful uses of space technology, and steps to create the appropriate environment for successful high technology commerce.

This rule implements three initial steps in transforming the relationship between the United States and India by: (1) Removing the Indian Space Research Organization (ISRO) Headquarters in Bangalore from the Department of Commerce Entity List contained in Supplement No. 4 to Part 744 of the Export Administration Regulations (EAR); (2) removing the license requirement for the seven (7) ISRO subsidiaries listed on the Entity List for all items subject to the Export Administration Regulations (EAR) having a classification of EAR99 or a classification where the third through fifth digits of the Export Commodity Classification Number (ECCN) are "999", *e.g.*, XX999.; and (3) establishing a presumption of approval for all items *not* controlled for nuclear proliferation reasons going to the "balance of plant" portion of Indian nuclear facilities subject to International Atomic Energy Agency safeguards (Rajasthan 1 & 2 and Tarapur 1 & 2). Balance of plant" refers to the part of a nuclear power plant used for power generation (*e.g.*, turbines, controllers, or power distribution) to distinguish it from the nuclear reactor. This explanation of "balance of plant" is added as a footnote to the Entity List.

The removal of ISRO Headquarters, Bangalore from the Entity List eliminates the existing license requirements in Supplement No. 4 to Part 744 for exports to this entity. The removal of entities from the Entity List does not relieve exporters or reexporters of their obligations under Part 744. Neither the removal of entities from the Entity List or the removal of license requirements for entities on the Entity List relieves exporters or reexporters of their obligations under General Prohibition 5 in § 736.2(b)(5) of the EAR which provides that, "you may not, without a license, knowingly export or reexport any item subject to the EAR to an end-user or end-use that is prohibited by part 744 of the EAR." BIS strongly urges the use of Supplement No. 3 to part 732 of the EAR, "BIS's "Know Your Customer" Guidance and Red Flags" when exporting or reexporting to India.

This rule also amends section 744.1 by revising the phrase "Exporters are" to read "The public is" in the second sentence of paragraph (c). BIS is revising this phrase in order to clarify the longstanding interpretation that when information regarding the Entity List was published in the **Federal Register**, BIS was informing the public. Therefore, this rule clarifies that BIS's intent has always been to notify all persons that entities listed in Supplement No. 4 are ineligible to receive any items subject to the EAR without a license to the extent specified in the supplement. The word "Exporter" should not be read to limit the scope of the notice.

Although the Export Administration Act expired on August 20, 2001, Executive Order 13222 of August 17, 2001 (3 CFR, 2001 Comp., p. 783 (2002)) as extended by the Notice of August 7, 2003 (3 CFR, 2003 Comp. 328 (2004)), continues the Regulations in effect under the International Emergency Economic Powers Act.

Rulemaking Requirements

1. This final rule has been determined to be not significant for purposes of E.O. 12866.

2. Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with a collection of information, subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. This rule involves a collection of information subject to the PRA. This collection has been approved by OMB under control number 0694–0088, "Multi-Purpose Application," which carries a burden hour estimate of 58 minutes for a manual or electronic submission. Send comments regarding these burden estimates or any other aspect of these collections of information, including suggestions for reducing the burden, to OMB Desk Officer, New Executive Office Building, Washington, DC 20503; and to the Office of Administration, Bureau of Industry and Security, Department of Commerce, 14th and Pennsylvania Avenue, NW., Room 6883, Washington, DC 20230.

3. This rule does not contain policies with Federalism implications as that term is defined under E.O. 13132.

4. The provisions of the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, the opportunity for public participation, and a delay in effective date, are inapplicable because this regulation involves a military and foreign affairs function of the United States (5 U.S.C. 553(a)(1)). Further, no other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this final rule. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule under the Administrative Procedure Act or by any other law, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are not applicable. Therefore, this regulation is issued in final form. Although there is no formal comment period, public comments on this regulation are welcome on a continuing basis. Comments should be submitted to Sharron Cook, Office of Exporter Services, Bureau of Industry and Security, Department of Commerce, PO Box 273, Washington, DC 20044.

List of Subjects in 15 CFR Part 744

Exports, Foreign trade, Reporting and recordkeeping requirements.

■ Accordingly, part 744 of the Export Administration Regulations (15 CFR parts 730–799) is amended as follows:

PART 744—[AMENDED]

■ 1. The authority citation for 15 CFR part 744 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; 22 U.S.C. 3201 *et seq.*; 42 U.S.C. 2139a; Sec. 901–911, Pub. L. 106–387; Sec. 221, Pub. L. 107–56; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 12947, 60 FR 5079, 3 CFR, 1995 Comp., p. 356; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13099, 63 FR 45167, 3 CFR, 1998 Comp., p. 208; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13224, 66 FR 49079, 3 CFR, 2001 Comp., p. 786; Notice of October 29, 2003, 68 FR 62209, 3 CFR, 2003 Comp., p. 347; Notice of August 6, 2004, 69 FR 48763 (August 10, 2004).

§ 744.1 [Amended]

■ 2. Section 744.1 is amended by revising the phrase "Exporters are" to read "The public is" in the second sentence of paragraph (c).

■ 3. In Supplement No. 4 to part 744, under the country of "India", the entities "Indian Space Research Organization (ISRO) headquarters in Bangalore" and "Department of Atomic Energy Agency entities" are revised to read as set forth below:

Supplement No. 4 to Part 744—Entity List

* * * * *

Country	Entity	License requirement	License review policy	Federal Register citation
*	* *	*	*	*
INDIA	The following Indian Space Research Organization (ISRO) subordinate entities: ISRO Telemetry, Tracking and Command Network (ISTRAC); ISRO Inertial Systems Unit (IISU), Thiruvananthapuram; Liquid Propulsion Systems Center; Solid Propellant Space Booster Plant (SPROB); Space Applications Center (SAC), Ahmadabad; Sriharikota Space Center (SHAR); Vikram Sarabhai Space Center (VSSC), Thiruvananthapuram.	For all items subject to the EAR having a classification other than (1) EAR99 or (2) a classification where the third through fifth digits of the ECCN are "999", *e.g.* XX999.	Case-by-case review for all items on the CCL.	63 FR 64322, 11/19/98; 65 FR 14444, 03/17/00; 66 FR 50090, 10/01/01; [Insert Federal Register citation 09/22/04.
	The following Department of Atomic Energy entities: Bhabha Atomic Research Center (BARC); Indira Gandhi Atomic Research Center (IGCAR); Indian Rare Earths; Nuclear reactors (including power plants) not under International Atomic Energy Agency (IAEA) safeguards, fuel reprocessing and enrichment facilities, heavy water production facilities and their collocated ammonia plants.	For all items subject to the EAR.	Case-by-case for all items listed on the CCL. Presumption of approval for EAR99 items.	63 FR 64322, 11/19/98; 65 FR 14444, 03/17/00; 66 FR 50090, 10/01/01; [Insert Federal Register citation 09/22/04.
	The following Department of Atomic Energy entities: Nuclear reactors (including power plants) subject to International Atomic Energy Agency (IAEA) safeguards: Tarapur (TAPS 1 & 2); Rajasthan (RAPS 1 & 2).	For all items subject to the EAR.	Case-by-case for all items listed on the CCL. Presumption of approval for EAR99 items. Presumption of approval for EAR99 items not controlled for Nuclear Proliferation (NP) reasons for use in the "balance of plant" (non-reactor-related end uses) [1] activities at nuclear facilities subject to International Atomic.	63 FR 64322, 11/19/98; 65 FR 14444, 03/17/00; 66 FR 50090, 10/01/01; [Insert Federal Register citation 09/22/04.

[1] "Balance of Plant" refers to the part of a nuclear power plant used for power generation (*e.g.*, turbines, controllers, or power distribution) to distinguish it from the nuclear reactor.

Dated: September 17, 2004.

Peter Lichtenbaum,

Assistant Secretary for Export Administration.

[FR Doc. 04–21303 Filed 9–21–04; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[CGD05–04–047]

RIN 1625–AA00

Security Zone; Atlantic Ocean, Chesapeake & Delaware Canal, Delaware Bay, Delaware River and Its Tributaries

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is establishing a security zone that will require all vessels in a 500-yard radius around escorted passenger vessels to operate at the minimum speed necessary to navigate safely and prohibit any vessels from entering within 100 yards of escorted passenger vessels in the Captain of the Port (COTP) Philadelphia. This security zone is needed to ensure public safety and enhance maritime security. The zone will ensure the security of the vessels during transit in the COTP Philadelphia zone.

DATES: This rule is effective September 10, 2004.

ADDRESSES: Comments and related material received from the public, as well as documents indicated in this preamble as being available in the docket, are part of docket CGD05–04–047 and are available for inspection or copying at Coast Guard Marine Safety Office Philadelphia, One Washington Avenue, Philadelphia, Pennsylvania 19147 between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Lieutenant Junior Grade Kevin Sligh or Ensign Jill Munsch, Coast Guard Marine Safety Office/Group Philadelphia, at (215) 271–4889.

SUPPLEMENTARY INFORMATION:

Regulatory History

On June 28, 2004 we published a notice of proposed rulemaking (NPRM) in the **Federal Register** entitled "Security Zone; Atlantic Ocean, Chesapeake & Delaware Canal, Delaware Bay, Delaware River and its tributaries" in the **Federal Register** (69 FR 36032). We received no letters commenting on the proposed rule.

In addition, a temporary final rule with the same title was published in the **Federal Register** on April 13, 2004 (69 FR 19326). That temporary final rule

established a security zone around escorted passenger vessels, but that rule was only effective through September 1, 2004.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. The temporary final rule has expired. Delaying the effective date of this rule would be contrary to public interest because immediate action is needed to protect against potential hazards and threats to passenger vessels.

Background and Purpose

This rule is necessary because hostile entities continue to operate with the intent to harm U.S. shipping interests. The President has continued the national emergencies he declared following the September 11, 2001 terrorist attacks. 67 FR 58317 ((Sept. 13, 2002) (continuing national emergency with respect to terrorist attacks)); 67 FR 59447 ((Sept. 20, 2002) continuing national emergency with respect to persons who commit, threaten to commit or support terrorism)); 68 FR 55189 ((Sept. 22, 2003 (continuing national emergency with respect to persons who commit, threaten to commit or support terrorism)).

The U.S. Maritime Administration (MARAD) recently issued Advisory 03–06 informing operators of maritime interests of increased threat possibilities to vessels and facilities and a higher risk of terrorist attack to the transportation community in the United States. The Coast Guard is establishing this final rule to ensure vessels transit safely in the COTP zone Philadelphia, . Pennsylvania.

Discussion of Comments and Changes

During the public comment period, we received no letters or comments concerning this zone. We did not make any changes to the proposed security zone after the comment period.

Regulatory Evaluation

This rule is not a "significant regulatory action" under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not "significant" under the regulatory policies and procedures of the Department of Homeland Security (DHS).

We expect the economic impact of this rule to be so minimal that a full Regulatory Evaluation under the regulatory policies and procedures of DHS is unnecessary. There is ample room for vessels to navigate around the security zone and the Captain of the Port may allow vessels to enter the zone on a case-by-case basis with the express permission of the Captain of the Port of Philadelphia or their designated representative.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

This rule will not have a significant impact on a substantial number of small entities because the restrictions affect only a limited area. Although this is a permanent rule, a security zone will be activated only when an escorted passenger vessel is in the COTP Philadelphia zone. Most vessel traffic can pass safely around the security zone, and maneuver-restricted vessels may seek permission from the COTP to pass within 100 yards of the vessel. Additionally, the opportunity to engage in recreational and charter fishing outside the limits of the security zone will not be disrupted.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule would not have a significant economic impact on a substantial number of small entities, as none were identified that will be affected by the final rule.

Vessel traffic counts indicate the waterway users will continue to have the same access to the waterway as in the past, with the exception of a small area surrounding transiting passenger vessels in the Captain of the Port Philadelphia zone.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), we want to assist small entities in understanding this rule so that they could better evaluate its effects on them and participate in the rulemaking process. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact Lieutenant Junior Grade Kevin Sligh or Ensign Jill Munsch, Coast Guard Marine Safety Office/Group Philadelphia, at (215) 271–4889.

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 or more in any one year. Though this rule will not result in such expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This rule will not affect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Security Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to security that may disproportionately affect children.

Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, 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. We

invite your comments on how this rule might impact tribal governments, even if that impact may not constitute a "tribal implication" under the Order.

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a "significant energy action" under that order because it is not a "significant regulatory action" under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies. This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this rule under Commandant Instruction M16475.1D, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2–1, paragraph (34)(g), of Commandant Instruction M16475.1D, from further environmental documentation.

We have considered the security zone access constraints around passenger vessels and have determined the public can safely transit the affected waterways outside the security zone, without significant impact on the environment.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701; 50 U.S.C. 191, 195; 33 CFR 1.05–1(g), 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.511.

§ 165.511 Security Zone; Atlantic Ocean, Chesapeake & Delaware Canal, Delaware Bay, Delaware River and its tributaries.

(a) *Location.* A 500-yard radius around escorted passenger vessels in the Captain of the Port, Philadelphia zone as defined in 33 CFR 3.25–05.

(b) *Regulations.* (1) All persons are required to comply with the general regulations governing security zones in § 165.33 of this part.

(2) All persons or vessels operating at the minimum safe speed necessary to maintain navigation may transit within 500 yards of an escorted passenger vessel without the permission of the Captain of the Port Philadelphia, PA or designated representative while the escorted passenger vessel is in the Captain of the Port Philadelphia zone.

(3) No person or vessel may transit or remain within 100 yards of an escorted passenger vessel without the permission of the Captain of the Port Philadelphia, PA or designated representative while the passenger vessel is in the Captain of the Port Philadelphia zone.

(4) Any person or vessel authorized to enter the security zone must operate in strict conformance with any directions given by the Captain of the Port Philadelphia, PA or designated representative and leave the security zone immediately if the Captain of the Port Philadelphia, PA or designated representative so orders.

(5) When an escorted passenger vessel approaches within 100 yards of any vessel that is moored or anchored, the stationary vessel must stay moored or anchored while it remains within 100 yards of the passenger vessel unless it is either ordered by or given permission by the Captain of the Port, Philadelphia or designated representative to do otherwise.

(6) The Coast Guard designated representative enforcing this section can be contacted on VHF Marine Band Radio, channels 13 and 16. The Captain of the Port can be contacted at (215) 271–4807.

(c) *Maneuver-restricted vessels.* When conditions permit, the Captain of the Port or designated representative should:

(1) Permit vessels constrained by their navigational draft or restricted in their ability to maneuver to pass within the 100 yards of the passenger vessel in order to ensure safe passage in accordance with the Navigation Rules as seen in 33 CFR chapter I, subchapters D and E; and

(2) Permit vessels constrained by their navigational draft or restricted in their ability to maneuver that must transit via a navigable channel or waterway to pass within 100 yards of an anchored passenger vessel.

(d) *Definitions.* As used in this section—

Captain of the Port means the Commanding Officer of the Coast Guard Marine Safety Office/Group Philadelphia or any Coast Guard commissioned, warrant, or petty officer who has been authorized by the Captain of the Port to act as a designated representative on his behalf.

Escort means assets (surface or air) with the Coast Guard insignia that accompany and protect the escorted vessel, armed with crew-served weapons that are manned and ready.

Passenger Vessels means vessels greater than 100 feet in length, over 100 gross tons that are authorized to carry 500 or more passengers, making voyages lasting more than 24 hours, except for ferries.

Dated: September 10, 2004.

Jonathan D. Sarubbi,

Captain, U.S. Coast Guard, Captain of the Port, Philadelphia.

[FR Doc. 04–21245 Filed 9–21–04; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 81

[OAR–2003–0083; FRL–7816–2]

Air Quality Classifications for the 8-Hour Ozone National Ambient Air Quality Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Clean Air Act (CAA) authorizes EPA to reclassify certain ozone nonattainment areas shortly after

the initial classification for such areas. In the April 30, 2004 **Federal Register** action establishing the 8-hour ozone designations and classifications, we described this reclassification process and listed criteria that we intended to use to evaluate a reclassification request. Requests to reclassify ozone nonattainment areas from moderate to marginal were submitted by the respective States for the following areas: Cass and Muskegon Counties, Michigan; Detroit, Michigan; Greensboro, North Carolina; Kent/Queen Anne Counties, Maryland; Lancaster, Pennsylvania; LaPorte, Indiana; Memphis, Arkansas/Tennessee; and Richmond, Virginia. This rule reclassifies certain areas that are designated nonattainment for the 8-hour ozone national ambient air quality standard (NAAQS).

DATES: *Effective Date:* This final rule is effective on November 22, 2004.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. OAR 2003–0083 (Designations). All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* 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 in EDOCKET or in hard copy at the Docket, EPA/DC, EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. 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 Office of Air and Radiation Docket and Information Center is (202) 566–1742. In addition, we have placed a copy of the rule and a variety of materials regarding designations on EPA's designation Web site at: *http://www.epa.gov/oar/oaqps/glo/designations.* Materials relevant to Early Action Compact (EAC) areas are on EPA's Web site at: *http://www.epa.gov/ttn/naaqs/ozone/eac/wl040218_eac_resources.pdf.*

FOR FURTHER INFORMATION CONTACT: Ms. Annie Nikbakht, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Mail Code C539–02, Research Triangle Park, NC 27711, phone number (919) 541–5246 or by e-mail at: *nikbakht.annie@epa.gov.* You may also contact Mr. Doug Grano, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Mail Code C539–02, Research Triangle Park, NC 27711, phone number (919) 541–3292 or by e-mail at: *grano.doug@epa.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

The following is an outline of the preamble.

I. What is the Purpose of this Document?
II. How is Ground-Level Ozone Formed?
III. What are the Health Concerns Addressed by the 8-Hour Ozone Standard?
IV. What is the Chronology of Events Leading Up to This Rule?
V. What are the CAA Requirements for Air Quality Classifications?
VI. What are the Requirements for Reclassifying 8-Hour Ozone Nonattainment Areas?
VII. What Reclassification Requests Did EPA Receive and What Action is EPA Taking on the Requests?
VIII. Does This Action Impact the Deferred Effective Date of Nonattainment Designations for the Greensboro EAC Area?
IX. If an Area is Bumped Down to Marginal, then Misses the Attainment Date and is Bumped Up from Moderate, What Due Dates Apply?
X. Statutory and Executive Order Reviews

I. What Is the Purpose of This Document?

The purpose of this document is to take action on requests from States to reclassify certain areas with respect to the 8-hour ground-level ozone NAAQS. The EPA is approving the requests for the following areas: Cass and Muskegon Counties, Michigan; Detroit, Michigan; Greensboro, North Carolina; Kent/Queen Anne Counties, Maryland; Lancaster, Pennsylvania; LaPorte, Indiana; Memphis, Arkansas/Tennessee; and Richmond, Virginia.

II. How Is Ground-Level Ozone Formed?

Ground-level ozone (sometimes referred to as smog) is formed by the reaction of volatile organic compounds (VOCs) and oxides of nitrogen (NO_x) in the atmosphere in the presence of sunlight. These two pollutants, often referred to as ozone precursors, are emitted by many types of pollution sources, including on-road and off-road motor vehicles and engines, power plants and industrial facilities, and smaller sources, collectively referred to as area sources. Ozone is predominately a summertime air pollutant. Changing weather patterns contribute to yearly differences in ozone concentrations from region to region. Ozone and the pollutants that form ozone also can be transported into an area from pollution sources found hundreds of miles upwind.

III. What Are the Health Concerns Addressed by the 8-Hour Ozone Standard?

During the hot summer months, ground-level ozone reaches unhealthy levels in several parts of the country. Ozone is a significant health concern, particularly for children and people with asthma and other respiratory diseases. Ozone has also been associated with increased hospitalizations and emergency room visits for respiratory causes, school absences, and reduced activity and productivity because people are suffering from ozone-related respiratory symptoms.

Breathing ozone can trigger a variety of health problems. Ozone can irritate the respiratory system, causing coughing, throat irritation, an uncomfortable sensation in the chest, and/or pain when breathing deeply. Ozone can worsen asthma and possibly other respiratory diseases, such as bronchitis and emphysema. When ozone levels are high, more people with asthma have attacks that require a doctor's attention or the use of additional medication. Ozone can reduce lung function and make it more difficult to breathe deeply, and breathing may become more rapid and shallow than normal, thereby limiting a person's normal activity. In addition, breathing ozone can inflame and damage the lining of the lungs, which may lead to permanent changes in lung tissue, irreversible reductions in lung function, and a lower quality of life if the inflammation occurs repeatedly over a long time period (months, years, a lifetime). People who are particularly susceptible to the effects of ozone include children and adults who are active outdoors, people with respiratory disease, such as asthma, and people with unusual sensitivity to ozone. More detailed information on the health effects of ozone can be found at the following Web site: *http://www.epa.gov/ttn/naaqs/standards/ozone/s_o3_index.html.*

IV. What Is the Chronology of Events Leading Up to This Rule?

In 1979, EPA promulgated the 0.12 parts per million (ppm) 1-hour ozone standard, (44 FR 8202, February 8, 1979). On July 18, 1997, we promulgated a revised ozone standard of 0.08 ppm, measured over an 8-hour period, *i.e.*, the 8-hour standard (62 FR 38856). The 8-hour NAAQS rule was challenged by numerous litigants and in

May 1999, the U.S. Court of Appeals for the DC Circuit issued a decision remanding, but not vacating, the 8-hour ozone standard. Among other things, the Court recognized that EPA is required to designate areas for any new or revised NAAQS in accordance with the CAA and addressed a number of other issues, which are not related to designations. *American Trucking Assoc.* v. *EPA,* 175 F.3d 1027, 1047–48, *on rehearing* 195 F.3d 4 (D.C. Cir., 1999). We sought review of two aspects of that decision in the U.S. Supreme Court. In February 2001, the Supreme Court upheld our authority to set the NAAQS and remanded the case back to the D.C. Circuit for disposition of issues the Court did not address in its initial decision. *Whitman* v. *American Trucking Assoc.,* 121 S.Ct. 903, 911–914, 916–919 (2001) (Whitman). In March 2002, the D.C. Circuit rejected all remaining challenges to the 8-hour ozone standard. *American Trucking Assoc.* v. *EPA,* 283 F.3d 355 (D.C. Cir., 2002).

The process for designations following promulgation of a NAAQS is contained in section 107(d)(1) of the CAA. The CAA defines "nonattainment area" in section 107(d)(1)(A)(i) as an area that is violating an ambient standard or is contributing to a nearby area that is violating the standard. If an area meets this definition, EPA is obligated to designate the area as nonattainment.

The final rule establishing designations for all areas of the country was signed by the EPA Administrator on April 15, 2004 and published in the **Federal Register** on April 30, 2004 (69 FR 23858). That rule also sets forth the classifications for certain ozone nonattainment areas. Section 181(a) of the CAA provides that areas will be classified at the time of designation. For further information on designations and classifications, the reader should consult the April 30, 2004 rulemaking action. Classifications are discussed below.

V. What Are the CAA Requirements for Air Quality Classifications?

The CAA contains two sets of provisions-subpart 1 and subpart 2-that address planning and control requirements for ozone nonattainment areas. Both are found in title I, part D. Subpart 1 (which we refer to as "basic" nonattainment) contains general, less prescriptive, requirements for nonattainment areas. Subpart 2 (which we refer to as "classified" nonattainment) provides more specific requirements for ozone nonattainment areas.[1] Some areas are subject only to the provisions of subpart 1. Other areas are subject to the provisions of subpart 2.[2] Subpart 2 areas are classified based on each area's design value. Control requirements are linked to each classification. Areas with more serious ozone pollution are subject to more prescribed requirements. Under our 8-hour ozone implementation rule, signed on April 15, 2004, an area was classified under subpart 2 based on its 8-hour design value[3] if it had a 1-hour design value at or above 0.121 ppm (69 FR 23954 and 40 CFR 51.902). All other areas are covered under subpart 1.

Any area with a 1-hour ozone design value (based on the most recent 3 years of data) that meets or exceeds the statutory level of 0.121 ppm that Congress specified in Table 1 of section 181 is classified under subpart 2 and is subject to the control obligations associated with its classification.[4] Subpart 2 areas were classified as marginal, moderate, serious, or severe based on the area's 8-hour design value calculated using the most recent 3 years of data.[5] As described in the Phase 1 implementation rule, since Table 1 is based on 1-hour design values, we promulgated in that rule a regulation translating the thresholds in Table 1 of section 181 from 1-hour values to 8-hour values. (See Table 1, below, "Classification for 8-Hour Ozone NAAQS" from 40 CFR 51.903.)

TABLE 1.—CLASSIFICATION FOR 8-HOUR OZONE NAAQS

Area class		8-hour design value (ppm ozone)	Maximum period for attainment in state plans (years after effective date of nonattainment designation for 8-hour NAAQS)
Marginal	from	0.085	3
	up to*	0.092	
Moderate	from	0.092	6
	up to*	0.107	
Serious	from	0.107	9
	up to*	0.120	
Severe-15	from	0.120	15
	up to*	0.127	
Severe-17	from	0.127	17
	up to*	0.187	
Extreme	equal to or above	0.187	20

*But not including.

[1] State Implementation Plans; General Preamble for the Implementation of Title I of the CAA Amendments of 1990; Proposed Rule." April 16, 1992 (57 FR 13498 at 13501 and 13510).

[2] Areas subject to subpart 2 are also subject to subpart 1 requirements that are not pre-empted by a more specific mandate under subpart 2.

[3] For the 1-hour ozone NAAQS, design value is defined at 40 CFR 51.900(c). For the 8-hour ozone NAAQS, design value is defined at 40 CFR 51.900(d).

[4] In the Phase 2 implementation rule, we will address the control obligations that apply to areas under both subpart 1 and subpart 2.

[5] At this time, there are no areas with design values in the extreme classification for the 8-hour ozone standard.

VI. What Are the Requirements for Reclassifying 8-Hour Ozone Nonattainment Areas?

Under section 181(a)(4), an ozone nonattainment area may be reclassified "if an area classified under paragraph (1) (Table 1) would have been classified in another category if the design value in the area were 5 percent greater or 5 percent less than the level on which such classification was based." The EPA previously described criteria to implement the section 181(a)(4) provisions in a final rule designating and classifying areas for the 1-hour ozone standard published on November 6, 1991 (56 FR 56698). As stated in that final rule, the provisions of section 181(a)(4) set out general criteria and grant the Administrator broad discretion in making or determining not to make, a reclassification. As part of the 1991 action, EPA developed more specific criteria to evaluate whether it is appropriate to reclassify a particular area. The EPA also described these criteria in the April 30, 2004 final rule. The general and specific criteria are as follows:

General: The EPA may consider the number of exceedances of the national primary ambient air quality standard for ozone in the area, the level of pollution transport between the area and other affected areas, including both intrastate and interstate transport, and the mix of sources and air pollutants in the area.

Request by State: The EPA does not intend to exercise its authority to bump down areas on EPA's own initiative. Rather, EPA intends to rely on the State to submit a request for a bump down. A Tribe may also submit such a request and, in the case of a multi-state nonattainment area, all affected States must submit the reclassification request.

Discontinuity: A five percent reclassification must not result in an illogical or excessive discontinuity relative to surrounding areas. In particular, in light of the area-wide nature of ozone formation, a reclassification should not create a "donut hole" where an area of one classification is surrounded by areas of higher classification.

Attainment: Evidence should be available that the proposed area would be able to attain by the earlier date specified by the lower classification in the case of a bump down.

Emissions reductions: Evidence should be available that the area would be very likely to achieve the appropriate total percent emission reduction necessary in order to attain in the shorter time period for a bump down.

Trends: Near- and long-term trends in emissions and air quality should support a reclassification. Historical air quality data should indicate substantial air quality improvement for a bump down. Growth projections and emission trends should support a bump down. In addition, we will consider whether vehicle miles traveled and other indicators of emissions are increasing at higher than normal rates.

Years of data: For the 8-hour ozone standard, the 2001–2003 period is central to determining classification. Data from 2004 may be used to corroborate a bump down request but should not be the sole foundation for the bump down request.

Limitations on Bump Downs: An area may only be reclassified to the next lower classification. An area cannot present data from other years as justification to be reclassified to an even lower classification. In addition, section 181(a)(4) does not permit moving areas from subpart 2 into subpart 1.

In 1991, EPA approved reclassifications when the area met the first requirement (a request by the State to EPA) and at least some of the other criteria and did not violate any of the criteria (emissions, reductions, trends, *etc.*). In our April 30, 2004 final rule on designations and classifications, we stated our intention to use this method and these criteria once again to evaluate reclassification requests under section 181(a)(4), with minor changes described in that action. In that action, we also described how we applied these criteria in 1991. For additional information, see section 5, "Areas requesting a 5% downshift per § 181(a)(4) and EPA's response to those requests," of the Technical Support Document, October 1991, for the 1991 rule. [Docket A–90–42A.]

The April 30, 2004 action invited States to submit the reclassification requests within 30 days of the effective date of the designations and classifications. The effective date was June 15 which means that reclassification requests were to be submitted by July 15, 2004. This relatively short timeframe is necessary because section 181(a)(4) only authorizes the Administrator to make such reclassifications within 90 days after the initial classification, September 15, 2004.

As described in the April 30, 2004 action, an ozone nonattainment area may also request reclassification under section 181(a)(4) to the next higher classification. While no State requested a reclassification upward during this time period, EPA notes that a State may make a request for a higher classification at any time under section 181(b)(3). This provision directs EPA to grant a State's request for a higher classification and to publish notice of the request and EPA's approval.

VII. What Reclassification Requests Did EPA Receive and What Action Is EPA Taking on the Requests?

This section describes each reclassification request received by EPA and the results of EPA's evaluation of each request. As described below, EPA evaluated the requests with respect to the criteria described in section IV of this notice. More detailed information is available in EPA's Technical Support Document for Five Percent Reclassifications, September 2004, which contains the requests, supporting documentation, and EPA's evaluation.

Cass County, Michigan

The EPA designated this area as a moderate ozone nonattainment on April 15, 2004 based on its 8-hour ozone value of 93 parts per billion (ppb). On July 15, 2004 the Michigan Department of Environmental Quality submitted a request to reclassify Cass County from moderate ozone nonattainment to marginal ozone nonattainment. Cass County has small population and very low emissions. Reclassification to marginal will not result in a discontinuity since all of the counties immediately bordering Cass County are either designated as attainment or are subpart 1 nonattainment.

The Lake Michigan Air Directors Consortium (LADCo) used modeling results performed to support the 1-hour ozone attainment demonstration for the Lake Michigan area and applied 8-hour ozone metrics. As noted in Michigan's petition, the LADCo modeling was designed to assess 1-hour ozone and, as such, there are some limitations with using it to assess 8-hour ozone. On the other hand, it should be noted that three of the four modeled episodes are representative periods for high 8-hour ozone and basecase model performance for 8-hour ozone was found to be as good as (or better than) that for 1-hour ozone. The local scale LADCo modeling indicates that Cass County will be in attainment (81 ppb) in 2007. Additionally, regional scale modeling from the proposed Clean Air Interstate Rule (CAIR) indicates the area will be in attainment (83 ppb) in 2010.

The emissions trend is expected to significantly decrease due to the implementation of various regional rules, including the NO_X SIP Call (63 FR 57356) and rules contained in 1-hour ozone attainment plans in the Lake Michigan area. The trend in the 4th

highest values for ozone from 2002, 2003 and 2004 show a decrease from 103 ppb, to 89 ppb and, 74 ppb, respectively. Further, it can be expected that ozone values will continue at these lower levels due to the implementation of national and regional rules.

In summary, the following factors support the request for reclassification to marginal for Cass County: The design value of 93 ppb meets our criteria to qualify for consideration of bump down, local and regional modeling analyses indicate air quality will be improving over the next several years and support attainment by the marginal area attainment date, a short term trends analysis shows ozone values decreasing, and additional reductions from regional and national regulations will continue this trend in lowering ambient ozone values. Thus, the reclassification request for Cass County meets all of the criteria (request, discontinuity, attainment, emission reductions, trends, and data) EPA established (69 FR 23863). Therefore, EPA is approving the reclassification request for Cass County.

Detroit-Ann Arbor, Michigan

The EPA designated this area as moderate on April 15, 2004 due to 8-hour values (design value is 97 ppb). On July 15, 2004, the Michigan Department of Environmental Quality (MDEQ) submitted a request to reclassify Detroit-Ann Arbor (Southeast Michigan) area from moderate to marginal ozone nonattainment. The Southeast Michigan Council of Governments (SEMCoG)is the lead local planning agency for the Detroit-Ann Arbor area. The MDEQ and SEMCoG worked jointly to prepare the reclassification request. Reclassification will not create a discontinuity since all adjacent nonattainment areas to the Detroit-Ann Arbor area are subpart 1 nonattainment.

Under section 181(a)(4), an ozone nonattainment area may be reclassified "if an area classified under paragraph (1) (Table 1) would have been classified in another category if the design value in the area were 5 percent greater or 5 percent less than the level on which such classification was based." In the April 30, 2004 notice, we indicated that an area with a moderate design value of 96 ppb (or less) would be eligible to request a bump down because five percent less than 96 ppb is 91 ppb, a marginal design value. In their petition, Michigan requested EPA to use a rounding convention that would allow the "5 percent" calculation to be a factor of up to 5.49 percent. After reviewing the methodology for handling of percentages in EPA's "Guideline on Data Handling Conventions For the 8-Hour Ozone NAAQS" (December 1998), EPA believes values up to 5.4% are acceptable for the bump down calculation. The Guideline indicates percent values are rounded up for the purpose of determining data completeness (specifically the Guideline states, 74.5% is 75% and 89.5 is 90%). Since there is nothing in the Guideline to suggest this percentage rounding convention is inappropriate for other calculations involving ambient air quality data, EPA believes it is acceptable for the bump down calculation. Using 0.054 as 5% and 97 ppb (moderate) as the design value, then (0.054) * 97 = 91.8, which is a marginal value. Thus, the area is eligible to request a bump down.

Modeling by LADCo to support the 1-hour ozone attainment demonstration for the Lake Michigan area was applied to 8-hour ozone metrics. This modeling indicates that the Detroit-Ann Arbor area may be very close to attainment (85 ppb) in 2007. However, as noted in Michigan's petition, the LADCO subregional modeling was designed to assess 1-hour ozone and, as such, there are some limitations with using it to assess 8-hour ozone. For example, the episodes and modeling domain were selected for the Lake Michigan region and may not accurately represent other cities in the modeling domain, such as Detroit. On the other hand, it should be noted that three of the four modeled episodes are representative periods for high 8-hour ozone and basecase model performance for 8-hour ozone was found to be as good as (or better than) that for 1-hour ozone. Additional, regional scale, CAIR modeling (January 2004 proposal) indicates the area will be in attainment (84 ppb) by 2010. The CAIR modeling, however, was not designed to provide results for years prior to 2010. In summary, EPA believes the LADCo and CAIR modeling analyses are not conclusive with respect to the area's attainment status in 2007. Although neither analysis is as comprehensive an assessment as would be expected with a SIP attainment demonstration, they do provide support for a decision to reclassify the area. Both modeling analyses indicate air quality will be improving over the next several years. Further decreases can be expected once MDEQ and SEMCoG have selected control measures for the area and these measures are implemented.

Emissions reductions are already occurring in various sectors throughout the area. VOC and NO_X from on-road mobile sources will decline by 40% and 37%, respectively, between 2002 and 2007, even after accounting for increasing levels of travel. This trend will continue to 2010, reaching reductions of 54% for both pollutants. Point sources' emissions of NO_X will decline from implementation of the NO_X SIP Call between 2004 and 2007. Additionally, MDEQ and SEMCoG have committed to evaluating a list of measures including vehicle inspection and maintenance, lower emitting fuels, degreasing, architectural and industrial maintenance coatings, consumer/commercial products, tighter VOC RACT rules, and gas can replacement. The process for choosing appropriate control measures for the area will be completed by June 2005. MDEQ and SEMCoG have also committed to an aggressive schedule to implement controls that will help the area attain by 2007.

While a long-term trends analysis for the Detroit-Ann Arbor area does not show a declining trend in ozone values, that can be attributed to the abnormally high values experienced in the area in June 2003. The maximum concentration in 2004, to date, is 83 ppb, which may mark the beginning of at least a short term air quality trend downward. It can be expected that ozone values will decrease due to the declines in NO_X and VOC emissions described in the preceding paragraph.

In summary, the following factors support the request for downward revision to the 8-hour ozone classification for Detroit-Ann Arbor area: the design value of 97 ppb meets our criteria to qualify for consideration of bump down, local and regional modeling analyses indicate air quality will be improving over the next several years, regional and national regulations will continue this trend in lowering ambient ozone values, the State and local agencies responsible for air quality planning have committed to an aggressive schedule to identify and implement controls that will help the area attain by the marginal attainment date of June 15, 2007. Thus, the request meets certain criteria EPA established (request, discontinuity, emission reductions, and data) and does not violate any of the criteria (attainment and trends). Therefore, EPA is approving the reclassification request for the Detroit-Ann Arbor area.

Greensboro, North Carolina

The Greensboro area was designated nonattainment for the 8-hour ozone standard on April 15, 2004 and classified moderate based on a design value of 93 ppb. The State of North Carolina presented a petition to EPA, Region 4, requesting downward reclassification of the Greensboro/Winston-Salem/High Point (Triad)

ozone nonattainment area from moderate to marginal for the 8-hour standard. The petition was presented to EPA July 14, 2004. Reclassification of the Greensboro area to marginal will not create a discontinuity since surrounding areas would include higher and lower classifications (the Charlotte area is designated moderate and the Raleigh area is subpart 1 nonattainment).

Local photochemical grid modeling, developed under the Early Action Compact (EAC) program, demonstrates attainment by 2007 for the Triad area which includes the Greensboro area. The modeling was developed according to EPA's draft 8-hour ozone modeling guidance and was used to support a deferral of the effective date for the nonattainment area. Updated local modeling data included in the June 2004 EAC progress report were referenced to support the attainment criteria of the reclassification petition. In addition, CAIR modeling analyses (January 2004) show that Greensboro is expected to continue to be in compliance with the 8-hour ozone standard in 2010.

Expected emissions reductions are detailed in the petition and the EAC progress report submittals and include, for example, an inspection and maintenance program phasing in between July 2002 and 2005. Emissions data demonstrate a decrease in NO_X emissions of about 382 tons per day between 2000 and 2007. Beyond 2007, further NO_X emissions reductions are expected due to the Federal, State and local control measures. VOC emissions will decrease by 20 tons per day between 2000 and 2007 with additional future reductions expected. An aggressive control program is being implemented throughout the State that affects stationary and mobile sources. Since 1998, monitored ozone levels at the Greensboro area monitors have steadily decreased and support reclassification.

In summary, the reclassification request for Greensboro meets all of the criteria EPA established (69 FR 23863), including request by the State, supporting trends in emissions and air quality, and modeling evidence that the area would be able to attain by the earlier date (2007). The EPA is approving the reclassification request for Greensboro because the request meets all of the criteria EPA established.

Kent/Queen Anne Counties, Maryland

The EPA designated this area as moderate on April 15, 2004 due to 8-hour ozone values (design value is 95 ppb). On July 15, 2004 the Maryland Department of the Environment submitted a request to reclassify Kent and Queen Anne's Counties from moderate to marginal ozone nonattainment. Kent and Queen Anne's Counties, MD are located on Maryland's eastern shore. Reclassification of Kent and Queen Anne's Counties will not create a discontinuity since there would be no area of one classification surrounded by areas of a higher classification. All of the other counties immediately bordering Kent and Queen Anne's Counties are either designated as attainment or moderate nonattainment.

Maryland submitted a modeling study that was performed as part of an earlier effort related to the Early Action Compact (EAC) program. This modeling was performed in accordance with EPA guidance. Initially, however, Maryland had applied the relative reduction factor (RRF) to the wrong ozone design value year. This was remedied by applying the RRF to the larger of the 2000 or 2003 ozone design value. When this correction was made, a value of 82.3 ppb was obtained, demonstrating that these counties should attain the ozone standard by 2007. The EPA's January 2004 CAIR modeling projects nonattainment for Kent County, MD in the 2010 attainment year (86 ppb). Because EPA guidance indicates that smaller scale modeling is generally more appropriate for attainment demonstrations, EPA believes that the local scale air quality modeling (EAC modeling) which projects attainment in 2007 should carry more weight. In summary, both modeling analyses indicate air quality will be improving over the next several years and EPA believes the EAC modeling analysis strongly indicates the area will attain the ozone standard by 2007.

The emissions trend is expected to decrease due to the implementation of various regional rules, including the NO_X SIP Call and regional rules contained in 1-hour ozone attainment plans in the Baltimore and Washington D.C. area. In addition, because the state of Maryland is located in the statutorily-established Ozone Transport Region (OTR), Kent and Queen Anne's Counties have been implementing several moderate nonattainment area level emission. Moderate area OTR controls include RACT, NSR, and Stage II comparable measures. Queen Anne's county, being part of the 1990 Baltimore Metropolitan Statistical Area (MSA) was also required under the OTR requirements, to implement a high enhanced I/M program and has been doing so.

The 17-year ozone air quality trends in Kent county (Queen Anne's does not have an ozone monitor) are relatively flat. The last two years of complete data, however, may mark the beginning of at least a short term air quality trend downward. The 4th highest values for ozone from 2002 and 2003 are 103 and 86 ppb, respectively. Further, it can be expected that ozone values will decline due to the implementation of national and regional rules relative to ozone levels in recent years.

In summary, the following factors support the request for reclassification to marginal for Kent and Queen Anne's Counties: the design value of 95 ppb meets our criteria to qualify for consideration of bump down, local modeling provides strong evidence that the area will attain by 2007, additional reductions from regional and national regulations should lower ambient ozone values. Thus, the request meets certain criteria EPA established (request, discontinuity, emission reductions, attainment, and data) and does not violate any of the criteria (trends). Therefore, EPA is approving the reclassification request for Kent and Queen Anne's Counties.

Lancaster, Pennsylvania

The EPA designated this area as moderate on April 15, 2004 due to 8-hour ozone values (design value is 92 ppb). On July 9, 2004 the Pennsylvania Department of Environmental Protection submitted a request to reclassify Lancaster County from moderate to marginal ozone nonattainment. Lancaster, PA is a single county 8 hour ozone nonattainment area located immediately west of the Philadelphia moderate 8 hour ozone nonattainment area and immediately north of the Baltimore moderate 8 hour ozone nonattainment area. The counties adjacent to and surrounding Lancaster on its west and north are designated subpart 1 ("basic") 8 hour ozone nonattainment areas. Reclassification of Lancaster County will not create a discontinuity since there would be no area of one classification surrounded by areas of a higher classification.

The EPA's January 2004 CAIR modeling projects attainment for Lancaster County, PA in the 2010 attainment year (83 ppb). No local air quality modeling is available. The EPA believes the CAIR modeling analysis is not conclusive with respect to Lancaster's attainment status in 2007; the analysis is not as comprehensive an assessment as would be expected with a SIP attainment demonstration. However the CAIR analysis provides support for a decision to reclassify the area since it indicates air quality will be improving over the next several years.

The emissions trend is expected to decrease due to the implementation of various regional rules, including the NO_X SIP Call and rules contained in 1-hour ozone attainment plans in the Baltimore, Philadelphia and Washington, DC areas. In addition, because the state of Pennsylvania is located in the statutorily-established Ozone Transport Region (OTR), Lancaster County has been implementing moderate nonattainment area level emission controls. Moderate area OTR controls include RACT, NSR, and Stage II comparable measures. In addition, Lancaster has an OTR enhanced I/M program that became state law in November 2003 and has been implemented since February 2004.

The area's design value is 92 ppb, just one ppb above the marginal classification design value based on 2001–2003 data. The 17-year ozone air quality trends in Lancaster County are relatively flat. The short-term trend in the 4th highest 8-hour ozone value over the last 3 years is downward (97, 96, and 83 ppb). Further, it can be expected that ozone values will decline due to the implementation of national and regional rules relative to ozone levels in recent years.

In summary, the following factors support the request for reclassification to marginal for Lancaster County: the design value of 92 ppb meets our criteria to qualify for consideration of bump down, CAIR modeling indicates air quality will be improving over the next several years, and additional reductions from regional and national regulations should lower ambient ozone values. Thus, the request meets certain criteria EPA established (request, discontinuity, emission reductions, and data) and does not violate any of the criteria (attainment and trends). Therefore, EPA is approving the reclassification request for Lancaster County.

LaPorte, Indiana

The EPA designated this area as moderate on April 15, 2004 due to 8-hour ozone values (design value is 93 ppb). On July 15, 2004 the Indiana Department of Environmental Management submitted a request to reclassify LaPorte County from moderate to marginal ozone nonattainment. LaPorte County is highly impacted by transport due to the Lake Michigan ozone phenomenon. LaPorte County has few major sources. Reclassification of LaPorte County to marginal will not result in a discontinuity since the only area that is adjacent to Laporte County that has a higher classification is the Chicago-Gary moderate nonattainment area. All of the other counties immediately bordering LaPorte County are either designated as attainment or are subpart 1 nonattainment.

Modeling by LADCo to support the 1-hour ozone attainment demonstration for the Lake Michigan area was applied to 8-hour ozone metrics. As noted in Michigan's petition, the LADCo modeling was designed to assess 1-hour ozone and, as such, there are some limitations with using it to assess 8-hour ozone. On the other hand, it should be noted that three of the four modeled episodes are representative periods for high 8-hour ozone and basecase model performance for 8-hour ozone was found to be as good as (or better than) that for 1-hour ozone. The local scale LADCo modeling indicates that air quality is expected to improve (from 93 to 89 ppb) in LaPorte County, but may not reach attainment in 2007. Since this modeling was performed before the Heavy Duty Engine rule was proposed, it does not reflect emission reductions from that national program. Use of a more recent emission inventory and base design value would likely result in lower predicted concentrations. Additional, regional scale, modeling from the CAIR proposal indicates the area will be in attainment (84 ppb) by 2010. The CAIR modeling, however, was not designed to provide results for years prior to 2010. In summary, EPA believes the LADCo and CAIR modeling analyses are not conclusive with respect to LaPorte's attainment status in 2007. Although neither analysis is as comprehensive an assessment as would be expected with a SIP attainment demonstration, they do provide support for a decision to reclassify the area. Both modeling analyses indicate air quality will be improving over the next several years.

The emissions trend is expected to significantly decrease due to the implementation of various regional rules, including the NO_X SIP Call and rules contained in 1-hour ozone attainment plans in the Lake Michigan area. The trend in the 4th highest values for ozone from 2002, 2003 and 2004 show a large decrease at both the Michigan City and the City of LaPorte monitors from 107/100 ppb in 2002, to 82/84 ppb and, most recently, 68/71 ppb. Further, it can be expected that ozone values will continue at these lower levels due to the implementation of national and regional rules.

In summary, the following factors support the request for downward revision to the 8-hour ozone classification for LaPorte County: The design value of 93 ppb meets our criteria to qualify for consideration of bump down, local modeling shows that the area will be close to attainment in 2007, proposed CAIR modeling shows the area will attain by 2010, a short term trends analysis shows large decreases in ozone values and additional reductions from regional and national regulations will support this trend in low ambient ozone values. Thus, the request meets certain criteria EPA established (request, discontinuity, emission reductions, trends, and data) and does not violate any of the criteria (attainment). Therefore, EPA is approving the reclassification request for LaPorte County.

Memphis, Arkansas/Tennessee

The EPA designated this area as moderate on April 15, 2004 due to 8-hour ozone values (design value is 92 ppb). The States of Tennessee and Arkansas submitted the petition by the date required. The petitioners have emphasized that the States of Tennessee and Arkansas, along with the local governments of Shelby and Crittenden Counties, have produced a plan of action which will result in real ozone reductions and attainment by 2007 through an exhaustive collaborative effort. Reclassification of the Memphis area will not create a discontinuity since there would be no area of one classification surrounded by an area of a higher classification.

The modeling submitted showed attainment when using a methodology for adjusting meteorology. The appropriateness of this method is under review by EPA. EPA's evaluation of the modeling submitted without a meteorology adjustment and other assumptions shows the design value declining to 88 ppb by 2007, which makes notable progress toward attainment. Also, EPA's CAIR modeling shows the area should have a design value of 86 ppb by 2010, which also shows notable progress towards attainment. In addition, the CAIR modeling does not include any local controls expected prior to 2007. Therefore, local controls could be expected to further lower the CAIR 2010 design value. Both modeling analyses indicate more reductions are needed beyond those relied on in the local modeling in order to attain by 2007. Additional controls beyond those modeled have been identified in the petition.

Attainment is expected because of the combination of measures to be implemented and potential measures listed in the petition along with the commitment of the areas to implement additional measures as needed to

achieve attainment As strong support for adequate emission reductions being implemented, Arkansas is conducting a study with limited additional modeling which should identify the sources affecting the monitors more precisely. Arkansas, Tennessee and the Memphis-Shelby County local agency are committed to assess the results of the study and implement additional controls beyond those modeled or identified in the reclassification petition by 2006, if required by the study results. This commitment is made by the Governors, State, and Local officials of both States as signatories to the petition. In addition, the State of Tennessee and the City of Memphis/Shelby County have submitted letters reinforcing the commitments to adopt and implement additional measures as the modeling and study results might identify.

The petition lists 19 emission reduction measures for potential implementation at the state and local level. These measures, when combined with potential Federal measures expected during the period, could bring the area into attainment by 2007. Tennessee is considering measures such as NO_X Reasonably Available Control Technology rules for stationary sources, expanded Stage I vapor recovery, emissions inspections, and anti-tampering measures. Memphis-Shelby county is considering measures such as diesel engine idling limits, reduced speed limits, controlled burning restrictions, and On Board Diagnostic II emission testing. Arkansas is considering measures such as Stage I vapor recovery, truck stop electrification, and replacement/retrofit construction equipment engines. The EPA has provided Arkansas with $100,000 in funds to implement truck stop electrification in Crittenden County.

The area's design value is 92 ppb, one ppb above the marginal classification design value based on 2001–2003 data. The area has not had any exceedences at the Crittenden County monitor in 2004 through September 10; the 4th highest monitor value is 78 ppb. If this value remains the 4th highest for 2004, the design value will decline to 87, well within the marginal range and only 3 ppb above the attainment level. Also, with the monitor values already established for 2002 and 2003 for the Shelby County monitors, the 2004 data, to date, are indicating attainment. The design value trends for the two Shelby County monitors have declined since 2000.

The emissions from ozone precursors VOC and NO_X from stationary sources in Shelby County, TN have declined significantly since 1993. Emissions estimates in the Memphis Early Action compact March 31, 2004 submittal, indicate that emissions should decrease by 28% for NO_X and 19% for VOCs from 2001 to 2007. Tennessee is included in the NO_X SIP Call region and pursuant to the State plan adopted to meet the SIP Call, the Tennessee Valley Authority (TVA) Allen Power Plant will reduce NO_X emissions by 57.5 tons per day (tpd). We anticipate the 2004 and 2005 design values will show air quality improvements from these measures. Thus, the air quality and emissions trends support reclassification.

In summary, the data, analysis, and commitments presented in the petition support the likelihood of attainment of the 8-hour ozone standard by 2007 and support the request for downward revision to the 8-hour ozone classification for the Memphis area. Specifically, the *Request by States* criteria is satisfied since the petition was submitted by the governors of Tennessee and Arkansas; the *Discontinuity* criteria is satisfied since there would be no area of one classification surrounded by one or more areas of a higher classification; the *Attainment* criteria is not failed since the modeling shows notable progress toward attainment; the *Emissions Reductions* criteria is satisfied because of the emission reductions available and the commitment by the state and local agencies to adopt and implement any controls necessary to attain the 8-hour standard based on a comprehensive study of sources contributing to nonattainment; the *Trends* criteria is satisfied since the downward trends in air quality monitor and emissions data over the time period to attainment are strong indicators of progress towards attainment; and the *Years of Data* criteria is satisfied since the years chosen (2001–2003) are consistent with the time period used for the designations for the 8-hour ozone standard. Thus, the request meets certain criteria EPA established (request, discontinuity, emission reductions, trends, and data) and does not violate any of the criteria (attainment). Therefore, EPA is approving the reclassification request for Memphis.

Muskegon County, Michigan

The EPA designated this area as moderate on April 15, 2004 due to 8-hour values (design value is 95 ppb). On July 15, 2004 MDEQ submitted a request to reclassify Cass County from moderate ozone nonattainment to marginal ozone nonattainment. Muskegon County is highly impacted by transport due to the Lake Michigan ozone phenomenon. Muskegon County has few major sources. Reclassification of Muskegon County to marginal will not result in a discontinuity since all of the counties immediately bordering Muskegon County are either designated as attainment or are subpart 1 nonattainment.

Modeling by LADCo to support the 1-hour ozone attainment demonstration for the Lake Michigan area was applied to 8-hour ozone metrics. As noted in Michigan's petition, the LADCo modeling was designed to assess 1-hour ozone and, as such, there are some limitations with using it to assess 8-hour ozone. On the other hand, it should be noted that three of the four modeled episodes are representative periods for high 8-hour ozone and basecase model performance for 8-hour ozone was found to be as good as (or better than) that for 1-hour ozone. The local scale LADCo modeling indicates that Muskegon County will be near attainment (86 ppb) in 2007. Since this modeling was performed before the Heavy Duty Engine rule was proposed, it does not reflect emission reductions from that national program. Use of a more recent emission inventory and base design value would likely result in lower predicted concentrations. Additional, regional scale, modeling from the January 2004 CAIR proposal indicates the area will be in attainment (82 ppb) by 2010. The CAIR modeling, however, was not designed to provide results for years prior to 2010. The EPA believes the LADCo and CAIR modeling analyses are not conclusive with respect to Muskegon's attainment status in 2007. Although neither analysis is as comprehensive an assessment as would be expected with a SIP attainment demonstration, they do provide support for a decision to reclassify the area. Both modeling analyses indicate air quality will be improving over the next several years.

The emissions trend is expected to significantly decrease due to the implementation of various regional rules, including the NO_X SIP Call and rules contained in 1-hour ozone attainment plans in the Lake Michigan area. The trend in the 4th highest values for ozone from 2002, 2003 and 2004 show a decrease from 96 ppb, to 94 ppb and, most recently, 70 ppb. Further, it can be expected that ozone values will continue at these lower levels due to the implementation of national and regional rules.

In summary, the following factors support the request for downward revision to the 8-hour ozone classification for Muskegon County: the design value of 95 ppb meets our

criteria to qualify for consideration of bump down, local and regional modeling analyses indicate air quality will be improving over the next several years, a short term trends analysis shows ozone values decreasing and additional reductions from regional and national regulations will continue this trend in lowering ambient ozone values. Thus, the request meets certain criteria EPA established (request, discontinuity, emission reductions, trends, and data) and does not violate any of the criteria (attainment). Therefore, EPA is approving the reclassification request for Muskegon County.

Richmond, Virginia

The EPA designated this area as moderate on April 15, 2004 due to 8-hour ozone values (design value is 94 ppb). On July 12, 2004 the Virginia Department of the Environmental Quality submitted a request to reclassify Richmond from moderate to marginal ozone nonattainment. The Richmond, VA moderate ozone nonattainment area consists of five counties (Charles City, Chesterfield, Hanover, Henrico, and Prince George) and four independent cities (Colonial Heights, Hopewell, Petersburg, and Richmond). This area is adjacent to the southeast edge of the Washington D.C. moderate 8-hour ozone nonattainment area. To the northeast of Richmond, and across the Chesapeake Bay, is the Philadelphia moderate 8-hour ozone nonattainment area. Richmond is also adjacent to and located to the northwest of the Norfolk-Virginia Beach, VA subpart 1 8-hour ozone nonattainment area. Reclassification of the Richmond area will not create a discontinuity since there would be no area of one classification surrounded by areas of a higher classification.

The modeling performed by Virginia for demonstrating attainment in Richmond by 2007 was based on modeling conducted for the Roanoke, VA EAC. While not optimized for the Richmond area, this modeling can be used to indicate whether Richmond might attain by 2007. The EAC modeling projects attainment in the Richmond area in 2007. The highest of these projected design values is 84.1 ppb for the Hanover monitor. In addition, EPA's January 2004 CAIR modeling projects Richmond's ozone concentrations to be well below the ozone standard in 2010 (77 ppb). Although neither analysis is as comprehensive an assessment as would be expected with a SIP attainment demonstration, together they provide support that the Richmond area will attain the ozone standard by 2007.

On August 30, 2004, the Director of Virginia's Department of Environmental Quality submitted a letter to EPA (followed up by a letter on September 2, 2004 from the VA Air Director) committing to adopt additional emission control measures to reduce ozone levels. Several of these measures are already in place in the smaller 1-hour Richmond ozone nonattainment area or in the northern Virginia (Washington DC) 1-hour ozone nonattainment area. This letter stated that control measures such as reformulated gasoline, stage I, and existing source RACT regulations would be extended into the larger Richmond 8-hour ozone nonattainment area. The northern Virginia control measures (solvent cleaning, architectural and maintenance coatings, motor vehicle refinishing, and portable fuel containers) would be studied and the process of adoption for the Richmond 8-hour ozone nonattainment area would commence. Therefore, the emissions trend is expected to decrease due to the implementation of various local, regional, and national rules.

The ozone air quality trends in the Richmond area are relatively flat. It can be expected that ozone values will decline due to the implementation of local, regional, and national rules relative to ozone levels in recent years.

In summary, the following factors support the request for reclassification to marginal for the Richmond area: the design value of 94 ppb meets our criteria to qualify for consideration of bump down, local and regional modeling together with declining emissions from local, regional and national regulations support the conclusion that Richmond is likely to attain by 2007. Thus, the request meets certain criteria EPA established (request, discontinuity, emission reductions, attainment, and data) and does not violate any of the criteria (trends). Therefore, EPA is approving the reclassification request for the Richmond area.

VIII. Does This Action Impact the Deferred Effective Date of Nonattainment Designations for the Greensboro EAC Area?

As long as the Greensboro area continues to meet the milestones and submissions that compact areas are required to complete, the area would continue to be eligible for a deferred effective date of the nonattainment designation for the 8-hour ozone standard. The effective date of the 8-hour ozone nonattainment designation for the compact area counties listed in 40 CFR part 81 remains deferred until September 30, 2005. Additional information on EACs is contained in the April 30, 2004 final rule (69 FR 23864–23876).

IX. If an Area is Bumped Down to Marginal, Then Misses the Attainment Date and is Bumped Up to Moderate, What Due Dates Apply?

Within 6 months following the applicable attainment date [including any extension thereof pursuant to section 181(a)(5)] for an ozone nonattainment area, the Administrator is required to determine, based on the area's design value (as of the attainment date), whether the area attained the standard by that date. Any area that the Administrator finds has not attained the standard by that date shall be reclassified by operation of law to the higher of (i) the next higher classification for the area, or (ii) the classification applicable to the area's design value as of the attainment date.

Section 182(i) of the CAA specifies that the deadlines provided under the requirements of section 182 remain applicable, except that the Administrator "may adjust any applicable deadlines (other than attainment dates) to the extent such adjustment is necessary or appropriate to assure consistency among the required submissions." All required controls and emissions reductions must be implemented or achieved on a schedule that facilitates attainment by the attainment date.

In previous rulemaking actions, EPA has provided 12–18 months for States to submit required SIP revisions.[6] However, States should plan to adopt controls as soon as possible because the determination of whether the area attains the NAAQS by the attainment deadline must be based on air quality during the preceeding three ozone seasons. That is, the determination of whether a moderate area attains the NAAQS by June 15, 2010 will be based on air quality during the 2007–2009 period. Thus, the sooner the moderate-area controls are implemented, the more likely the area will reach attainment by the 2010 attainment date.

X. Statutory and Executive Order Reviews

Upon promulgation of a new or revised NAAQS, the CAA requires EPA to designate and classify areas. The CAA then specifies requirements for areas based on whether such areas are attaining or not attaining the NAAQS

[6] *See* notices under the heading "1-Hour Ozone **Federal Register** Notices Changes to a Higher Classification" at *http://www.epa.gov/oar/oaqps/greenbk/ofr2rpt2.html.*

and their classification, if any. In this final rule, we reclassify certain areas designated nonattainment.

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether the regulatory action is "significant" and, therefore, subject to Office of Management and Budget (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, it has been determined that this rule is not a "significant regulatory action" because none of the above factors applies. As such, this final rule was not formally submitted to OMB for review.

B. Paperwork Reduction Act

This final action to reclassify nine ozone nonattainment areas from moderate to marginal does not impose an information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedures Act or any other statute unless the agency certifies the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For purposes of assessing the impacts of today's final rule on small entities, small entity is defined as: (1) A small business that is a small industrial entity as defined in the U.S. Small Business Administration (SBA) size standards. (See 13 CFR 121.); (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.

This rule is not subject to the RFA because it was not subject to notice and comment rulemaking requirements. After considering the economic impacts of today's final rule on small entities, I certify that this rule will not have a significant economic impact on a substantial number of 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 1 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.

Today's final action does not include a Federal mandate within the meaning of UMRA that may result in expenditures of $100 million or more in any 1 year by either State, local, or Tribal governments in the aggregate or to the private sector, and therefore, is not subject to the requirements of sections 202 and 205 of the UMRA. It does not create any additional requirements beyond those of the 8-hour National Ambient Air Quality Standards (NAAQS) for Ozone (62 FR 38894; July 18, 1997), therefore, no UMRA analysis is needed. This rule reclassifies certain areas with respect to the 8-hour ozone standard. The CAA requires States to develop plans, including control measures, based on their designations and classifications.

The EPA believes that any new controls imposed as a result of this action will not cost in the aggregate $100 million or more annually. Thus, this Federal action will not impose mandates that will require expenditures of $100 million or more in the aggregate in any 1 year. Nonetheless, EPA carried out consultations with governmental entities affected by this rule, including States and local air pollution control agencies.

E. Executive Order 13132: Federalism

Executive Order 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 13132. The CAA establishes the scheme whereby States take the lead in developing plans to meet the NAAQS. This rule will not modify the relationship of the States and EPA for purposes of developing programs to implement the NAAQS. Thus, Executive Order 13132 does not apply to this rule.

Although Executive Order 13132 does not apply to this rule, EPA discussed the reclassification process with representatives of State and local air pollution control agencies and Tribal governments. This rule is not subject to notice and comment and, therefore, no proposed rulemaking was prepared which specifically solicited comment on the reclassifications. However, we provided notification of the reclassification process and our criteria in the April 30, 2004 **Federal Register** action.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Executive Order 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 13175. This rule concerns the reclassification of certain areas for the 8-hour ozone standard. The CAA provides for States to develop plans to regulate emissions of air pollutants within their jurisdictions. The Tribal Authority Rule (TAR) gives Tribes the opportunity to develop and implement CAA programs such as programs to attain and maintain the 8-hour ozone NAAQS, but it leaves to the discretion of the Tribe whether to develop these programs and which programs, or appropriate elements of a program, they will adopt.

This final rule does not have Tribal implications as defined by Executive Order 13175. It does not have a substantial direct effect on one or more Indian Tribes, since no Tribe has implemented a CAA program to attain the 8-hour ozone NAAQS at this time. Furthermore, this rule does not affect the relationship or distribution of power and responsibilities between the Federal government and Indian Tribes. The CAA and the TAR establish the relationship of the Federal government and Tribes in developing plans to attain the NAAQS, and this rule does nothing to modify that relationship. Because this rule does not have Tribal implications, Executive Order 13175 does not apply. Although Executive Order 13175 does not apply to this rule, EPA did outreach to Tribal representatives regarding the reclassifications.

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

Executive Order 13045: "Protection of Children From Environmental Health 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 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.

The final rule is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866, and because the Agency does not have reason to believe the environmental health risks or safety risks addressed by this rule present a disproportionate risk to children. Nonetheless, we have evaluated the environmental health or safety effects of the 8-hour ozone NAAQS on children. The results of this risk assessment are contained in the National Ambient Air Quality Standards for Ozone, Final Rule (62 FR 38855–38896; specifically, 62 FR 38854, 62 FR 38860 and 62 FR 38865).

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This rule is not subject to Executive Order 13211, "Actions That Significantly Affect Energy Supply, Distribution, or Use," (66 FR 28355, May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer Advancement Act

Section 12(d) of the National Technology Transfer Advancement Act of 1995 (NTTAA), Public Law No. 104–113, section 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards (VCS) 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 VCS bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable VCS.

This action does not involve technical standards. Therefore, EPA did not consider the use of any VCS.

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. The 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).

K. Judicial Review

Sections 172(a)(1)(B) and 181(a)(3) provide that classification determinations "shall not be subject to judicial review until the Administrator takes final action" approving or disapproving a SIP revision or triggering sanctions under section 179 with respect to a SIP revision required for an area's classification. Thus, any petitions for review of a classification decision made in this action must be filed within 60 days of publication of a final EPA action triggering sanctions with respect to a SIP submission required for the area's classification or approving or disapproving a SIP required for the area's classification. Since such challenge would be brought in conjunction with EPA's action regarding a SIP submission, a petition for review challenging the classification decision should be brought in the United States Court of Appeals for the appropriate circuit.

List of Subjects in 40 CFR Part 81

Environmental protection, Air pollution control, National Parks, Wilderness areas.

Dated: September 15, 2004.

Michael O. Leavitt,

Administrator.

■ For the reasons set forth in the preamble, 40 CFR part 81, subpart C is amended as follows:

PART 81—DESIGNATIONS OF AREAS FOR AIR QUALITY PLANNING PURPOSES

■ 1. The authority citation for part 81 continues to read as follows:

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

Subpart C—Section 107 Attainment Status Designations

PART 81—[AMENDED]

■ 2. In § 81.304, the table entitled "Arkansas-Ozone (8-Hour Standard)" is amended by revising the entry for "Crittenden County" to read as follows:

§ 81.304 Arkansas.

* * * * *

ARKANSAS-OZONE (8-HOUR STANDARD)

Designated area	Designation [a]		Category/classification	
	Date [1]	Type	Date [1]	Type
Memphis,TN–AR: (AQCR 018 Metropolitan Memphis Interstate)				
Crittenden County	(2)	Nonattainment	(2)	Subpart 2/Marginal
* * *	*	*	*	*

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is June 15, 2004, unless otherwise noted.
[2] November 22, 2004.

■ 3. In § 81.315, the table entitled "Indiana-Ozone (8-Hour Standard)" is amended by revising the entry for "La Porte County" to read as follows:

§ 81.315 Indiana.

* * * * *

INDIANA-OZONE (8-HOUR STANDARD)

Designated area	Designation [a]		Category/classification	
	Date [1]	Type	Date [1]	Type
* * *	*	*	*	*
La Porte Co., IN:				
La Porte County	(2)	Nonattainment	(2)	Subpart 2/Marginal
* * *	*	*	*	*

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is June 15, 2004, unless otherwise noted.
[2] November 22, 2004.

■ 4. In § 81.321, the table entitled "Maryland-Ozone (8-Hour Standard)" is amended by revising the entries for "Kent and Queen Anne's Counties" to read as follows:

§ 81.321 Maryland.

* * * * *

MARYLAND-OZONE (8-HOUR STANDARD)

Designated area	Designation [a]		Category/classification	
	Date [1]	Type	Date [1]	Type
* * *	*	*	*	*
Kent and Queen Anne's Cos., MD:				
Kent County	(3)	Nonattainment	(3)	Subpart 2/Marginal
Queen Anne's County	(3)	Nonattainment	(3)	Subpart 2/Marginal
* * *	*	*	*	*

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is June 15, 2004, unless otherwise noted.
* * * * * * *
[3] November 22, 2004.

■ 5. In § 81.323, the table entitled "Michigan-Ozone (8-Hour Standard)" is amended by revising the entries for "Cass, Lenawee, Livingston, Macomb, Monroe, Oakland, St. Clair, Washtenaw, Wayne, and Muskegon Counties' to read as follows:

§ 81.323 Michigan.

* * * * *

MICHIGAN-OZONE (8-HOUR STANDARD)

Designated area	Designation [a]		Category/classification	
	Date [1]	Type	Date [1]	Type
* * *	*	*	*	*
Cass County, MI:				
Cass County	(2)	Nonattainment	(2)	Subpart 2/Marginal
Detroit-Ann Arbor, MI:				
Lenawee County	(2)	Nonattainment	(2)	Subpart 2/Marginal
Livingston County	(2)	Nonattainment	(2)	Subpart 2/Marginal
Macomb County	(2)	Nonattainment	(2)	Subpart 2/Marginal
Monroe County	(2)	Nonattainment	(2)	Subpart 2/Marginal
Oakland County	(2)	Nonattainment	(2)	Subpart 2/Marginal
St. Clair County	(2)	Nonattainment	(2)	Subpart 2/Marginal
Washtenaw County	(2)	Nonattainment	(2)	Subpart 2/Marginal
Wayne County	(2)	Nonattainment	(2)	Subpart 2/Marginal
* * *	*	*	*	*
Muskegon, MI:				
Muskegon County	(2)	Nonattainment	(2)	Subpart 2/Marginal
* * *	*	*	*	*

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is June 15, 2004, unless otherwise noted.
[2] November 22, 2004.

■ 6. In § 81.334, the table entitled "North Carolina-Ozone (8-Hour Standard)" is amended by revising the entries for "Alamance, Caswell, Davidson, Davie, Forsyth, Guilford, Randolph, and Rockingham Counties' to read as follows:

§ 81.334 North Carolina.

* * * * *

NORTH CAROLINA-OZONE (8-HOUR STANDARD)

Designated area	Designation [a]		Category/classification	
	Date [1]	Type	Date [1]	Type
* * *	*	*	*	*
Greensboro-Winston-Salem-High Point, NC:				
Alamance County	(2) (3)	Nonattainment	(3)	Subpart 2/Marginal
Caswell County	(2) (3)	Nonattainment	(3)	Subpart 2/Marginal
Davidson County	(2) (3)	Nonattainment	(3)	Subpart 2/Marginal
Davie County	(2) (3)	Nonattainment	(3)	Subpart 2/Marginal
Forsyth County	(2) (3)	Nonattainment	(3)	Subpart 2/Marginal
Guilford County	(2) (3)	Nonattainment	(3)	Subpart 2/Marginal
Randolph County	(2) (3)	Nonattainment	(3)	Subpart 2/Marginal
Rockingham County	(2) (3)	Nonattainment	(3)	Subpart 2/Marginal
* * *	*	*	*	*

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is June 15, 2004, unless otherwise noted.
[2] Early Action Compact Area, effective date deferred until September 30, 2005.
[3] November 22, 2004.

■ 7. In § 81.339, the table entitled "Pennsylvania-Ozone (8-Hour Standard)" is amended by revising the entry for "Lancaster County" to read as follows:

§ 81.339 Pennsylvania.

* * * * *

PENNSYLVANIA-OZONE (8-HOUR STANDARD)

Designated area	Designation [a]		Category/classification	
	Date [1]	Type	Date [1]	Type
* * *	*	*	*	*
Lancaster, PA:				
Lancaster County	(2)	Nonattainment	(2)	Subpart 2/Marginal

PENNSYLVANIA-OZONE (8-HOUR STANDARD)—Continued

Designated area	Designation [a]		Category/classification	
	Date [1]	Type	Date [1]	Type
* * *	*	*	*	*

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is June 15, 2004, unless otherwise noted.
[2] November 22, 2004.

■ 8. In § 81.343, the table entitled "Tennessee-Ozone (8-Hour Standard)" is amended by revising the entry for "Shelby County" to read as follows:

§ 81.343 Tennessee.

* * * * *

TENNESSEE-OZONE (8-HOUR STANDARD)

Designated area	Designation [a]		Category/classification	
	Date [1]	Type	Date [1]	Type
* * *	*	*	*	*
Memphis,TN–AR:				
Shelby County	(3)	Nonattainment	(3)	Subpart 2/Marginal
* * *	*	*	*	*

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is June 15, 2004, unless otherwise noted.
* * * * *
[3] November 22, 2004.

■ 9. In § 81.347, the table entitled "Virginia-Ozone (8-Hour Standard)" is amended by revising the entries for "Charles City County, Chesterfield County, Colonial Heights City, Hanover County, Henrico County, Hopewell City, Petersburg City, Prince George County, and Richmond City" to read as follows:

§ 81.347 Virginia.

* * * * *

VIRGINIA-OZONE (8-HOUR STANDARD)

Designated area	Designation [a]		Category/classification	
	Date [1]	Type	Date [1]	Type
* * *	*	*	*	*
Richmond-Petersburg, VA:				
Charles City County	(3)	Nonattainment	(3)	Subpart 2/Marginal
Chesterfield County	(3)	Nonattainment	(3)	Subpart 2/Marginal
Colonial Heights City	(3)	Nonattainment	(3)	Subpart 2/Marginal
Hanover County	(3)	Nonattainment	(3)	Subpart 2/Marginal
Henrico County	(3)	Nonattainment	(3)	Subpart 2/Marginal
Hopewell City	(3)	Nonattainment	(3)	Subpart 2/Marginal
Petersburg City	(3)	Nonattainment	(3)	Subpart 2/Marginal
Prince George County	(3)	Nonattainment	(3)	Subpart 2/Marginal
Richmond City	(3)	Nonattainment	(3)	Subpart 2/Marginal
* * *	*	*	*	*

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is June 15, 2004, unless otherwise noted.
* * * * *
[3] November 22, 2004.

[FR Doc. 04–21184 Filed 9–21–04; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0278; FRL–7679–5]

Tribenuron Methyl; Pesticide Tolerance

AGENCY: Environmental Protection Agency EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of tribenuron methyl in or on canola, seed; cotton, gin byproducts; cotton, undelinted seed; and flax, seed. E.I. DuPont De Nemours and Company requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). In addition, this regulatory action is part of the tolerance reassessment requirements of section 408(q) of the FFDCA 21 U.S.C. 346a(q), as amended by the FQPA of 1996. By law, EPA is required to reassess 100% of the tolerances in existence on August 2, 1996, by August 2006. This regulatory action will count for eight reassessments toward the August 2006 deadline.

DATES: This regulation is effective September 22, 2004. Objections and requests for hearings must be received on or before November 22, 2004.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number OPP–2004–0278. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket*. 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 EDOCKET 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: James Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460–0001; telephone number: 703–305–5697 e-mail address: *tompkins.jim@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does This Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

This listing is not intended to be exhaustive, but rather provides a guide for readers 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) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

B. How Can I Access Electronic Copies of This Document and Other Related Information?

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/*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gpo/opptsfrs/home/guidelin.htm/*.

II. Background and Statutory Findings

In the **Federal Register** of July 7, 2004 (69 FR 40909) (FRL–7364–8), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 0F6135) by E.I. DuPont de Nemours and Company, DuPont Crop Protection, Barley Mill Plaza, Wilmington, DE 19880–0038. The petition requested that 40 CFR 180.451 be amended by establishing a tolerance for residues of the herbicide tribenuron methyl, [methyl 2-[[[[(4-methoxy -6-methyl-1, 3, 5-triazin-2-yl) methylamino] carbobyl]amino]sulfonyl]benzoate], in or on imazethapyr tolerant canola at 0.02 parts per million (ppm), cotton gin trash at 0.02 ppm, cotton seed at 0.02 ppm, and Crop Development Center (CDC) triffid flax at 0.02 ppm. That notice included a summary of the petition prepared by E. I. DuPont de Nemours and Company, the registrant. There were no comments received in response to the notice of filing.

During the course of the review the Agency decided to correct the Company address and correct the listings for the commodities canola, cotton and flax. The company address is changed to DuPont Crop Protection, Stine-Haskell Research Center, Newark, DE 19714. The listing of the commodities imazethapyr tolerant canola, cotton seed, cotton gin trash and Crop Development Center (CDC) triffid flax are corrected to read canola, seed; cotton, undelinted seed; cotton, gin byproducts and flax, seed; respectively.

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. * * *"

EPA performs a number of analyses to determine the risks from aggregate

exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of FFDCA, for a tolerance for residues of tribenuron methyl on canola, seed at 0.02 ppm, cotton, gin byproducts at 0.02 ppm, cotton, undelinted seed at 0.02 ppm, and flax, seed at 0.02 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by tribenuron methyl are discussed in Table 1 of this unit as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies reviewed.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90-Day oral toxicity--rodents	NOAEL = 7 (males and 8 (females) milligrams/kilogram/day (mg/kg/day) LOAEL = 118 (males) and 135 (females) mg/kg/day based on decreased body weight gain, food consumption and food efficiency; decreased absolute heart, liver, and kidney weights; increase relative brain, heart, liver, kidney, testes, and spleen weights; decreased serum glucose and globulin; no histopathologic lesions; likely cachexia
870.3150	90–Day oral toxicity--non-rodents	NOAEL = > 73.3 (males) and > 78.0 (females) HDT mg/kg/day
870.3200	21/28-Day dermal toxicity	NOAEL = limit dose, 1,000 mg/kg/day, resulted in serious toxicity and death. No NOAEL or LOEAL defined. Toxicity included treatment site lesions, hypokinesia, decreased body weights and food consumption, and kidney pathology, but the cause of death could not be determined. Although this study is core supplementary, another study is not needed. Worker exposure is expected to be 4 to 5 orders of magnitude less than limit dose.
870.3700	Prenatal developmental--rodents	Maternal NOAEL = 20 mg/kg/day Maternal LOAEL = 125 mg/kg/day based on decreased maternal body weight gain and food consumption Developmental NOAEL = 20 mg/kg/day Developmental LOAEL = 125 mg/kg/day based on decreased body weight. At 500 mg/kg/day (HDT) there were increased resorption, fetal deaths, and incomplete ossifications
870.3700	Prenatal developmental--non-rodents	Maternal NOAEL = 20 mg/kg/day Maternal LOAEL = 80 (HDT) mg/kg/day based on 10% decreased food consumption, increased abortions Developmental NOAEL = 20 mg/kg/day Developmental LOAEL = 80 mg/kg/day based on HDT-10% decrease in body weight compared to controls-not statistically significant). Abortions were increased at 80 mg/kg/day. Teratology was not observed.
870.3800	Reproduction and fertility effects	Parental/Systemic NOAEL = 2 mg/kg/day Parental/Systemic LOAEL = 21 mg/kg/day based on decreased body weight gain in F_{1a} adult females Reproductive NOAEL = 2.5 mg/kg/day Reproductive LOAEL = 25 mg/kg/day based on decreased body weight gain during lactation for F_{1b} and F_{2b} pups Offspring NOAEL = 2.5 mg/kg/day Offspring LOAEL = 25 mg/kg/day based on decreased absolute splenic weights
870.4100	Chronic toxicity--rodents	NOAEL = 0.95 (males)/1.2 (females) mg/kg/day LOAEL = 10 (males)/13 (females) mg/kg/day based on decreased body weight gain in both sexes. Statistically significant increase in mammary gland adenocarcinomas in female rats at 76 mg/kg/day highest dose tested (HDT)
870.4100	Chronic toxicity--dogs	NOAEL = 0.79 (males)/8.16 (females) mg/kg/day LOAEL = 8.18 (males)/52.02 (females) mg/kg/day based on elevated serum bilirubin, AST, and urinary volume, reduced body weight gain (20%) in females; increased serum creatinine, bilirubin, AST, and globulin, decreased body weight gain of 18.2% in males.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
870.4200	Carcinogenicity--rats	NOAEL = 0.95 (males)/1.2 (females) mg/kg/day LOAEL = 10 (males)/13 (females) mg/kg/day based on decreased body weight gain in both sexes. Statistically significant increase in mammary gland adenocarcinomas in female rats at 76 mg/kg/day (HDT)
870.4300	Supplement-Estrogenic Activity in Rats	Dose levels: 0 and 390 mg/kg/day for 90 days. Weak estrogenic activity was observed in female rats. The technical and seven metabolites may be agonists for the estrogen receptor.
870.4300	Carcinogenicity--mice	NOAEL = 3 (males) mg/kg/day LOAEL = 30 mg/kg/day based on bilateral seminiferous degenertion and oligospermia. Although frank toxicity was not observed in the females, HED peer review judged the dose levels to be adequate. No evidence of carcinogenicity
870.5100	Gene mutation Bacterial	negative in *Salmonella Typhimurium*
870.5300	Gene Mutation Mammalian	negative in Chinese hamster ovary cells in *in vitro*
870.5375	Cytogenetics	negative for structural chromosomal damage and when tested in a micronucleus test in mice
870.7485	Metabolism and pharmacokinetics	The major route of excretion in rats is the urine. Urine samples contained two to four times of the administered radioactivity than the feces. Tissue levels of tribenuron methyl and its metabolites increased with dose, but there was no concentration of radioactivity in any particular organ or tissue.

B. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

Three other types of safety or uncertainty factors may be used: "Traditional uncertainty factors;" the "special FQPA safety factor;" and the "default FQPA safety factor." By the term "traditional uncertainty factor," EPA is referring to those additional uncertainty factors used prior to FQPA passage to account for database deficiencies. These traditional uncertainty factors have been incorporated by the FQPA into the additional safety factor for the protection of infants and children. The term "special FQPA safety factor" refers to those safety factors that are deemed necessary for the protection of infants and children primarily as a result of the FQPA. The "default FQPA safety factor" is the additional 10X safety factor that is mandated by the statute unless it is decided that there are reliable data to choose a different additional factor (potentially a traditional uncertainty factor or a special FQPA safety factor).

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (aRfD or cRfD) where the RfD is equal to the NOAEL divided by an UF of 100 to account for interspecies and intraspecies differences and any traditional uncertainty factors deemed appropriate (RfD = NOAEL/UF). Where a special FQPA safety factor or the default FQPA safety factor is used, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of safety factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (*e.g.*, risk). An example of how such a probability risk is expressed would be to describe the risk as one in one hundred thousand (1×10^{-5}), one in a million (1×10^{-6}), or 1 in 10 million (1×10^{-7}). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a "point of departure" is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated.

A summary of the toxicological endpoints for tribenuron methyl used for human risk assessment is shown in the following Table 2:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR TRIBENURON METHYL FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, Interspecies and Intraspecies and any Traditional UF	Special FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Chronic Dietary (All populations)	NOAEL= 0.8 mg/kg/day UF = 100 ..... Chronic RfD = 0.008 mg/kg/day.	Special FQPA SF = 1 cPAD = chronic RfD ÷ Special FQPA SF = 0.008 mg/kg/day.	Chronic Dog LOAEL = 8.2 mg/kg/day based on elevated bilirubin, elevated serum liver enzymes, increased urinary volume, and 20% reduction in body weight gain.
Cancer (oral, dermal, inhalation)	Classified as Group C (possible human carcinogen) not mutagenic)	chronic risk assessment protective of any potential carcinogenic risk	NA

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.451) for the residues of tribenuron methyl, in or on a variety of raw agricultural commodities. Tolerances are established for barley, oats, wheat, and grass forage and hay group. No tolerances for meat products, eggs, or milk are established. Risk assessments were conducted by EPA to assess dietary exposures from tribenuron methyl in food as follows:

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

There are no studies that identify an acute hazard based on toxic effects observed following a single oral exposure (dose) of tribenuron methyl. The developmental toxicity rat study in which a 9% reduction in body weight occurred on the fourth day of dosing (day 9) was considered. However, this reduction in body weight gain was only slight and could not be attributed to a single dose since the reduction occurred on day 4 of dosing. Other effects observed in the developmental toxicity study such as decreased fetal wight (7.4%) and increased incidence of fetal resorptions (not statistically significant) were considered for an endpoint in reproductive females, but again, effects could not be attributed to a single dose. Since there was no litter loss or other acute effects, the aRfD is not appropriate for the assessment.

ii. *Chronic exposure.* Dietary exposure estimates were conducted using the Lifeline model (Version 2.0) which incorporates consumption data from the USDA Continuing Surveys of Food Intakes by Individuals (CSFII), 1994-96 and 1998. The 1994-96, 1998 data are based on reported consumption of more than 20,000 individuals over two non-consecutive survey days. Foods "as consumed" are linked to EPA-defined food commodities using publicly available recipe translation files (developed jointly by USDA/ARS and EPA). Lifeline models individual dietary exposures over a season by selecting a new CSFII diary each day from a set of similar individuals, based on age and season attributes. The Lifeline chronic dietary exposure estimate is based on an average daily exposure from a profile of 1,000 individuals over a 1–year period. Further information regarding the Lifetime model can be found at the following we site:*www.Lifeline ™group.org.*

The following assumptions were made for the chronic exposure assessments: Tolerance level, 100% crop treated (CT), and default processing factors were used. Percent crop treated (PCT) or anticipated residues were not used.

iii. *Cancer.* Tribenuron methyl is classified as a Group C (Possible Human Carcinogen). The Agency also concluded that the carcinogenic response observed may be associated with a hormonal imbalance that may not occur at doses below a maximum tolerated dose (MTD). A quantitative carcinogenic risk assessment for tribenuron methyl is not considered appropriate because: (1) The increased incidence of mammary gland tumors was observed in female rats treated at the dose levels exceeding the (MTD; (2) there was no evidence of genetic toxicity shown in several studies; (3) structural analogs of tribenuron methyl were not associated with carcinogenic responses in rats and mice. In conclusion the Agency considers the chronic risk assessment, making use of the cPAD, to be protective of any potential carcinogenic risk.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for tribenuron methyl in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of tribenuron methyl.

The Agency uses the FQPA Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The SCI-GROW model is used to predict pesticide concentrations in shallow ground water. For a screening-level assessment for surface water EPA will use FIRST (a tier 1 model) before using PRZM/EXAMS (a tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. Both FIRST and PRZM/EXAMS incorporate an index reservoir environment, and both models include a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a screen for sorting out pesticides for which it is unlikely that drinking water concentrations would exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs), which are the model estimates of a pesticide's concentration in water. EECs derived from these models are used to quantify drinking water exposure and risk as a %RfD or %PAD. Instead, drinking water levels of comparison (DWLOCs) are

calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to tribenuron methyl they are further discussed in the aggregate risk Unit III.E.

Based on the FIRST, and SCI-GROW models, the EECs of tribenuron methyl for chronic exposures are estimated to be .413 ppb for surface water and 0.000006 ppb for ground water.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Tribenuron methyl is not registered for use on any sites that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to tribenuron methyl and any other substances and tribenuron methyl does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that tribenuron methyl has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs (OPP) concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's web site at *http://www.epa.gov/pesticides/cumulative/.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408 of FFDCA provides that EPA shall apply an additional 10-fold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a maragin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional safety factor value based on the use of traditional uncertainty factors and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity.* Developmental and reproductive toxicity studies indicated no increased susceptibility of offspring to tribenuron methyl. However, increased number of resorptions (not statistically significant) and fetal deaths were observed at the highest dose tested when administered during the critical gestation period of pregnancy, in both the rat and the rabbit. The resorptions and fetal deaths indicate an effect due to maternal toxicity. In a two-generation reproduction study, reproductive effects of tribenuron methyl were limited to decreased body weight gain during lactation.

3. *Conclusion.* There is a complete toxicity database for tribenuron methyl and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. The impact of tribenuron methyl on the nervous system has not been specifically evaluated in neurotoxicity studies. However, there was no evidence of neurotoxicity or neuropathology seen in either acute, subchronic, chronic, or reproductive studies, and there are no concerns for potential developmental neurotoxicity. Therefore, neurotoxicity data are not required for tribenuron methyl. EPA determined that the 10X SF to protect infants and children should be removed. The FQPA factor is removed because of the completeness of the toxicity and exposure database and because the available data provided no indication of increased susceptibility (quantitative or qualitative) to rats or rabbits following *in utero* exposure to tribenuron methyl, or to prenatal and/or postnatal exposure in rat reproduction studies and there are no concerns for potential developmental neurotoxicity.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs (drinking water level of concern) which are used as a point of comparison against EECs. DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (*i.e.*, the PAD) is available for exposure through drinking water *e.g.*, allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the EPA's Office of Water are used to calculate DWLOCs: 2 liter (L)/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, OPP concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, OPP will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk.* An acute risk assessment was not performed; there were no studies that identify an acute hazard based on toxic effects observed following a single oral exposure (dose) of tribenuron methyl.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to tribenuron methyl from food will utilize <1% of the cPAD for the U.S. population, <1% of the cPAD for all infants <1 year old, and <1% of the cPAD for children 3 to 5 years old. There are no residential uses for tribenuron methyl that result in chronic residential exposure to tribenuron methyl. In addition, there is potential for chronic dietary exposure to tribenuron methyl in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 3:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO TRIBENURON METHYL

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U. S. Population	0.008	<1	.413	.000006	300
All infants < 1 year old	0.008	<1	.413	.000006	100
Children 1–2 years old	0.008	<1	.413	.000006	100
Children 3–5 years old	0.008	<1	.413	.000006	100
Females 13–49 years old	0.008	<1	.413	.000006	200

3. *Short-term risk.* Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Tribenuron methyl is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Tribenuron methyl is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

5. *Aggregate cancer risk for U.S. population.* The Agency considers the chronic aggregate risk assessment, making use of the cPAD, to be protective of any aggregate cancer risk. See Table 3, Unit III.E.2. Therefore, the aggregate risk is not expected to exceed the Agency's level of concern.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to tribenuron methyl residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate analytical methodology including liquid chromatography with a photoconductivity detector; high-performance liquid chromatography with UV detection (HPLC/UV); and gas chromatography using mass spectral detection (GC/MS) are available for enforcement of reassessed tolerances. These methods are published in PAM II.

Adequate enforcement methodology —liquid chromatography with detection via electospray mass spectroscopy is available to enforce the tolerance expression for canola, flax, and cotton. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov.*

B. International Residue Limits

The maximum residue level (MRL) in Canada for tribenuron methyl on canola is 0.1 ppm. Available residue data and use pattern support a U.S. tolerance of 0.02 ppm. No Mexican or Codex MRLs exist for tribenuron methyl on canola. There are no Canadian, Mexican, or Codex MRLs for tribenuron methyl on cotton or flax.

C. Conditions

Based on the tolerance reassessment for barley, oats, and wheat, residue data are required for barley, hay; oat forage and hay; and wheat forage and hay. Submission of this data and proposal of appropriate tolerances will be required. There are no conditions of registration for the establishment of tolerances on canola, cotton, or flax.

V. Conclusion

Therefore, the tolerance is established for residues of tibenuron methyl, methyl 2-[[[[(4-methoxy-6-methyl-1, 3, 5-triazin-2-yl) methylamino]carbobyl]amino] sulfonyl]benzoate, in or on canola, seed at 0.02 ppm; cotton, gin byproducts at 0.02 ppm; cotton, undelinted seed at 0.02 ppm, and flax, seed at 0.02 ppm. This action results in the reassessment of 8 tolerances as follows: barley, grain at 0.05 ppm; barley, straw at 0.10 ppm; oat, grain at 0.05 ppm; oat, straw at 0.1 ppm; wheat, grain at 0.05 ppm; wheat, straw at 0.10 ppm; and tolerances with regional registration for grass, forage, fodder, and hay group (except bermudagrass); forage at 0.10 ppm; and grass, forage, fodder, and hay group (except bermudagrass); hay at 0.10 ppm listed in 40 CFR 180.451. Also, even though many of the tolerancs for the current commodities listed in § 180.451 have not been changed and only tolerances for canola, seed; cotton, gin byproducts; cotton, undelinted seed; and flax, seed are being added, EPA is printing § 180.451 in its entirety to restructure the section so that it matched the other sections in subpart C.

VI. Objections and Hearing Requests

Under section 408(g) of FFDCA, as amended by FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to FFDCA by FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of FFDCA provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a

tolerance issued by EPA under new section 408(d) of FFDCA, as was provided in the old sections 408 and 409 of FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do To File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2004–0278. in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before November 22, 2004.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 564–6255.

2. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP–2004–0278, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to 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). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on 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, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 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 directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any "tribal implications" as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, 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." "Policies that have tribal implications" is defined in the Executive order to include regulations that have "substantial direct effects on one or more Indian tribes, 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." This rule will not have substantial direct effects on tribal governments, 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 in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. 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 this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 10, 2004.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—AMENDED

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.451 is revised to read as follows:

§ 180.451 Tribenuron methyl; tolerances for residues.

(a) *General.* Tolerances are established for the residues of the herbicide tribenuron methyl (methyl-2-[[[[N-(4-methoxy-6-methyl-1,3,5-triazin-2-yl) methylamino] carbonyl]amino]sulfonyl] benzoate) in or on the following raw agricultural commodities:

Commodity	Parts per million
Barley, grain	0.05
Barley, straw	0.10
Canola, seed	0.02
Cotton, gin byproducts	0.02
Cotton, undelinted seed	0.02
Flax, seed	0.02
Oat, grain	0.05
Oat, straw	0.10
Wheat, grain	0.05
Wheat, straw	0.10

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* Tolerances with regional registration, as defined in § 180.1(n) are established for residues of the herbicide tribenuron methyl (methyl-2-[[[[N-(4-methoxy-6-methyl-1,3,5-triazin-2-yl) methylamino] carbonyl]amino]sulfonyl] benzoate) in or on the following raw agricultural commodities:

Commodity	Parts per million
Grass, forage, fodder and hay, group (except Bermudagrass); forage	0.10
Grass, forage, fodder and hay, group (except Bermudagrass); hay	0.10

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 04–20982 Filed 9–21–04; 8:45 am]

BILLING CODE 6560–50–S

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

45 CFR Parts 2552 and 2553

Senior Corps

AGENCY: Corporation for National and Community Service.

ACTION: Final rule; correction.

SUMMARY: The Corporation for National and Community Service (hereinafter the "Corporation") hereby amends its regulations for the Senior Corps. These amendments make technical corrections to the final rules issued on April 14, 2004, for the Foster Grandparent Program and on April 19, 2004, for the Retired and Senior Volunteer Program. Two amendments herein provide technical corrections to the Foster Grandparent Program and Retired and Senior Volunteer Program regulations to ensure consistency concerning the allowability of volunteer expenses among the Foster Grandparent, Retired and Senior Volunteer, and Senior Companion Programs and bring them in line with the corresponding provision for the Senior Companion Program, as it was amended on April 19, 2004. The third amendment deletes one sentence in the Retired and Senior Volunteer Program regulations so as to ensure consistency throughout the entire section.

DATES: These changes are effective as of September 22, 2004.

FOR FURTHER INFORMATION CONTACT: Mr. Peter Boynton at (202) 606–5000, ext. 499 or by e-mail: *pboynton@cns.gov.*

List of Subjects

45 CFR Part 2552

Aged, Grant programs—social programs, Volunteers.

45 CFR Part 2553

Aged, Grant programs—social programs, Volunteers.

■ For the reasons discussed in the Summary, the Corporation for National and Community Service amends 45 CFR parts 2552 and 2553 as follows:

PART 2552—FOSTER GRANDPARENT PROGRAM

■ 1. The authority citation for part 2552 continues to read as follows:

Authority: 42 U.S.C. 4950 *et seq.*

■ 2. In § 2552.45, revise paragraph (f) to read as follows:

§ 2552.45 What cost reimbursements are provided to Foster Grandparents?

* * * * *

(f) *Other volunteer expenses.* Foster Grandparents may be reimbursed for expenses incurred while performing their volunteer assignments, provided these expenses are described in the Memorandum of Understanding negotiated with the volunteer station to which the volunteer is assigned and there are sufficient funds available to cover these expenses and meet all other requirements identified in the notice of grant award.

PART 2553—RETIRED AND SENIOR VOLUNTEER PROGRAM

■ 3. The authority citation for part 2553 continues to read as follows:

Authority: 42 U.S.C. 4950 *et seq.*

■ 4. In § 2553.43, remove the last sentence of paragraph (a) and revise paragraph (e) to read as follows:

§ 2553.43 What cost reimbursements are provided to RSVP volunteers?

* * * * *

(e) *Other volunteer expenses.* RSVP volunteers may be reimbursed for

expenses incurred while performing their volunteer assignments, provided these expenses are described in the Memorandum of Understanding negotiated with the volunteer station and there are sufficient funds available to cover these expenses and meet all other requirements identified in the notice of grant award.

Dated: September 14, 2004.

Tess Scannell,

Director, Senior Corps.

[FR Doc. 04–21235 Filed 9–21–04; 8:45 am]

BILLING CODE 6050–$$–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 635

[I.D. 091604A]

Atlantic Highly Migratory Species; Atlantic Bluefin Tuna Fisheries

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Atlantic bluefin tuna retention limit adjustment.

SUMMARY: NMFS has determined that the Atlantic bluefin tuna (BFT) General category daily retention limit should be adjusted to allow for maximum utilization of the U.S. landings quota of BFT, while maintaining a fair distribution of fishing opportunities. Therefore, NMFS increases the daily retention limit to provide increased opportunities to harvest the General category quota.

DATES: The effective dates for the daily retention limits specified in this rule are provided in Table 1 under **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Brad McHale, 978–281–9260.

SUPPLEMENTARY INFORMATION: Regulations implemented under the authority of the Atlantic Tunas Convention Act (16 U.S.C. 971 *et seq.*) and the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act; 16 U.S.C. 1801 *et seq.*) governing the harvest of BFT by persons and vessels subject to U.S. jurisdiction are found at 50 CFR part 635. Section 635.27 subdivides the U.S. BFT quota recommended by the International Commission for the Conservation of Atlantic Tunas (ICCAT) among the various domestic fishing categories, and General category effort controls (including time-period sub-quotas) are specified annually under the procedures identified at 50 CFR 635.23(a) and 635.27(a). NMFS is in the process of establishing the 2004 annual BFT quota specifications and in the meantime, sufficient General category quota is available for 2004 per the 2002 recommendation from ICCAT.

Adjustment of Daily Retention Limit

NMFS is increasing the General category daily retention limit effective from September 20, 2004, through October 20, 2004, inclusive, to two large medium or giant BFT per vessel (see Table 1). Under § 635.23(a)(4), NMFS may increase or decrease the General category daily retention limit of large medium and giant BFT over a range from zero to three per vessel to allow for maximum utilization of the quota for BFT. Based on a review of dealer reports, daily landing trends, available quota, and the availability of BFT on the fishing grounds, NMFS has determined that an increase of the daily retention limit from September 20, 2004, through October 20, 2004, inclusive, is appropriate and necessary.

TABLE 1—DAILY RETENTION LIMITS

Category	Effective Date	Areas	BFT Size Class Limit
General	September 20, 2004–October 20, 2004	All	Two BFT per vessel, measuring 73 inches (185 cm) curved fork length or larger
	October 21, 2004–January 31, 2005	All	One BFT per vessel, measuring 73 inches (185 cm) curved fork length or larger

Current catch rates in the General category amount to approximately 0.5 metric tons (mt) per day. Current catch rates are lower than the low landings rates that occurred at this time last year when it was also determined that the daily retention should be increased. In combination with a quota rollover from the previous sub-period, the current 2004 landing rate would not lead to harvest of the full September sub-quota, and would result in an excessive quota rollover into the next sub-period. Adding an excessive amount of unused quota from one time-period sub-quota to the subsequent time-period sub-quota is undesirable because it effectively changes the time-period sub-quota allocation percentages established in the Fishery Management Plan for Atlantic Tunas, Swordfish, and Sharks (HMS FMP). This issue has been discussed extensively during public comment periods for annual quota specifications and during HMS Advisory Panel meetings. This adjustment, which will be in effect for approximately 30 days, is scheduled for approximately the same time period when catch rates increased in New England in 2003. Catch rates for the regional New England fishery are expected to increase during the limited time period this adjustment is in effect. BFT are expected to begin the annual southward migration at approximately the time the retention limit is reduced (October 21, 2004) and by reverting to a retention limit of one fish per vessel per day, sub-period quota for subsequent regional fisheries will be maintained. Experience in prior years has shown that similar adjustments to the General category retention limit had positive impacts on the fishery and favorable public response.

The intent of this adjustment is to allow for maximum utilization of the U.S. landings quota of BFT (specified under 50 CFR 635.27(a)) while maintaining a fair distribution of fishing opportunities, to help achieve optimum yield in the General category fishery, to collect a broad range of data for stock monitoring purposes, and to be consistent with the objectives of the HMS FMP.

The default daily General category retention limit of one large medium or giant BFT (specified at 50 CFR 635.23(a)(2)), will apply to all vessels fishing under the General category quota effective October 21, 2004, through the remainder of the General category fishery, which ends January 31, 2005 (see Table 1).

Closures or subsequent adjustments to the daily retention limit, if any, will be published in the **Federal Register**. In addition, owners/operators may call the Atlantic Tunas Information Line at (888) 872–8862 or (978) 281–9305 for updates on quota monitoring and retention limit adjustments.

Classification

The Assistant Administrator for Fisheries, NOAA (AA), finds that it is impracticable and contrary to the public interest to provide prior notice of, and an opportunity for, public comment on this action. Catch rates for the 2004 BFT season have been extremely low to date. NMFS has recently become aware of increased availability of BFT on the New England fishing grounds. This increase in abundance provides the potential to increase landings rates for the New England fishery if participants are authorized to harvest two BFT per day. In order to provide access to BFT while they are available on the New England fishing grounds, the retention limit adjustment must be performed expeditiously. Delay in increasing the retention limits would adversely affect regional General category vessels since BFT will soon migrate south away from the New England fishing grounds. The regulations implementing the HMS FMP provide for retention limit in-season adjustments in order to respond to the unpredictable nature of BFT availability on the fishing grounds, the migratory nature of this species, and the regional variations in the BFT fishery. Immediate adjustment of retention limits is also necessary in order to avoid excessive quota rollovers to subsequent management periods. Impediments to the harvest of available quota will have negative social and economic impacts to U.S. fishermen that depend upon catching the available quota within the time periods designated in the HMS FMP. Therefore, the AA finds good cause under 5 U.S.C. 553(b)(B) to waive prior notice and the opportunity for public comment. In addition to the above reasons and because this action relieves a restriction (i.e., allows the retention of more fish), the AA also finds good cause to waive the delay in effectiveness normally required for this action is provided pursuant to 5 U.S.C. 553(d).

This action is being taken under 50 CFR 635.23(a)(4) and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 971 *et seq.* and 1801 *et seq.*

Dated: September 17, 2004.

Bruce C. Morehead,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 04–21290 Filed 9–17–04; 2:37 pm]

BILLING CODE 3510–22–S

Proposed Rules

Federal Register
Vol. 69, No. 183
Wednesday, September 22, 2004

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.

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 531

RIN 3206–AJ45

General Schedule Locality Pay Areas

AGENCY: Office of Personnel Management.

ACTION: Proposed rule.

SUMMARY: The Office of Personnel Management is issuing proposed regulations on behalf of the President's Pay Agent to link the definitions of General Schedule locality pay area boundaries to the geographic scope of metropolitan area definitions established by the Office of Management and Budget. This proposal makes use of new criteria for evaluating areas adjacent to locality pay areas. The proposed regulations would retain all of the existing locality pay areas, which would be expanded to include a number of additional locations.

DATES: We must receive comments on or before November 8, 2004.

ADDRESSES: Send or deliver comments to Donald J. Winstead, Deputy Associate Director for Pay and Performance Policy, Office of Personnel Management, Room 7H31, 1900 E Street, NW., Washington, DC 20415–8200; FAX: (202) 606–4264; or e-mail: *pay-performance-policy@opm.gov.*

FOR FURTHER INFORMATION CONTACT: Allan Hearne, (202) 606–2838; FAX: (202) 606–4264; e-mail: *pay-performance-policy@opm.gov.*

SUPPLEMENTARY INFORMATION: Section 5304 of title 5, United States Code, authorizes locality pay for General Schedule (GS) employees with duty stations in the contiguous United States and the District of Columbia. By law, locality pay is set by comparing GS pay rates with non-Federal pay rates for the same levels of work in each locality pay area. Non-Federal pay levels are estimated by means of salary surveys conducted by the Bureau of Labor Statistics (BLS). Currently, there are 32 locality pay areas: 31 separate metropolitan locality pay areas and a Rest of U.S. (RUS) locality pay area that consists of all locations in the contiguous United States that are not part of one of the 31 separate metropolitan locality pay areas.

Section 5304(f) of title 5, United States Code, authorizes the President's Pay Agent (the Secretary of Labor, the Director of the Office of Management and Budget (OMB), and the Director of the Office of Personnel Management (OPM)) to determine locality pay areas. The boundaries of locality pay areas must be based on appropriate factors, which may include local labor market patterns, commuting patterns, and the practices of other employers. The Pay Agent must give thorough consideration to the views and recommendations of the Federal Salary Council, a body composed of experts in the fields of labor relations and pay policy and representatives of Federal employee organizations. The President appoints the members of the Federal Salary Council, which submits annual recommendations to the President's Pay Agent about the locality pay program.

Based on the Council's 1993 recommendations, the Pay Agent approved using Metropolitan Statistical Area (MSA) and Consolidated Metropolitan Statistical Area (CMSA) definitions established by OMB as the basis for defining GS locality pay areas. In the 1990s, OMB defined MSAs and CMSAs based on population size, population density, and commuting patterns. Each MSA consisted of a densely populated and highly integrated core composed of central counties and outlying counties with a high level of commuting to/from the central counties meeting certain population size/density criteria. CMSAs were composed of adjacent MSAs that met specified commuting criteria. The criteria for establishing MSAs in the 1990s are available on the Internet at: *http://www.census.gov/population/www/estimates/mastand.html.*

OMB defines MSAs to establish geographic standards to be used by all Federal agencies in reporting statistical data. MSAs are not specifically designed for use in any non-statistical program. Nevertheless, the Council and the Pay Agent concluded that MSAs should serve as the basis for locality pay areas because they were based on population and commuting patterns, two factors that are also important in defining local labor markets. Furthermore, MSAs already existed, were used in BLS salary survey programs, and covered large areas, all of which were thought to reduce the level of controversy over locality pay area boundaries and simplify Federal pay administration.

The Council also recommended and the Pay Agent approved criteria for adding adjoining areas to locality pay areas that were not part of the MSA or CMSA as defined by OMB. The Council's criteria for adding adjoining areas to locality pay areas were based on GS employment, population density, and commuting patterns. The criteria were intentionally made difficult to pass in order to limit the number of added areas because the use of MSAs and CMSAs already resulted in very large locality pay areas.

OMB redefines MSAs after each census and released new MSA definitions based on new criteria and 2000 census data in June 2003. Under the new criteria, OMB now identifies outlying counties for MSAs based only on commuting rates. Population size and population density are no longer considered. Any county where 25 percent or more of the resident workers commute to central counties, or 25 percent of the persons employed in the county commute from central counties, is included in the MSA. Adjacent highly-related MSAs where 25 percent or more resident workers commute to/from the adjacent MSA are now incorporated into Combined Statistical Areas (CSAs). Finally, OMB created a new category of Micropolitan Statistical Areas, which have a core population of less than 50,000. The new criteria for establishing MSAs are available on the Internet at: *http://www.whitehouse.gov/omb/fedreg/metroareas122700.pdf,* and the new MSA definitions can be found at: *http://www.whitehouse.gov/omb/bulletins/fy04/b04-03.html.*

Because MSAs are designed for statistical reporting purpose only, OMB cautions that other Federal agencies should carefully consider MSAs before using the definitions in their non-statistical programs. The Federal Salary Council's Working Group met six times and the full Council met twice in 2003 to review the new MSA definitions, new commuting pattern data from the 2000 census, and other information. In its

letter of October 28, 2003, to the President's Pay Agent, the Council recommended that the Pay Agent use the new MSA definitions in the locality pay program as the basis for defining locality pay areas in 2005 and beyond. The Council's recommendations can be found at: *http://www.opm.gov/oca/fsc/recommendation03.asp*.

The Council concluded that Micropolitan Areas that are not part of a CSA should not be considered in the locality pay program. The Pay Agent notes that some CSAs are composed solely of Micropolitan Areas. The Pay Agent concludes that Micropolitan Areas will be considered for the locality pay program only if they are part of a CSA that includes one or more MSAs.

The Council also recommended that full county MSAs be used in New England. In the 1990s, MSAs and CMSAs composed of townships had been used to define locality pay areas in New England.

The Pay Agent tentatively approved these recommendations of the Council in its 2003 Report to the President (see *http://www.opm.gov/oca/payagent/2003/index.asp*) and has asked OPM to revise subpart F of part 531 of title 5, Code of Federal Regulations, accordingly.

Effect of Adopting New MSA and CSA Definitions on Locality Pay Areas

Adopting the new MSA and CSA definitions would add the following counties to existing locality pay areas effective in January 2005:

Atlanta-Sandy Springs-Gainesville, GA Combined Statistical Area

Butts County, GA; Chambers County, AL; Dawson County, GA; Hall County, GA; Haralson County, GA; Heard County, GA; Jasper County, GA; Lamar County, GA; Meriwether County, GA; Pike County, GA; Polk County, GA; Troup County, GA; and Upson County, GA.

Boston-Worcester-Manchester, MA–NH Combined Statistical Area

Belknap County, NH; the remainder of Hillsborough, Merrimack, Rockingham, and Strafford Counties, NH; and the remainder of Worcester County, MA.

Chicago-Naperville-Michigan City, IL–IN–WI Combined Statistical Area

Jasper County, IN; LaPorte County, IN; and Newton County, IN.

Cincinnati-Middletown-Wilmington, OH–KY–IN Combined Statistical Area

Bracken County, KY; Clinton County, OH; and Franklin County, IN.

Columbus-Marion-Chillicothe, OH Combined Statistical Area

Fayette County, OH; Knox County, OH; Marion County, OH; Morrow County, OH; Ross County, OH; and Union County, OH.

Dallas-Fort Worth, TX Combined Statistical Area

Cooke County, TX; Delta County, TX; Palo Pinto County, TX; Somervell County, TX; and Wise County, TX.

Dayton-Springfield-Greenville, OH Combined Statistical Area

Champaign County, OH; Darke County, OH; and Preble County, OH.

Denver-Aurora-Boulder, CO Combined Statistical Area

Clear Creek County, CO; Elbert County, CO; Gilpin County, CO; and Park County, CO.

Hartford-West Hartford-Willimantic, CT Combined Statistical Area

The remainder of Hartford, Middlesex, Tolland, and Windham Counties, CT.

Houston-Baytown-Huntsville, TX Combined Statistical Area

Austin County, TX; Matagorda County, TX; San Jacinto County, TX; and Walker County, TX.

Huntsville-Decatur, AL Combined Statistical Area

Lawrence County, AL, and Morgan County, AL.

Indianapolis-Anderson-Columbus, IN Combined Statistical Area

Bartholomew County, IN; Brown County, IN; Henry County, IN; Jennings County, IN; Montgomery County, IN; and Putnam County, IN.

Kansas City-Overland Park-Kansas City, MO–KS Combined Statistical Area

Atchison County, KS; Bates County, MO; Caldwell County, MO; Franklin County, KS; Johnson County, MO; and Linn County, KS.

Miami-Fort Lauderdale-Miami Beach, FL Metropolitan Statistical Area

Palm Beach County, FL.

Minneapolis-St. Paul-St. Cloud, MN–WI Combined Statistical Area

Benton County, MN; Goodhue County, MN; McLeod County, MN; Rice County, MN; and Stearns County, MN.

New York-Newark-Bridgeport, NY–NJ–CT–PA Combined Statistical Area

The remainder of Litchfield County, CT, and Ulster County, NY.

Orlando-The Villages, FL Combined Statistical Area

Sumter County, FL.

Pittsburgh-New Castle, PA Combined Statistical Area

Armstrong County, PA, and Lawrence County, PA.

Portland-Vancouver-Beaverton, OR–WA Metropolitan Statistical Area

Skamania County, WA.

Richmond, VA Metropolitan Statistical Area

Amelia County, VA; Caroline County, VA; Cumberland County, VA, King and Queen County, VA; King William County, VA; Louisa County, VA; and Sussex County, VA.

Sacramento-Arden-Arcade-Truckee, CA–NV Combined Statistical Area

Douglas County, NV, and Nevada County, CA.

St. Louis-St. Charles-Farmington, MO–IL Combined Statistical Area

Bond County, IL; Calhoun County, IL; Macoupin County, IL; St. Francois County, MO; Washington County, MO.

San Jose-San Francisco-Oakland, CA Combined Statistical Area

San Benito County, CA.

Seattle-Tacoma-Olympia, WA Combined Statistical Area

Mason County, WA.

Washington-Baltimore-Northern Virginia, DC-MD-VA-WV Combined Statistical Area

Frederick County, VA, the City of Winchester, VA; and Hampshire County, WV.

Criteria for Areas of Application

The Council also recommended changes in the criteria used to evaluate areas adjacent to an MSA-based locality pay area for inclusion in the pay area as one or more "areas of application." The criteria currently in effect require that adjacent counties (or partial counties in New England) in the RUS locality pay area must have—

- 2,000 or more GS employees,
- a 5 percent or higher level of commuting to/from the core of the MSA, and
- 200 or more persons per square mile OR 80 percent of the population living in urbanized areas.

Under another criterion recommended by the Council and approved by the Pay Agent in the 1990s, the State of Rhode Island was evaluated under the county criteria as a single

county. There are also existing criteria for evaluating a Federal facility that crosses locality pay area boundaries. These criteria require that the portion of the facility outside the locality pay area must have—

- at least 1,000 GS employees,
- the duty stations of the majority of GS employees within 10 miles of the locality, and
- a significant number of employees who commute from the pay locality.

In its letter of October 28, 2003, the Council recommended new criteria for evaluating adjacent areas for inclusion in a locality pay area based on GS employment and commuting rates. In the Council's view, the most relevant criteria are GS employment and commuting rates. The GS employment criterion measures the magnitude of potential problems in terms of the Federal workforce, and the commuting criterion measures the economic linkage among the areas and the likely recruitment or retention problems that might result if the county is excluded from the adjacent locality pay area. The Council recommended that metropolitan areas adjacent to locality pay areas be evaluated first and that single adjacent counties be evaluated second.

Proposed New Criteria for Areas of Application

The Council recommended three new sets of criteria for evaluating adjacent areas:

1. *For adjacent MSAs and CSAs:* To be included in an adjacent locality pay area, an adjacent MSA or CSA currently in the RUS locality pay area must have at least 1,500 GS employees and an employment interchange measure of at least 7.5 percent.

2. *For adjacent counties that are not part of a multi-county MSA or CSA:* To be included in an adjacent locality pay area, an adjacent county that is currently in the RUS locality pay area must have at least 400 GS employees and an employment interchange measure of at least 7.5 percent.

3. *For Federal facilities that cross locality pay area boundaries:* To be included in an adjacent locality pay area, that portion of a Federal facility outside of a higher-paying locality pay area must have at least 750 GS employees, the duty stations of the majority of those employees must be within 10 miles of the separate locality pay area, and a significant number of those employees must commute to work from the higher-paying locality pay area.

For the purpose of evaluating areas under the Council's new criteria, OPM used a 4-quarter average of GS employment from its Central Personnel Data File. Commuting rates were calculated from data obtained from the Bureau of the Census. OPM used full MSAs and CSAs for calculating commuting rates, not central counties only. For calculating commuting rates, OPM used the Employment Interchange Measure defined by the Bureau of the Census as "the sum of the percentage of employed residents of the smaller entity who work in the larger entity and the percentage of the employment in the smaller entity that is accounted for by workers who reside in the larger entity."

Proposed New MSA-Based Areas of Application

Application of the Council's first set of criteria to adjacent MSAs and CSAs would result in the following MSAs being included in a separate metropolitan locality pay area:

Boston-Worcester-Manchester, MA-NH Combined Statistical Area

The Providence-New Bedford-Fall River, RI–MA MSA, composed of Bristol County, MA and all five counties in Rhode Island.

Denver-Aurora-Boulder, CO Combined Statistical Area

The Fort Collins-Loveland, CO MSA, composed of Larimer County, CO.

Hartford-West Hartford-Willimantic, CT Combined Statistical Area

The Springfield, MA MSA, composed of Franklin, Hampden, and Hampshire Counties, MA.

Los Angeles-Long Beach-Riverside, CA Combined Statistical Area

The Santa Barbara-Santa Maria-Goleta, CA MSA, composed of Santa Barbara County, CA.

San Jose-San Francisco-Oakland, CA Combined Statistical Area

The Salinas, CA MSA, composed of Monterey County, CA.

Washington-Baltimore-Northern Virginia, DC–MD–VA–WV Combined Statistical Area

The Hagerstown-Martinsburg, MD–WV MSA, composed of Washington County, MD, and Berkeley and Morgan Counties, WV.

New Single County Areas of Application

Application of the Council's second set of criteria to single counties that are not part of a multi-county MSA or CSA would result in the following counties being included in a separate metropolitan locality pay area:

Boston-Worcester-Manchester, MA–NH Combined Statistical Area

Barnstable County, MA.

Hartford-West Hartford-Willimantic, CT Combined Statistical Area

New London County, CT.

Indianapolis-Anderson-Columbus, IN Combined Statistical Area

Grant County, IN.

Miami-Fort Lauderdale-Miami Beach, FL Metropolitan Statistical Area

Monroe County, FL.

New York-Newark-Bridgeport, NY–NJ–CT–PA Combined Statistical Area

Monroe County, PA.

Philadelphia-Camden-Vineland, PA–NJ–DE–MD Combined Statistical Area

Kent County, DE.

Sacramento—Arden-Arcade—Truckee, CA–NV Combined Statistical Area

Carson City, NV.

San Jose-San Francisco-Oakland, CA Combined Statistical Area

San Joaquin County, CA.

Washington-Baltimore-Northern Virginia, DC–MD–VA–WV Combined Statistical Area

King George County, VA.

Effect on Federal Facilities That Cross County Lines

Application of the Council's third set of criteria would result in the continued inclusion of all of Edwards Air Force Base, CA, in the Los Angeles locality pay area.

Retained Areas

The Council also recommended that any county (or partial county in the case of portions of York County, ME) currently included in a metropolitan locality pay area be retained in the locality pay area if the county or partial county has an Employment Interchange Measure of 15 percent or more with the area covered by the new MSA or CSA definition. Application of this rule would result in the following areas being retained in separate metropolitan locality pay areas:

Boston-Worcester-Manchester, MA-NH Combined Statistical Area

Berwick town, Eliot town, Kittery town, South Berwick town, and York town in York County, ME.

Denver-Aurora-Boulder, CO Combined Statistical Area

Weld County, CO.

Detroit-Warren-Flint, MI Combined Statistical Area

Lenawee County, MI.

New York-Newark-Bridgeport, NY–NJ–CT–PA Combined Statistical Area

Warren County, NJ.

Philadelphia-Camden-Vineland, PA–NJ–DE–MD Combined Statistical Area

Atlantic County, NJ, and Cape May County, NJ.

Portland-Vancouver-Beaverton, OR-WA Metropolitan Statistical Area

Marion County, OR, and Polk County, OR.

Washington-Baltimore-Northern Virginia, DC–MD–VA–WV Combined Statistical Area

Culpeper County, VA.

Locality Pay Areas the Council Recommended Be Discontinued

Noting the disparity between Federal and non-Federal pay levels in the Kansas City, Orlando, and St. Louis locality pay areas as compared to the disparity in the RUS locality pay area, the Council recommended that the Pay Agent discontinue these three locality pay areas. The Pay Agent tentatively agreed to this change in its 2003 report to the President. Upon further review, however, the Pay Agent has determined that it would be advisable to continue to monitor the disparity between Federal and non-Federal pay levels in the Kansas City, Orlando, and St. Louis areas before determining whether those areas should be discontinued. The Pay Agent will seek the views of the Federal Salary Council on this matter and include its findings in its annual report to the President on the GS locality pay program later this year.

Impact and Implementation

The Pay Agent plans to implement the Council's recommendations on locality pay area boundaries, as described above, in January 2005. Overall, the proposed changes in locality pay area boundaries would move about 15,000 GS employees to metropolitan locality pay areas from the RUS locality pay area, and retain about 16,000 GS employees in metropolitan locality pay areas that would have been excluded if only the new MSA definitions were used.

In the event of a change in the geographic coverage of a locality pay area as a result of the addition by OMB of a new area(s) to the definition of an MSA or CSA or as the result of any change made by the President's Pay Agent in the definition of a locality pay area, the proposed regulations provide that any change in an employee's entitlement to a locality rate of pay will be made effective as of the first pay period that begins on or after January 1 of the next calendar year. In addition, the proposed regulations provide that any area removed by OMB from coverage within an MSA or CSA that serves as the basis for defining a locality pay area must be reviewed by the Federal Salary Council and the President's Pay Agent before a decision is made regarding the locality pay status of that area.

E.O. 12866, Regulatory Review

The Office of Management and Budget has reviewed this rule in accordance with E.O. 12866.

Regulatory Flexibility Act

I certify that these regulations would not have a significant economic impact on a substantial number of small entities because they would apply only to Federal agencies and employees.

List of Subjects in 5 CFR Part 531

Government employees, Law enforcement officers, Wages.

Office of Personnel Management.

Kay Coles James,

Director.

Accordingly, OPM is proposing to amend 5 CFR part 531 as follows:

PART 531—PAY UNDER THE GENERAL SCHEDULE

1. The authority citation for part 531 continues to read as follows:

Authority: 5 U.S.C. 5115, 5307, and 5338; sec. 4 of Pub. L. 103–89, 107 Stat. 981; and E.O. 12748, 56 FR 4521, 3 CFR, 1991 Comp., p. 316; Subpart B also issued under 5 U.S.C. 5303(g), 5333, 5334(a), and 7701(b)(2); Subpart C also issued under 5 U.S.C. 5304, 5305, and 5553; sections 302 and 404 of Federal Employees Pay Comparability Act of 1990 (FEPCA), Pub. L. 101–509, 104 Stat. 1462 and 1466; and section 3(7) of Pub. L. 102–378, 106 Stat. 1356; Subpart D also issued under 5 U.S.C. 5335(g) and 7701(b)(2); Subpart E also issued under 5 U.S.C. 5336; Subpart F also issued under 5 U.S.C. 5304, 5305(g)(1), and 5553; and E.O. 12883, 58 FR 63281, 3 CFR, 1993 Comp., p. 682 and E.O. 1306, 63 FR 68151, 3 CFR, 1998 Comp., p. 224; Subpart G also issued under 5 U.S.C. 5304, 5305, and 5553; section 302 of the FEPCA, Pub. L. 101–509, 104 Stat. 1462; and E.O. 12786, 56 FR 67453, 3 CFR, 1991 Comp., p. 376.

Subpart F—Locality-Based Comparability Payments

2. In § 531.602, the definition of *CMSA* is removed, a definition of *CSA* is added, and the definition of *MSA* is revised to read as follows:

§ 531.602 Definitions.

* * * * *

CSA means the geographic scope of a Combined Statistical Area, as defined by the Office of Management and Budget (OMB) in OMB Bulletin No. 04–03, plus any areas subsequently added to the CSA by OMB.

* * * * *

MSA means the geographic scope of a Metropolitan Statistical Area, as defined by the Office of Management and Budget (OMB) in OMB Bulletin No. 04–03, plus any areas subsequently added to the MSA by OMB.

* * * * *

3. In § 531.603, paragraph (b) is revised to read as follows:

§ 531.603 Locality pay areas.

* * * * *

(b) The following are locality pay areas for purposes of this subpart:

(1) Atlanta-Sandy Springs-Gainesville, GA–AL—consisting of the Atlanta-Sandy Springs-Gainesville, GA–AL CSA;

(2) Boston-Worcester-Manchester, MA–NH–ME–RI—consisting of the Boston-Worcester-Manchester, MA–NH CSA, plus the Providence-New Bedford-Fall River, RI–MA MSA, Barnstable County, MA, and Berwick, Eliot, Kittery, South Berwick, and York towns in York County, ME;

(3) Chicago-Naperville-Michigan City, IL–IN–WI—consisting of the Chicago-Naperville-Michigan City, IL–IN–WI CSA;

(4) Cincinnati-Middletown-Wilmington, OH–KY–IN—consisting of the Cincinnati-Middletown-Wilmington, OH–KY–IN CSA;

(5) Cleveland-Akron-Elyria, OH—consisting of the Cleveland-Akron-Elyria, OH CSA;

(6) Columbus-Marion-Chillicothe, OH—consisting of the Columbus-Marion-Chillicothe, OH CSA;

(7) Dallas-Fort Worth, TX—consisting of the Dallas-Fort Worth, TX CSA;

(8) Dayton-Springfield-Greenville, OH–sconsisting of the Dayton-Springfield-Greenville, OH CSA;

(9) Denver-Aurora-Boulder, CO—consisting of the Denver-Aurora-Boulder, CO CSA, plus the Ft. Collins-Loveland, CO MSA and Weld County, CO;

(10) Detroit-Warren-Flint, MI—consisting of the Detroit-Warren-Flint, MI CSA, plus Lenawee County, MI;

(11) Hartford-West Hartford-Willimantic, CT–MA—consisting of the Hartford-West Hartford-Willimantic, CT CSA, plus the Springfield, MA MSA and New London County, CT;

(12) Houston-Baytown-Huntsville, TX—consisting of the Houston-Baytown-Huntsville, TX CSA;

(13) Huntsville-Decatur, AL—consisting of the Huntsville-Decatur, AL CSA;

(14) Indianapolis-Anderson-Columbus, IN—consisting of the Indianapolis-Anderson-Columbus, IN CSA, plus Grant County, IN;

(15) Kansas City-Overland Park-Kansas City, MO–KS—consisting of the Kansas City-Overland Park-Kansas City, MO–KS CSA;

(16) Los Angeles-Long Beach-Riverside, CA—consisting of the Los Angeles-Long Beach-Riverside, CA CSA, plus the Santa Barbara-Santa Maria-Goleta, CA MSA and all of Edwards Air Force Base, CA;

(17) Miami-Fort Lauderdale-Miami Beach, FL—consisting of the Miami-Fort Lauderdale-Miami Beach, FL MSA, plus Monroe County, FL;

(18) Milwaukee-Racine-Waukesha, WI—consisting of the Milwaukee-Racine-Waukesha, WI CSA;

(19) Minneapolis-St. Paul-St. Cloud, MN–WI—consisting of the Minneapolis-St. Paul-St. Cloud, MN–WI CSA;

(20) New York-Newark-Bridgeport, NY–NJ–CT–PA—consisting of the New York-Newark-Bridgeport, NY–NJ–CT–PA CSA, plus Monroe County, PA, and Warren County, NJ;

(21) Orlando-The Villages, FL—consisting of the Orlando-The Villages, FL CSA;

(22) Philadelphia-Camden-Vineland, PA–NJ–DE–MD—consisting of the Philadelphia-Camden-Vineland, PA–NJ–DE–MD CSA, plus Kent County, DE, Atlantic County, NJ, and Cape May County, NJ;

(23) Pittsburgh-New Castle, PA—consisting of the Pittsburgh-New Castle, PA CSA;

(24) Portland-Vancouver-Beaverton, OR–WA—consisting of the Portland-Vancouver-Beaverton, OR–WA MSA, plus Marion County, OR, and Polk County, OR;

(25) Richmond, VA—consisting of the Richmond, VA MSA;

(26) Sacramento—Arden-Arcade—Truckee, CA–NV—consisting of the Sacramento—Arden-Arcade—Truckee, CA–NV CSA, plus Carson City, NV;

(27) St. Louis-St. Charles-Farmington, MO–IL—consisting of the St. Louis-St. Charles-Farmington, MO–IL CSA;

(28) San Diego-Carlsbad-San Marcos, CA—consisting of the San Diego-Carlsbad-San Marcos, CA MSA;

(29) San Jose-San Francisco-Oakland, CA—consisting of the San Jose-San Francisco-Oakland, CA CSA, plus the Salinas, CA MSA and San Joaquin County, CA;

(30) Seattle-Tacoma-Olympia, WA—consisting of the Seattle-Tacoma-Olympia, WA CSA;

(31) Washington-Baltimore-Northern Virginia, DC–MD–VA–WV—consisting of the Washington-Baltimore-Northern Virginia, DC–MD–VA–WV CSA, plus the Hagerstown-Martinsburg, MD–WV MSA, Culpeper County, VA, and King George County, VA; and

(32) Rest of U.S.—consisting of those portions of the continental United States not located within another locality pay area.

4. In § 531.606, paragraph (g) is revised to read as follows:

§ 531.606 Administration of locality rates of pay.

* * * * *

(g) In the event of a change in the geographic coverage of a locality pay area as a result of the addition by OMB of a new area(s) to the definition of an MSA or CSA or as the result of any change made by the President's Pay Agent in the definition of a locality pay area, the effective date of any change in an employee's entitlement to a locality rate of pay under this subpart is the first day of the first pay period beginning on or after January 1 of the next calendar year. Any area removed by OMB from coverage within an MSA or CSA that serves as the basis for defining a locality pay area must be reviewed by the Federal Salary Council and the President's Pay Agent before a decision is made regarding the locality pay status of that area.

* * * * *

[FR Doc. 04–21302 Filed 9–17–04; 2:47 pm]

BILLING CODE 6325–39–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 1032

[Docket No. AO–313–A48; DA–04–06]

Milk in the Central Marketing Area; Notice of Hearing on Proposed Amendments To Tentative Marketing Agreement and Order

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule; Notice of public hearing on proposed rulemaking.

SUMMARY: A public hearing is being held to consider proposals that would amend certain pooling and related provisions of the Central Federal milk marketing order (Order 32). Proposals under consideration would: modify performance standards for supply plants, adjust diversion limits, modify the "touch base" provision, limit the pooling of milk that was not pooled in prior months and establish transportation and assembly credits for the order. Additional proposals under consideration would: Eliminate all supply plant provisions, establish a "dairy farmer for other markets" provision, eliminate or modify "split plant" provisions, eliminate or modify system pooling for supply plants and modify the payment date from the producer settlement fund to handlers.

DATES: The hearing will convene at 1 p.m. on Monday, October 18, 2004.

ADDRESSES: The hearing will be held at the Hilton Kansas City Airport, 8801 NW. 112th Street, Kansas City, Missouri 64153; (816) 891–8900.

FOR FURTHER INFORMATION CONTACT: Jack Rower, Marketing Specialist, Order Formulation and Enforcement Branch, USDA/AMS/Dairy Programs, Stop 0231—Room 2971, 1400 Independence Avenue, SW., Washington, DC 20250–0231, (202) 720–2357, e-mail address: *Jack.Rower@usda.gov.*

Persons requiring a sign language interpreter or other special accommodations should contact Bob Vanderlinden at (913) 495–9313 or Dave Stukenberg at (913) 495–9326; e-mail *market.administrator@fmmacentral.com* before the hearing begins.

SUPPLEMENTARY INFORMATION: This administrative action is governed by the provisions of sections 556 and 557 of Title 5 of the United States Code and, therefore, is excluded from the requirements of Executive Order 12866.

Notice is hereby given of a public hearing to be held at the Hilton Kansas City Airport, 8801 NW. 112th Street, Kansas City, Missouri 64153; (816) 891–8900, beginning at 1 p.m., on Monday, October 18, 2004, with respect to proposed amendments to the tentative marketing agreement and to the order regulating the handling of milk in the Central milk marketing area.

The hearing is called pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), and the applicable rules of practice and procedure governing the formulation of marketing agreements and marketing orders (7 CFR Part 900).

The purpose of the hearing is to receive evidence with respect to the economic and marketing conditions that relate to the proposed amendments, hereinafter set forth, and any appropriate modifications thereof, to the tentative marketing agreement and to the order.

Evidence also will be taken at the hearing to determine whether emergency marketing conditions exist that would warrant omission of a recommended decision under the rules of practice and procedure (7 CFR 900.12(d)) with respect to any proposed amendments.

Actions under the Federal milk order program are subject to the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). This Act seeks to ensure that, within the statutory authority of a program, the regulatory and informational requirements are tailored to the size and nature of small businesses. For the purpose of the Act, a dairy farm is a "small business" if it has an annual gross revenue of less than $750,000, and a dairy products manufacturer is a "small business" if it has fewer than 500 employees. Most parties subject to a milk order are considered as a small business. Accordingly, interested parties are invited to present evidence on the probable regulatory and informational impact of the hearing proposals on small businesses. Also, parties may suggest modifications of these proposals for the purpose of tailoring their applicability to small businesses.

The amendments to the rules proposed herein have been reviewed under Executive Order 12988, Civil Justice Reform. They are not intended to have a retroactive effect. If adopted, the proposed amendments would not preempt any state or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule.

The Agricultural Marketing Agreement Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 8c(15)(A) of the Act, any handler subject to an order may request modification or exemption from such order by filing with the Department of Agriculture (Department) a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with the law. A handler is afforded the opportunity for a hearing on the petition. After a hearing, the Department would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has its principal place of business, has jurisdiction in equity to review the Department's ruling on the petition, provided a bill in equity is filed not later than 20 days after the date of the entry of the ruling.

This public hearing is being conducted to collect evidence for the record concerning inequities among producers caused by provisions that allow reserve milk, which is used in cheese, butter, or nonfat dry milk production, to share in the benefits of pooling, but do not require such milk to pool when there is a cost (when the Class III price or Class IV price is above the blend price). At the hearing, evidence will also be collected to consider changes in pooling standards and other related provisions including shipping standards, diversion limits, "touch base" requirements, establishment of transportation and assembly credits, and modification of the payment date from the producer settlement fund to handlers.

Interested parties who wish to introduce exhibits should provide the Presiding Officer at the hearing with (4) copies of such exhibits for the Official Record. Also, it would be helpful if additional copies are available for the use of other participants at the hearing.

List of Subjects in 7 CFR Part 1032

Milk marketing orders.

The authority citation for 7 CFR Part 1032 continues to read as follows:

Authority: 7 U.S.C. 601–674.

The proposed amendments, as set forth below, have not received the approval of the Department.

Proposal No. 1

Proposed by Dairy Farmers of America, Inc., and Prairie Farms Cooperative

This proposal would increase for all months the amount of milk a supply plant would need to ship to a pool distributing plant in order to be pooled. In addition, this proposal would limit the states from which milk could be diverted in order to maintain pool status, establish a minimum "touch base" requirement of at least one day a month during August through November and January through February in order to maintain association with the pool, and reduce for all months the diversion limits.

1. Amend § 1032.7 by revising paragraph (c) introductory text to read as follows:

§ 1032.7 Pool plant.

* * * * *

(c) A supply plant from which the quantity of bulk fluid milk products shipped to (and physically unloaded into) plants described in paragraph (c)(1) of this section is not less than 25 percent during the months of August through February and 20 percent in all other months of the Grade A milk received from dairy farmers (except dairy farmers described in § 1032.12(b)) and from handlers described in § 1000.9(c), including milk diverted pursuant to § 1032.13, subject to the following conditions:

* * * * *

2. Amend § 1032.13 by revising paragraphs (d) introductory text and (d)(1), redesignating paragraphs (d)(2) through (6) as paragraphs (d)(4) through (8), adding new paragraphs (d)(2) and (d)(3), and revising redesignated paragraph (d)(4) to read as follows:

§ 1032.13 Producer milk.

* * * * *

(d) Diverted by the operator of a pool plant or a cooperative association described in § 1000.9(c) located in the States of Colorado, Illinois, Iowa, Kansas, Minnesota, Missouri, Nebraska, New Mexico, Oklahoma, South Dakota and Wisconsin to a nonpool plant subject to the following conditions:

(1) Milk of a dairy farmer shall not be eligible for diversion until milk of such dairy farmer has been physically received as producer milk at a pool plant and the dairy farmer has continuously retained producer status since that time. If a dairy farmer loses producer status under the order in this part (except as a result of a temporary loss of Grade A approval), the dairy farmer's milk shall not be eligible for diversion until milk of the dairy farmer has been physically received as producer milk at a pool plant;

(2) The equivalent of at least one day's milk production is caused by the handler to be physically received at a pool plant in each of the months of August through November and January through February;

(3) The equivalent of at least one days' milk production is caused by the handler to be physically received at a pool plant in each of the months of March through July and December if the requirement of paragraph (d)(2) of this section (§ 1032.13) in each of the prior months of August through November and January through February are not met, except in the case of a dairy farmer who marketed no Grade A milk during each of the prior months of August through November or January through February.

(4) Of the quantity of producer milk received during the month (including diversions, but excluding the quantity of producer milk received from a handler described in § 1000.9(c)) the handler diverts to nonpool plants not more than 75 percent during the months of August through February, and not more than 80 percent during the months of March through July, provided that not less than 25 percent of such receipts in the months of August through February and 20 percent of the remaining months'

receipts are delivered to plants described in § 1032.7(a) and (b);
* * * * *

Proposal No. 2

Proposed by Dairy Farmers of America, Inc., and Prairie Farms Cooperative

This proposal would limit the pooling of milk normally associated with the market that was not pooled in a prior month to 125 percent of the producer milk receipts pooled by a handler during the prior month.

Amend § 1032.13 by adding new paragraph (f) to read as follows:

§ 1032.13 Producer milk.
* * * * *

(f) The quantity of milk reported by a handler pursuant to § 1032.30(a)(1) and/or § 1032.30(c)(1) for the current month may not exceed 125 percent of the producer milk receipts pooled by the handler during the prior month. Milk diverted to nonpool plants reported in excess of this limit shall be removed from the pool. Milk received at pool plants in excess of the 125 percent limit, other than pool distributing plants, shall be classified pursuant to § 1000.44(a)(3)(v). The handler must designate, by producer pick-up, which milk is to be removed from the pool. If the handler fails to provide this information the provisions of § 1032.13(d)(5) shall apply. The following provisions apply:

(1) Milk shipped to and physically received at pool distributing plants shall not be subject to the 125 percent limitation;

(2) Producer milk qualified pursuant to § ____.13 of any other Federal order in the previous month shall not be included in the computation of the 125 percent limitation, provided that the producers comprising the milk supply have been continuously pooled on any Federal order for the entirety of the most recent three consecutive months.

(3) The market administrator may waive the 125 percent limitation:

(i) For a new handler on the order, subject to the provisions of § 1032.13(f)(3), or

(ii) For an existing handler with significantly changed milk supply conditions due to unusual circumstances;

(4) A bloc of milk may be considered ineligible for pooling if the market administrator determines that handlers altered the reporting of such milk for the purpose of evading the provisions of this paragraph.

Proposal No. 3

Proposed by Foremost Farms USA Cooperative, Associated Milk Producers Inc., First District Association, and Land O'Lakes, Inc. (Foremost, et al.)

This proposal would add a transportation credit to recover part of the shipping costs and an assembly credit for recovery of a portion of the overhead and procurement costs involved in service to the market. The proposal would establish a "milk reload station" provision to implement the credits.

1. Add § 1032.20 to read as follows:

§ 1032.20 Milk reload station.

Milk reload station means a location that is used as a reload point for transferring bulk milk directly from one tank truck to another.

2. Add § 1032.55 to read as follows:

§ 1032.55 Transportation credits and assembly credits.

(a) Each handler operating a pool supply plant described in § 1032.7(c) or (f) that transfers bulk milk, or a milk reload station described in § 1032.20 that delivers bulk milk to a pool distributing plant described in 1032.7(a), (b), or (e) shall receive a transportation credit for such milk computed as follows:

(1) Determine the hundredweight of milk eligible for the credit by completing the steps in paragraph (c) of this section;

(2) Multiply the hundredweight of milk eligible for the credit by 0.30 cents ($0.003) times the number of miles between the transferor plant and the transferee plant (not to exceed 500 miles);

(3) Subtract the effective Class I price at the transferor plant from the effective Class I price at the transferee plant;

(4) Multiply any positive amount resulting from the subtraction in paragraph (a)(3) of this section by the hundredweight of milk eligible for the credit; and

(5) Subtract the amount computed in (a)(4) of this section from the amount computed in paragraph (a)(2) of this section. If the amount computed in paragraph (a)(4) of this section exceeds the amount computed in paragraph (a)(2) of this section, the transportation credit shall be zero.

(b) Each handler operating a pool distributing plant described in § 1032.7(a), (b), or (e) that receives milk from dairy farmers, each handler that transfers or diverts bulk milk from a pool plant to a pool distributing plant, and each handler described in § 1000.9(c) that delivers milk to a pool distributing plant shall receive an assembly credit on the portion of such milk eligible for the credit pursuant to paragraph (c) of this section. The credit shall be computed by multiplying the hundredweight of milk eligible for the credit by 10 cents.

(c) The following procedure shall be used to determine the amount of milk eligible for transportation and assembly credits pursuant to paragraphs (a) and (b) of this section:

(1) At each pool distributing plant, determine the aggregate quantity of Class I milk, excluding beginning inventory of packaged fluid milk products;

(2) Subtract the quantity of packaged fluid milk products received at the pool distributing plant from other pool plants and from nonpool plants if such receipts are assigned to Class I;

(3) Subtract the quantity of bulk milk shipped from the pool distributing plant to other plants to the extent that such milk is classified as Class I milk;

(4) Subtract the quantity of bulk milk received at the pool distributing plant from other order plants and unregulated supply plants that is assigned to Class I pursuant to §§ 1000.43(d) and 1000.44; and

(5) Assign the remaining quantity pro rata to physical receipts during the month from:

(i) Producers;

(ii) Handlers described in § 1000.9(c); and

(iv) Other pool plants.

(d) For purposes of this section, the distances to be computed shall be determined by the market administrator using the shortest available state and/or Federal highway mileage. Mileage determinations are subject to redetermination at all times. In the event a handler requests a redetermination of the mileage pertaining to any plant, the market administrator shall notify the handler of such redetermination within 30 days after the receipt of such request. Any financial obligations resulting from a change in mileage shall not be retroactive for any periods prior to the redetermination by the market administrator.

3. Amend § 1032.60 by adding a new paragraph (k) to read as follows:

§ 1032.60 Handler's value of milk.
* * * * *

(k) Compute the amount of credits applicable pursuant to § 1032.55.

Proposal No. 4

Proposed by Dean Foods Company

This proposal would eliminate all supply plant provisions.

Amend § 1032.7 by removing paragraphs (c), (d), (f) and (g) and revise § 1032.9 to read as follows:

§ 1032.9 Handler.

Handler means:

(a) Any person who operates a pool plant or a nonpool plant.

(b) Any person who receives packaged fluid milk products from a plant for resale and distribution to retail or wholesale outlets, any person who as a broker negotiates a purchase or sale of fluid milk products or fluid cream products from or to any pool or nonpool plant, and any person who by purchase or direction causes milk of producers to be picked up at the farm and/or moved to a plant. Persons who qualify as handlers only under this paragraph under any Federal milk order are not subject to the payment provisions of §§ ___.70, ___.71, ___.72, ___.73, ___.76, and ___.85 of that order.

(c) Any organization with respect to milk that it receives for its account from the farm of a producer and delivers to pool plants or diverts to nonpool plants pursuant to § ___.13 of the order. The operator of a pool plant receiving milk from such organization may be the handler for such milk if both parties notify the market administrator of this agreement prior to the time that the milk is delivered to the pool plant and the plant operator purchases the milk on the basis of farm bulk tank weights and samples.

Proposal No. 5

Proposed by Dean Foods Company

This proposal would increase supply plant shipping standards by 20 percentage points, from 15 percent to 35 percent, for the month of July; 15 percentage points, from 20 percent to 35 percent, for the months of August through January; 5 percentage points, from 20 percent to 25 percent, for the month of February; and 10 percentage points, from 15 percent to 25 percent, for the months of March through June. This proposal would also require the milk of a dairy farmer to "touch base" for four days during the months of July through November in order for the milk to be diverted and would establish diversion limits of 65 percent for the months of July through January and 75 percent for the months of February through June.

1. Amend § 1032.7 by revising paragraph (c) introductory text to read as follows:

§ 1032.7 Pool plant.

* * * * *

(c) A supply plant from which the quantity of bulk fluid milk products shipped to (and physically unloaded into) plants described in paragraph (c)(1) of this section is not less than 35 percent during the months of July through January and 25 percent in all other months of the Grade A milk received from dairy farmers (except dairy farmers described in § 1032.12(b)) and from handlers described in § 1000.9(c), including milk diverted pursuant to § 1032.13, subject to the following conditions:

* * * * *

2. Amend § 1032.13 by redesignating paragraphs (d)(3) through (6) as paragraphs (d)(5) through (8), revising paragraphs (d)(1) and (2), and adding paragraphs (d)(3) and (4) to read as follows:

§ 1032.13 Producer milk.

* * * * *

(d) * * *

(1) Milk of a dairy farmer shall not be eligible for diversion until milk of such dairy farmer has been physically received as producer milk at a pool plant and the dairy farmer has continuously retained producer status since that time. If a dairy farmer loses producer status under the order in this part (except as a result of loss of Grade A approval not to exceed 10 days), the dairy farmer's milk shall not be eligible for diversion until milk of the dairy farmer has been physically received as producer milk at a pool plant;

(2) The equivalent of at least four days' milk production is caused by the handler to be physically received at a pool plant in each of the months of July through November;

(3) The equivalent of at least four days' milk production is caused by the handler to be physically received at a pool plant in each of the months of December through June if the requirement of paragraph (d)(2) of this section (§ 1032.13) in each of the prior months of July through January are not met, except in the case of a dairy farmer who did not market any Grade A milk during each of the prior months of July through January.

(4) Of the quantity of producer milk received during the month (including diversions, but excluding the quantity of producer milk received from a handler described in § 1000.9(c)) the handler diverts to nonpool plants not more than 65 percent during the months of July through January, and not more than 75 percent during the months of February through June, provided that not less than 35 percent of such receipts in the months of July through January and 25 percent of the remaining months' receipts are delivered to plants described in § 1032.7(a) and (b);

* * * * *

Proposal No. 6

Proposed by Dean Foods Company

This proposal would establish a *dairy farmer for other markets* provision that would require a year round commitment in order for milk to be pooled.

Amend § 1032.12 by adding a new paragraph (b)(5) to read as follows:

§ 1032.12 Producer.

* * * * *

(b) * * *

(5) For any month, any dairy farmer whose milk is received at a pool plant or by a cooperative association handler described in § 1000.9(c), if the pool plant operator or the cooperative association caused milk from the same farm to be delivered to any plant as other than producer milk, as defined under the order in this part or any other Federal milk order, during the month or any of the preceding 11 months, unless the equivalent of at least ten days' milk production has been physically received otherwise as producer milk at a pool distributing plant during the month.

Proposal No. 7

Proposed by Dean Foods Company

This proposal would establish a *dairy farmer for other markets* provision that would require a 2 to 4 month commitment in order for milk to be pooled.

Amend § 1032.12 by adding new paragraphs (b)(5) and (b)(6) to read as follows:

§ 1032.12 Producer.

* * * * *

(b) * * *

(5) For any month of February through June, any dairy farmer whose milk is received at a pool plant or by a cooperative association handler described in § 1000.9(c) if the pool plant operator or the cooperative association caused milk from the same farm to be delivered to any plant as other than producer milk, as defined under the order in this part or any other Federal milk order, during the month, any of the 3 preceding months, or during any of the preceding months of July through January, unless the equivalent of at least ten days' milk production has been physically received otherwise as producer milk at a pool distributing plant during the month; and

(6) For any month of July through January, any dairy farmer whose milk is received at a pool plant or by a cooperative association handler

described in § 1000.9(c) if the pool plant operator or the cooperative association caused milk from the same farm to be delivered to any plant as other than producer milk, as defined under the order in this part or any other Federal milk order, during the month or the preceding month, unless the equivalent of at least ten days' milk production has been physically received otherwise as producer milk at a pool distributing plant during the month.

Proposal No. 8

Proposed by Dean Foods Company

This proposal would limit the pooling of milk normally associated with the market that was not pooled in a prior month to 115 percent of the producer milk receipts pooled by a handler during the prior month.

Amend § 1032.13 by adding a new paragraph (f) to read as follows:

§ 1032.13 Producer milk.

* * * * *

(f) The quantity of milk reported by a handler pursuant to § 1032.32(a)(1) and/or § 1032.30(c)(1) may not exceed 115 percent of the producer milk receipts pooled by the handler during the prior month. Milk diverted to nonpool plants reported in excess of this limit shall be removed from the pool by the market administrator. Milk received at pool plants, other than pool distributing plants, shall be classified pursuant to § 1000.44(a)(3)(v) and § 1000.44(b). The handler must designate, by producer pick-up, which milk is to be removed from the pool. If the handler fails to provide this information, the market administrator will make the determination. The following provisions apply:

(1) Milk shipped to and physically received at pool distributing plants shall not be subject to the 115 percent limitation;

(2) Producer milk qualified pursuant to § __ .13 of any other Federal order and continuously pooled in any Federal order for the previous six months shall not be included in the computation of the 115 percent limitation;

(3) The market administrator may waive the 115 percent limitation utilizing:

(i) For a new handler on the order, subject to the provisions of § 1032.13(f)(3), or

(ii) For an existing handler with significantly changed milk supply conditions due to unusual circumstances;

(4) The market administrator may increase or decrease the applicable limitation for a month consistent with the procedures in § 1032.7(g); and

(5) A bloc of milk may be considered ineligible for pooling if the market administrator determines that handlers altered the reporting of such milk for the purpose of evading the provisions of this paragraph.

Proposal No. 9

Proposed by Dean Foods Company

This proposal would eliminate the split plant provision. Amend § 1032.7 by removing paragraph (h)(7).

Proposal No. 10

Proposed by Dean Foods Company

This proposal would require the nonpool side of a split plant to maintain nonpool status for at least 12 months as opposed to the current ability to return whenever desired.

Amend § 1032.7 by revising paragraph (h)(7) to read as follows:

§ 1032.7 Pool plant.

* * * * *

(h) * * *

(7) That portion of a regulated plant designated as a nonpool plant that is physically separate and operated separately from the pool portion of such plant. The designation of a portion of a plant must be requested in advance and in writing by the handler and must be received by the market administrator. Such nonpool status shall be effective on the first day of the month following receipt of the request by the market administrator and thereafter for the longer of twelve (12) consecutive months or until notification of the desire to requalify as a pool plant, in writing, is received by the market administrator. Requalification will require deliveries to a pool distributing plant(s) as provided for in § 1032.7(c). For requalification, handlers may not use milk delivered directly from producer's farms pursuant to § 1000.9(c) or § 1032.13(c) for the first month.

Proposal No. 11

Proposed by Dean Foods Company

This proposal would eliminate system pooling for supply plants and the ability for supply plants to qualify for pooling by shipping milk directly from producer farms or by diversion.

Amend § 1032.7 by removing paragraph (f), redesignating paragraphs (g) and (h) as paragraphs (f) and (g), and revising paragraph (c)(2) to read as follows:

§ 1032.7 Pool plant.

* * * * *

(c) * * *

(2) The operator of a pool plant under paragraph (c) located in the marketing area may not include as qualifying shipments milk delivered directly from producer's farms pursuant to § 1000.9(c) or § 1032.13(c). Handlers may not use shipments pursuant to § 1000.9(c) or § 1032.13(c) to qualify plants located outside the marketing area;

* * * * *

Proposal No. 12

Proposed by Dean Foods Company

This proposal would still allow supply plant systems, but would only allow a single handler as opposed to the current provision allowing multiple handlers to form a system.

Amend § 1032.7 by revising the introductory text of paragraph (f) to read as follows:

§ 1032.7 Producer milk.

* * * * *

(f) A system of supply plants may qualify for pooling if 2 or more plants operated by one handler meet the applicable percentage requirements of paragraph (c) of this section in the same manner as a single plant, subject to the following additional requirements:

* * * * *

Proposal No. 13

This proposal would require each supply plant pooled within a system to ship at least 40 percent of the total milk needed for pooling.

Amend § 1032.7 by revising paragraph (c)(2) and adding a new paragraph (f)(5) and to read as follows:

§ 1032.7 Pool plant.

* * * * *

(c) * * *

(2) The operator of a pool plant located in the marketing area may not include as qualifying shipments milk delivered directly from producer's farms pursuant to § 1000.9(c) or § 1032.13(c). Handlers may not use shipments pursuant to § 1000.9(c) or § 1032.13(c) to qualify plants located outside the marketing area;

* * * * *

(f) * * *

(5) Provided no single plant ships less than 40 percent of the applicable percentage requirement of paragraph (c) of this section.

* * * * *

Proposal No. 14

Proposed by the Central Order Market Administrator

This proposal would require payments from the producer settlement fund to be made no later than the next business day after the due date for

payments into the producer settlement fund.

Revise § 1032.72 to read as follows:

§ 1032.72 Payments from the producer-settlement fund.

No later than the next business day following the due date for payments to the producer-settlement fund (§ 1032.71), the market administrator shall pay to each handler the amount, if any, by which the amount computed pursuant to § 1032.71(b) exceeds the amount computed pursuant to § 1032.71(a). If, at such time, the balance in the producer-settlement fund is insufficient to make all payments pursuant to this section, the market administrator shall reduce uniformly such payments and shall complete the payments as soon as the funds are available.

Proposal No. 15

Proposed by Dairy Programs, Agricultural Marketing Service

Make such changes as may be necessary to make the entire marketing agreement and the order conform with any amendments thereto that may result from this hearing.

Copies of this notice of hearing and the orders may be procured from the Market Administrator of the aforesaid marketing area, or from the Hearing Clerk, United States Department of Agriculture, Room 1083–STOP 9200, 1400 Independence Avenue, SW., Washington, DC 20250–9200, or may be inspected there.

Copies of the transcript of testimony taken at the hearing will not be available for distribution through the Hearing Clerk's Office. If you wish to purchase a copy, arrangements may be made with the reporter at the hearing.

From the time that a hearing notice is issued and until the issuance of a final decision in a proceeding, Department employees involved in the decision-making process are prohibited from discussing the merits of the hearing issues on an *ex parte* basis with any person having an interest in the proceeding. For this particular proceeding, the prohibition applies to employees in the following organizational units: Office of the Secretary of Agriculture; Office of the Administrator, Agricultural Marketing Service; Office of the General Counsel; Dairy Programs, Agricultural Marketing Service (Washington Office) and the Office of the Market Administrator of the Central Milk Marketing Area.

Procedural matters are not subject to the above prohibition and may be discussed at any time.

Dated: September 17, 2004.

A.J. Yates,

Administrator, Agricultural Marketing Service.

[FR Doc. 04–21281 Filed 9–17–04; 3:29 pm]

BILLING CODE 3410–02–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2004–19144; Directorate Identifier 2003–NE–18–AD]

RIN 2120–AA64

Airworthiness Directives; General Electric Company (GE) CF6–80C2 and CF6–80E1 Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain GE CF6–80C2 and CF6–80E1 turbofan engines. This proposed AD would require you to:

- Inspect the high pressure compressor rotor (HPCR) stage 11–14 spool shaft for circumferential repair cuts, and
- Repair or replace the spool shaft if you find certain circumferential cuts.

This proposed AD results from an updated stress analysis. We are proposing this AD to prevent failure of the HPCR stage 11–14 spool shaft due to low-cycle fatigue that could result in an uncontained engine failure.

DATES: We must receive any comments on this proposed AD by November 22, 2004.

ADDRESSES: Use one of the following addresses to send comments 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 20590–001.
- Fax: (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.

You can get the service information identified in this proposed AD from General Electric Company via Lockheed Martin Technology Services, 10525 Chester Road, Suite C, Cincinnati, Ohio 45215, telephone (513) 672–8400, fax (513) 672–8422.

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: Karen Curtis, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; telephone (781) 238–7192; fax (781) 238–7199.

SUPPLEMENTARY INFORMATION: We invite you to submit any written relevant data, views, or arguments regarding this proposal. Send your comments to an address listed under **ADDRESSES.** Include "Docket No. FAA–2004–19144; Directorate Identifier 2003–NE–18–AD" in the subject line 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 AD. Using the search function of the DMS Web site, anyone can find and read the comments in 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*.

We are reviewing the writing style we currently use in regulatory documents. We are interested in your comments on whether the style of this document is clear, and your suggestions to improve the clarity of our communications that affect you. You can get more information about plain language at *http://www.faa.gov/language* and *http://www.plainlanguage.gov*.

Examining the AD Docket

You may examine the docket that contains the proposal, any comments received and, any final disposition in person at the DMS Docket Offices between 9 a.m. and 5 p.m., Monday

through Friday, except Federal holidays. The Docket Office (telephone (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 DMS receives them.

Discussion

In 1996, GE developed a circumferential cut repair to remove damaged material from seal wire grooves in the outer rim of HPCR stage 11–14 spool shafts installed in certain CF6–80C2 and CF6–80E1 turbofan engines. The damage was due to wear of the seal wire from engine operation. At that time, analysis showed that there was no impact on spool shaft life from the repair geometry. GE performed updated stress analyses in 1999 and 2003. Those stress analyses showed that the circumferential cut geometry resulted in a high-stress concentration. This high-stress concentration could result in a service life that is lower than the published service life of the spool shaft, depending on the spool shaft part number (P/N) and location of the repair. GE reports that as many as 135 CF6–80C2 and CF6–80E1 HPCR 11–14 spool shafts have had this repair. This condition, if not corrected, could result in failure of the HPCR stage 11–14 spool shaft due to low-cycle fatigue that could result in an uncontained engine failure.

Relevant Service Information

We have reviewed and approved the technical contents of GE Aircraft Engines (GEAE) Service Bulletins (SBs) CF6–80C2 S/B 72–1052, Revision 01, dated February 5, 2004; and CF6–80E1 S/B 72–0232, Revision 01, dated February 5, 2004, that describe procedures for inspection and repair of the circumferential cuts in the seal wire grooves of the HPCR stage 11–14 spool shaft.

Differences Between the Proposed AD and the Manufacturer's Service Information

This proposed AD does not require the operator to take further action when a circumferential cut repair is on the forward seal wire groove of the stage 14 disk of a CF6–80E1 or CF6–80C2 Group 2 spool shaft. GEAE, however, recommends repairing these disks at the next exposure, regardless of the number of cycles-since-repair.

FAA's Determination and Requirements of the Proposed AD

We have evaluated all pertinent information and identified an unsafe condition that is likely to exist or develop on other products of this same type design. We are proposing this AD, which would require:

- Inspection of the spool shaft for circumferential repair cuts at the next piece-part level exposure, but not to exceed a specific service cap specified in this proposed AD, and
- Repair or replacement of certain spool shafts.

You must use the service information described previously to perform these proposed actions.

Costs of Compliance

There are approximately 135 GE CF6–80C2 and CF6–80E1 turbofan engines of the affected design in the worldwide fleet. We estimate that 27 engines installed on airplanes of U.S. registry would be affected by this proposed AD. We also estimate that it would take about 1 work hour per engine to inspect for the location of previous circumferential cut repairs and 5 work hours per engine to repair the spool shaft. We estimate that 24 engines would be repaired and that three spool shafts would be replaced. The average labor rate is $65 per work hour. Each replacement spool shaft would cost approximately $447,400. Based on these figures, we estimate the total cost of the proposed AD to U.S. operators to be $1,351,755.

Regulatory Findings

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. Would 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 summary of the costs to comply with this proposal and placed it in the AD Docket. You may get a copy of this summary by sending a request to us at the address listed under **ADDRESSES.** Include "AD Docket No. 2003–NE–18–AD" in your request.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

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 adding the following new airworthiness directive:

General Electric Company: Docket No. FAA–2004–19144; Directorate Identifier 2003–NE–18–AD.

Comments Due Date

(a) The Federal Aviation Administration (FAA) must receive comments on this airworthiness directive (AD) action by November 22, 2004.

Affected ADs

(b) None.

Applicability

(c) This AD applies to certain GE CF6–80C2 and CF6–80E1 turbofan engines that have a high pressure compressor rotor (HPCR) stage 11–14 spool shaft with a part number (P/N) listed in Table 1 of this AD and that had a seal wire groove repaired using a circumferential cut at a location specified in Table 2 of this AD. These engines are installed on, but not limited to, Airbus Industrie A300, A310, and A330 series airplanes and Boeing 747, 767, and MD–11 series airplanes.

TABLE 1.—STAGE 11–14 SPOOL SHAFT P/NS BY ENGINE MODEL AND FORGING GROUP DESIGNATIONS

Engine model	Stage 11–14 spool shaft P/Ns	Forging group designations
CF6–80C2	9380M30G07, 9380M30G08, 9380M30G09, 9380M30G10, 9380M30G12, 1509M71G02, 1509M71G03, 1509M71G04, and 1509M71G05.	Group 1.

TABLE 1.—STAGE 11–14 SPOOL SHAFT P/NS BY ENGINE MODEL AND FORGING GROUP DESIGNATIONS—Continued

Engine model	Stage 11–14 spool shaft P/Ns	Forging group designations
CF6–80C2	1531M21G01, 1531M21G02, 1531M21G04, 1509M71G06, 1509M71G07, 1509M71G08, 1509M71G11, 1509M71G12, 1703M74G01, and 1703M74G03.	Group 2.
CF6–80E1	1509M71G11, 1509M71G12, 1509M71G13, 1644M99G03, 1703M74G01, and 1703M74G03	Not Applicable.

Unsafe Condition

(d) This AD results from an updated stress analysis. We are issuing this AD to prevent failure of the HPCR stage 11–14 spool shaft due to low-cycle fatigue that could result in an uncontained engine failure.

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.

CF6–80C2 Engines

(f) For CF6–80C2 series engines with HPCR stage 11–14 spool shaft serial numbers listed in 1.A.(2) of GE Aircraft Engines (GEAE) Service Bulletin (SB) No. CF6–80C2 S/B 72–1052, Revision 1, dated February 5, 2004, inspect the spool shaft for the location of the circumferential cut repair at the next piece-part exposure.

(1) If the stage and location of the repair is specified in the engine records, inspect prior to exceeding the cycles-since-repair (CSR) limit specified in the column titled, Replace By (CSR), in Table 2.

(2) If the stage or location of the repair is not known from the engine records, remove the spool shaft for inspection before exceeding 4,200 CSR for the Group 1 or before exceeding 10,000 CSR for Group 2. Use 3.A.(1) of the Accomplishment Instructions of GEAE SB No. CF6–80C2 S/B 72–1052, Revision 1, dated February 5, 2004, for the inspection. Table 2 follows:

TABLE 2.—REPAIR AND REPLACEMENT LIMITS FOR SPOOL SHAFTS BY FORGING GROUP AND LOCATION OF THE CIRCUMFERENTIAL CUT REPAIR

Engine model	Forging group (from table 1)	Stage	Location of circumferential cut repair	Repair by (CSR) limit	Replace by (CSR) limit
(1) CF6–80C2	Group 1	14	(i) Aft Seal Wire Groove—Not in Area X	3,600	4,200
			(ii) Aft Seal Wire Groove—In Area X	None—Replace spool.	4,200
			(iii) Forward Seal Wire Groove—Not in Area X.	7,100	7,100
			(iv) Forward Seal Wire Groove—In Area X	None—Replace spool.	7,100
(2) CF6–80C2	Group 1	13	(i) Aft Seal Wire Groove—Not in Area X	7,100	7,100
			(ii) Aft Seal Wire Groove—In Area X	2,740	7,100
			(iii) Forward Seal Wire Groove—Not in Area X.	7,100	7,100
			(iv) Forward Seal Wire Groove—In Area X	7,100	7,100
(3) CF6–80C2	Group 1	12	Aft Seal Wire Groove—In Area X	7,100	7,100
(4) CF6–80C2	Group 2	14	(i) Aft Seal Wire Groove—Not in Area X	13,700	13,700
			(ii) Aft Seal Wire Groove—In Area X	None—Replace spool.	13,700
			(iii) Forward Seal Wire Groove—In Area X	9,830	10,000
(5) CF6–80C2	Group 2	13	(i) Aft Seal Wire Groove—In Area X	9,830	10,000
			(ii) Forward Seal Wire Groove—In Area X	9,830	10,000
(6) CF6–80C2	Group 2	12	Aft Seal Wire Groove—In Area X	9,830	10,000
(7) CF6–80E1	Not Applicable	14	(i) Aft Seal Wire Groove—Not in Area X	11,600	11,600
			(ii) Aft Seal Wire Groove—In Area X	None—Replace spool.	11,600
			(iii) Forward Seal Wire Groove—In Area X	8,080	11,600
(8) CF6–80E1	Not Applicable	13	(i) Aft Seal Wire Groove—In Area X	8,080	11,600
			(ii) Forward Seal Wire Groove—In Area X	8,080	11,600
(9) CF6–80E1	Not Applicable	12	Aft Seal Wire Groove—In Area X	8,080	11,600

(g) If you have a Group 2 spool shaft, and the circumferential cut repair is in the Stage 14 forward location, and not in Area X, no further action is required by this AD. However, GEAE recommends that you repair these spools at the next exposure of the spool shaft.

Replacement of the Spool Shaft

(h) If the spool shaft exceeds the CSR limit in the column titled, Replace by (CSR), in Table 2 of this AD, replace the spool shaft within 420 cycles-in-service (CIS) after the effective date of this AD or within the published part life limit, whichever occurs first.

Repair of the Spool Shaft

(i) You may repair the spool if the CSR on the spool shaft are fewer than or equal to the limit in the column titled, Repair by (CSR), in Table 2 of this AD. Use 3.B. of the Accomplishment Instructions of GEAE SB CF6–80C2 S/B 72–1052, Revision 01, dated February 5, 2004, for the repair.

CF6–80E1 Engines

(j) For CF6–80E1 series engines with HPCR stage 11–14 spool shafts with SNs listed in 1.A.(2) of GEAE SB No. CF6–80E1 S/B 72–0232, Revision 01, dated February 5, 2004, do the following:

(1) Inspect the spool shaft for the location of the cut circumferential repair at the next piece-part exposure, but before exceeding 11,600 CSR. Use 3.A.(1) of the Accomplishment Instructions of GEAE SB No. CF6–80E1 S/B 72–0232, Revision 01, dated February 5, 2004 for the inspection.

(2) If the circumferential cut repair is in the Stage 14 forward location, and not in Area X, no further action is required by this AD. However, GEAE recommends that you repair these spools at the next exposure of the spool shaft.

Replacement of the Spool Shaft

(k) If the CSR are higher than 11,600 CSR, replace the spool shaft within 420 CIS after the effective date of this AD or within the published part life limit, whichever occurs first.

Repair of the Spool Shaft

(l) You may repair the spool if the CSR on the spool shaft are fewer than or equal to the limit in the column titled, Repair by (CSR), in Table 2 of this AD. Use 3.B. of the Accomplishment Instructions of GEAE SB CF6–80E1 S/B 72–0232, Revision 01, dated February 5, 2004, for the repair.

Alternative Methods of Compliance (AMOCs)

(m) The Manager, Engine Certification Office, has the authority to approve alternative methods of compliance for this AD if requested using the procedures found in 14 CFR 39.19.

Material Incorporated by Reference

(n) None.

Related Information

(o) None.

Issued in Burlington, Massachusetts, on September 15, 2004.

Jay J. Pardee,

Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 04–21275 Filed 9–21–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2004–18597; Directorate Identifier 2004–CE–21–AD]

RIN 2120–AA64

Airworthiness Directives; The New Piper Aircraft, Inc. Models PA–23–235, PA–23–250, and PA–E23–250 Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede Airworthiness Directive (AD) 74–06–01, which applies to certain The New Piper Aircraft, Inc. (Piper) Models PA–23–235, PA–23–250, and PA–E23–250 airplanes equipped with Garrett Aviation Services (Garrett) (formerly AiResearch) turbosuperchargers installed under supplemental type certificate (STC) SA852WE, SA909WE, or SA978WE; or installed under Piper Aircraft Drawing Number 32016. AD 74–06–01 currently requires you to replace turbosupercharger oil tanks, install fire shrouds, seal all openings in the fire shrouds, and add drainage provisions in the oil tank fairings for airplane serial numbers 27–1 through 27–2504; and add drainage provisions in the air scoops on serial numbers 27–2505 and higher. This proposed AD is the result of a report of a fatal accident related to the breakdown of the turbocharger oil reservoir following a fire in the engine nacelle. Consequently, this proposed AD would require you to replace the oil reservoir and related hoses with a fireproof oil tank and fire-shielded hoses. We are issuing this proposed AD to prevent turbosupercharger oil reservoirs with inadequate fire resistance from failing when exposed to flame or exhaust gases. This failure could lead to an in-flight fire within the nacelle area penetrating the firewall and subsequent failure of the wing spar.

DATES: We must receive any comments on this proposed AD by November 22, 2004.

ADDRESSES: Use one of the following to submit comments 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 20590–001.
- *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.

You may get the service information identified in this proposed AD from:

—*For any installation under supplemental type certificate (STC) SA852WE, SA909WE, or SA978WE:* The Nordam Group, Nacelle/Thrust Reverser Division, 6911 N. Whirlpool Drive, Tulsa, OK. 74117; telephone: (918) 878–4000; facsimile: (918) 878–4808; and

—*For any installation under Piper Aircraft Drawing Number 32016:* The New Piper Aircraft, Inc., 2926 Piper Drive, Vero Beach, Florida, 32960; and The Nordam Group, Nacalle/Thrust Reverser Division, 6911 N. Whirlpool Drive, Tulsa, OK 74117; telephone: (918) 878–4000; facsimile: (918) 878–4808.

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

FOR FURTHER INFORMATION CONTACT: Roger Pesuit, Aerospace Engineer, FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; telephone: (562) 627–5251; facsimile: (562) 627–5210.

SUPPLEMENTARY INFORMATION:

Comments Invited

How do I comment on this proposed AD? We invite you to submit any written relevant data, views, or arguments regarding this proposal. Send your comments to an address listed under **ADDRESSES.** Include the docket number, "FAA–2004–18597; Directorate Identifier 2004–CE–21–AD" at the beginning of your 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 our 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.*). This is docket number FAA–2004–18597. 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.*

Are there any specific portions of this proposed AD I should pay attention to? We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. If you contact us through a nonwritten communication and that contact relates to a substantive part of this proposed AD, we will summarize the contact and place the summary in the docket. We will consider all comments received by the closing date and may amend this proposed AD in light of those comments and contacts.

Docket Information

Where can I go to view the docket information? You may view the AD docket that contains the proposal, any comments received, and any final disposition in person at the DMS Docket Offices between 9 a.m. and 5 p.m. (eastern standard time), 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.** You may also view the AD docket on the Internet at *http://dms.dot.gov.* The comments will be available in the AD docket shortly after the DMS receives them.

Discussion

Has FAA taken any action to this point? The need to minimize fire hazards in the engine compartment on Piper Models PA–23–235, PA–23–250, and PA–E23–250 airplanes equipped with AiResearch turbosuperchargers installed under STC SA852WE, SA909WE, or SA978WE; or installed under Piper Aircraft Drawing 32016 caused FAA to issue AD 74–06–01, Amendment 39–1977. AD 74–06–01 currently requires the following on any Piper Models PA–23–235, PA–23–250, and PA–E23–250 airplanes equipped with AiResearch turbosuperchargers installed under STC SA852WE, SA909WE, or SA978WE; or installed under Piper Aircraft Drawing Number 32016:

- Replacing the existing turbosupercharger oil tanks;
- Installing fire shrouds;
- Sealing all openings in the fire shrouds;
- (For airplane serial numbers 27–1 through 27–2504) adding drainage provisions in the oil tank fairings; and
- (For airplane serial numbers 27–2505 and higher) adding drainage provisions in the air scoops.

What has happened since AD 74–06–01 to initiate this proposed action? The FAA has received a report of a fatal accident related to the breakdown of the turbosupercharger oil reservoir. A Piper Model PA 23–250 airplane equipped with the STC turbocharger installation was involved in a fatal accident. The accident investigation revealed a breakdown of the turbosupercharger oil reservoir. Examination of the aircraft wreckage revealed evidence of an in-flight fire where the turbosupercharger oil reservoir was burned to include the rear firewall portion of the reservoir allowing fire to move aft, softening the wing spar.

What is the potential impact if FAA took no action? Failure of the turbosupercharger oil reservoir when exposed to flame or exhaust gases could lead to an in-flight fire and failure of the wing spar.

Is there service information that applies to this subject? The following service information relates to this subject:

—*For any installation under supplemental type certificate (STC) SA852WE, SA909WE, or SA978WE:* Garrett has issued Service Bulletin No. 1002143, Revision A, dated June 18, 2004; and

—*For any installation under Piper Aircraft Drawing Number 32016:* Piper has issued Vendor Service Publication No. 166, dated August 20, 2004.

What are the provisions of this service information? The service information includes procedures for:

—replacing the oil reservoir (part number (P/N) 286–P23–028–81 or 286–P23–028–111) with a fireproof oil tank (P/N 10ND79200–1 or 10ND79200–3); and

—replacing the oil reservoir hoses with fire-shielded hoses.

FAA's Determination and Requirements of This Proposed AD

What has FAA decided? We have evaluated all pertinent information and identified an unsafe condition that is likely to exist or develop on other products of this same type design. Therefore, we are proposing AD action.

What would this proposed AD require? This proposed AD would supersede AD 74–06–01 with a new AD that would incorporate the actions in the previously-referenced service information.

How does the revision to 14 CFR part 39 affect this proposed AD? On July 10, 2002, we published a new version of 14 CFR part 39 (67 FR 47997, July 22, 2002), which governs FAA's AD system. This regulation now includes material that relates to altered products, special flight permits, and alternative methods of compliance. This material previously was included in each individual AD. Since this material is included in 14 CFR part 39, we will not include it in future AD actions.

Costs of Compliance

How many airplanes would this proposed AD impact? We estimate that this proposed AD affects 250 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 modification:

Labor cost	Parts cost	Total cost per airplane	Total cost on U.S. operators
14 workhours × $65 per hour = $910	$2,500	$3,410	$852,500

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.

Would this proposed AD involve a significant rule or regulatory action? For the reasons discussed above, I certify that this proposed AD:

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 summary of the costs to comply with this proposed AD and placed it in the AD Docket. You may get a copy of this summary by sending a request to us at the address listed under **ADDRESSES.** Include "AD Docket No. 2004–CE–21" in your request.

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) 74–06–01, Amendment 39–1977, and by adding a new AD to read as follows:

The New Piper Aircraft, Inc.: Docket No. FAA–2004–18597; Directorate Identifier 2004–CE–21–AD.

When Is the Last Date I Can Submit Comments on This Proposed AD?

(a) We must receive comments on this proposed airworthiness directive (AD) by November 22, 2004.

What Other ADs Are Affected by This Action?

(b) This AD supersedes AD 74–06–01.

What Airplanes Are Affected by This AD?

(c) This AD affects Models PA–23–235, PA–23–250, and PA-E23–250 airplanes, all serial numbers, that are (1) certificated in any category; and (2) equipped with Garrett Aviation Services (Garrett) (formerly AiResearch) turbosuperchargers installed under supplemental type certificate (STC) SA852WE, SA909WE, or SA978WE; or installed under The New Piper, Inc. (Piper) Aircraft Drawing Number 32016.

Note: Piper manufactured the majority of affected airplanes with the turbocharger system. The turbocharger system installed under Piper Aircraft Drawing Number 32016 (STC SA909WE) was a factory option on the Piper Model PA–23–250 or PA-E23–250 with serial numbers 27–2505 through 27–3943.

What Is the Unsafe Condition Presented in This AD?

(d) This AD is the result of a report of a fatal accident related to the breakdown of the turbocharger oil reservoir due to a fire in the engine nacelle. The actions specified in this AD are intended to prevent turbosupercharger oil reservoirs with inadequate fire resistance from failing when exposed to flame or exhaust gases. This failure could lead to an in-flight fire within the nacelle area penetrating the firewall and subsequent failure of the wing spar.

What Must I Do To Address This Problem?

(e) To address this problem, you must do the following:

Actions	Compliance	Procedures
(1) *For any turbosupercharger installation under supplemental type certificate (STC) SA852WE, SA909WE, or SA978WE:* (i) replace any oil reservoir (part number (P/N) 286–P23–028–81 or 286–P23–028–111, or FAA-approved equivalent P/N) with a fireproof oil tank (P/N 10ND79200–1 or 10ND79200–3, or FAA-approved equivalent P/N); and (ii) replace the installed oil reservoir hoses with fire-shielded hoses.	Within the next 100 hours time-in-service (TIS) after the effective date of this AD, unless already done.	Follow the procedures in Garrett Aviation Service Bulletin No. 1002143, Revision A, dated June 18, 2004.
(2) *For any turbosupercharger installation under Piper Aircraft Drawing Number 32016:* (i) replace any oil reservoir (P/N 286–P23–028–81 or 286–P23–028–111, or FAA-approved equivalent P/N) with a fireproof oil tank (P/N 10ND79200–1 or 10ND79200–3, or FAA-approved equivalent P/N); and (ii) replace the installed oil reservoir hoses with fire-shielded hoses.	Within the next 100 hours time-in-service (TIS) after the effective date of this AD, unless already done.	Follow the procedures in The New Piper Aircraft, Inc. Vendor Service Publication No. 166, dated August 20, 2004, and the procedures in Garrett Aviation Service Bulletin No. 1002143, Revision A, dated June 18, 2004.
(3) *For any turbosupercharger installation under STC SA852WE, SA909WE, or SA978WE; or Piper Aircraft Drawing Number 32016:* Do not install any oil reservoir (P/N 286–P23–028–81 or 286–P23–028–111, or FAA-approved equivalent P/N) or any oil reservoir hose that is not fire-shielded.	As of the effective date of this AD	Not Applicable.

May I Request an Alternative Method of Compliance?

(f) You may request a different method of compliance or a different compliance time for this AD by following the procedures in 14 CFR 39.19. Unless FAA authorizes otherwise, send your request to your principal inspector. The principal inspector may add comments and will send your request to the Manager, Los Angeles Aircraft Certification Office (ACO), FAA. For information on any already approved alternative methods of compliance, contact Roger Pesuit, Aerospace Engineer, FAA, Los Angeles ACO, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; telephone: (562) 627–5251; facsimile: (562) 627–5210.

May I Get Copies of the Documents Referenced in This AD?

(g) You may get copies of the documents referenced in this AD from (for any installation under STC SA852WE, SA909WE, or SA978WE) The Nordam Group Nacelle/Thrust Reverser Systems Division, 6911 N. Whirlpool Drive, Tulsa, OK 74117 telephone: (918) 878–4000; facsimile: (918) 878–4808; and (for any installation under Piper Aircraft Drawing Number 32016) The New Piper Aircraft, Inc., 2926 Piper Drive, Vero Beach, Florida, 32960; and The Nordam Group Nacalle/Thrust Reverser Systems Division, 6911 N. Whirlpool Drive, Tulsa, OK. 74117 telephone: (918) 878–4000; facsimile: (918) 878–4808. You may view the AD docket at 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.*

Issued in Kansas City, Missouri, on September 16, 2004.

Dorenda D. Baker,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04–21274 Filed 9–21–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2002–NM–89–AD]

RIN 2120–AA64

Airworthiness Directives; Empresa Brasileira de Aeronautica S.A. (EMBRAER) Model EMB–135 and –145 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Supplemental notice of proposed rulemaking; reopening of comment period.

SUMMARY: This document revises an earlier proposed airworthiness directive

(AD), applicable to certain EMBRAER Model EMB–135 and –145 series airplanes. That AD would have required repetitive inspections for cracks, ruptures, or bends in certain components of the elevator control system, and replacement of discrepant components. This proposal also would have required eventual modification of the elevator gust lock system to replace the mechanical system with an electromechanical system, which would terminate the repetitive inspections. This new action revises the proposed rule by adding requirements for installing a new spring cartridge and implementing new logic for the electromechanical gust lock system. This action is necessary to prevent discrepancies in the elevator control system, which could result in reduced control of the elevator and consequent reduced controllability of the airplane. This action is intended to address the identified unsafe condition.

DATES: Comments must be received by October 18, 2004.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2002–NM–89–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays. Comments may be submitted via fax to (425) 227–1232. Comments may also be sent via the Internet using the following address: *9-anm-nprmcomment@faa.gov*. Comments sent via fax or the Internet must contain "Docket No. 2002–NM–89–AD" in the subject line and need not be submitted in triplicate. Comments sent via the Internet as attached electronic files must be formatted in Microsoft Word 97 or 2000 or ASCII text.

The service information referenced in the proposed rule may be obtained from Empresa Brasileira de Aeronautica S.A. (EMBRAER), PO Box 343—CEP 12.225, Sao Jose dos Campos—SP, Brazil. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

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

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this action may be changed in light of the comments received.

Submit comments using the following format:

- Organize comments issue-by-issue. For example, discuss a request to change the compliance time and a request to change the service bulletin reference as two separate issues.
- For each issue, state what specific change to the proposed AD is being requested.
- Include justification (*e.g.*, reasons or data) for each request.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this action must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 2002–NM–89–AD." The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2002–NM–89–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to add an airworthiness directive (AD), applicable to certain EMBRAER Model EMB–135 and –145 series airplanes, was published as a notice of proposed rulemaking (NPRM) in the **Federal Register** on January 5, 2004 (69 FR 284). That NPRM would have required repetitive inspections for cracks, ruptures, or bends in certain components of the elevator control system, and replacement of discrepant components. That NPRM also would have required eventual modification of the elevator gust lock system to replace the mechanical system with an electromechanical system, which would terminate the repetitive inspections. That NPRM was prompted by a report that cracks have been found in certain components of the elevator control system in the horizontal stabilizer area of several airplanes equipped with a mechanical gust lock system. That condition, if not corrected, could result in discrepancies in the elevator control system, which could result in reduced control of the elevator and consequent reduced controllability of the airplane.

Explanation of New Relevant Service Information

Since the preparation of the original NPRM, EMBRAER has issued Service Bulletin 145–27–0086, Change 02, dated December 23, 2003. Paragraph (c)(2) of the original NPRM refers to Change 01 of that service bulletin, dated July 3, 2002, as the appropriate source of service information for several actions associated with replacing the mechanical gust lock system with a new electromechanical gust lock system. Part V of Change 02 of that service bulletin describes additional procedures for installing a new spring cartridge and implementing new logic for the electromechanical gust lock system. Change 02 of the service bulletin refers to EMBRAER Service Bulletins 145–27–0101 and 145–27–0102, both dated December 23, 2003, as additional sources of service information for the accomplishment of those actions. The FAA finds that accomplishing these actions will preclude the possibility of components of the spring cartridges unscrewing and allowing the gust lock system to unlock when it is supposed to be locked. Thus, we have added a new paragraph (c)(2)(iv) to this supplemental NPRM.

In addition, EMBRAER has added Parts VI, VII, VIII, and IX to the Accomplishment Instructions of EMBRAER Service Bulletin 145–27–0086, Change 02. These sections apply to airplanes under Joint Airworthiness Authority (JAA) certification and provide procedures similar to those in Parts I, II, III, and IV of the service bulletin. We have revised paragraphs (c)(2)(i), (c)(2)(ii), and (c)(2)(iii) of this supplemental NPRM to include appropriate references to Parts VI, VII, VIII, and IX of the service bulletin.

Conclusion

Since these changes expand the scope of the originally proposed rule, we have determined that it is necessary to reopen the comment period to provide additional opportunity for public comment.

Explanation of the FAA's Determination

The Departmento de Aviacao Civil (DAC), which is the airworthiness authority for Brazil, approved EMBRAER Service Bulletin 145–27–0086, Change 02, but, at this time, does not intend to revise Brazilian airworthiness directive 2002–01–01R3, dated November 8, 2002 (which the original NPRM references as the Brazilian airworthiness directive that parallels the original NPRM). The DAC does not consider it necessary to revise Brazilian airworthiness directive 2002–01–01R3 because that airworthiness directive refers to EMBRAER Service Bulletin 145–27–0086, Revision 1, or further approved revisions, as the acceptable source of service information for certain actions in that airworthiness directive. However, as stated above, we have determined that it is necessary to issue a supplemental NPRM and reopen the comment period to provide additional opportunity for public comment. We have coordinated this issue with the DAC; the DAC does not object to our action.

Cost Impact

We estimate that 300 airplanes of U.S. registry would be affected by this proposed AD.

It would take approximately 1 work hour per airplane, per inspection cycle, to accomplish the proposed inspection, at an average labor rate of $65 per work hour. Based on these figures, the cost impact of the proposed AD on U.S. operators is estimated to be $19,500, or $65 per airplane, per inspection cycle.

For airplanes subject to EMBRAER Service Bulletin 145–27–0075, Change 06, it would take up to 55 work hours to accomplish the proposed modification in that service bulletin, at an average labor rate of $65 per work hour. Required parts would cost up to $9,554 per airplane. Based on these figures, the cost impact of this proposed action is estimated to be up to $13,129 per airplane.

For airplanes subject to EMBRAER Service Bulletin 145–27–0086, Change 02, it would take approximately 133 work hours to accomplish the proposed modification in that service bulletin, at an average labor rate of $65 per work hour. Required parts would cost up to $23,164 per airplane. Based on these figures, the cost impact of this proposed action is estimated to be $31,809 per airplane.

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of the proposed 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.

Regulatory Impact

The regulations proposed herein 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. Therefore, it is determined that this proposal would not have federalism implications under Executive Order 13132.

For the reasons discussed above, I certify that this 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) if promulgated, 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 copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend 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:

Empresa Brasileira De Aeronautica S.A. (EMBRAER): Docket 2002-NM–89-AD.

Applicability: Model EMB–135 and EMB–145 series airplanes, certificated in any category; serial numbers 145001 through 145189 inclusive, 145191 through 145362 inclusive, 145364 through 145373 inclusive, 145375, 145377 through 145411 inclusive, 145413 through 145424 inclusive, 145426 through 145430 inclusive, 145434 through 145436 inclusive, 145440 through 145445 inclusive, 145448, 145450, and 145801; equipped with a mechanical gust lock system.

Compliance: Required as indicated, unless accomplished previously.

To prevent discrepancies in the elevator control system, which could result in reduced control of the elevator and consequent reduced controllability of the airplane, accomplish the following:

Repetitive Inspections

(a) Within 800 flight hours after the effective date of this AD, do a detailed inspection of the elevator control system for any crack, rupture, or bend in any component, per the Accomplishment Instructions of EMBRAER Service Bulletin 145–27–0087, Change 03, dated September 27, 2002. Where this service bulletin specifies to return discrepant parts and report inspection results to the manufacturer, this AD does not require these actions. Repeat the inspection thereafter at intervals not to exceed 2,500 flight hours or 15 months, whichever is first.

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

Replacement of Discrepant Parts

(b) If any discrepant part is found during any inspection required by paragraph (a) of this AD, before further flight, replace the discrepant part with a new part having the same part number, per the Accomplishment Instructions of EMBRAER Service Bulletin 145–27–0087, Change 03, dated September 27, 2002.

Modification

(c) Within 10,000 flight hours or 60 months after the effective date of this AD, whichever is first, modify the elevator gust lock by accomplishing paragraph (c)(1) or (c)(2) of this AD, as applicable. This modification terminates the repetitive inspections required by paragraph (a) of this AD.

(1) For airplanes listed in EMBRAER Service Bulletin 145–27–0075, Change 06, dated July 16, 2002: Do paragraph (c)(1)(i) or (c)(1)(ii) of this AD, as applicable.

(i) Replace the mechanical gust lock system with an electromechanical gust lock system, and replace the control stand with a reworked control stand, by doing all the actions (including a detailed inspection to ensure that certain parts have been removed previously per EMBRAER Service Bulletin 145–27–0076) in and per section 3.A. (Part I) or 3.B. (Part II) of the Accomplishment Instructions of the service bulletin, as applicable. If the inspection reveals that certain subject parts have not been removed previously, before further flight, remove the subject parts per the service bulletin. Where Parts I and II of the Accomplishment Instructions of the service bulletin specify to remove and "send the control stand to be reworked in a workshop," replace the control stand with a control stand reworked as specified in the service bulletin.

(ii) Replace the return spring and spring terminal of the gust lock control lever with improved parts by doing all the actions in and per section 3.C. (Part III) of the Accomplishment Instructions of the service bulletin.

(2) For airplanes listed in EMBRAER Service Bulletin 145–27–0086, Change 02, dated December 23, 2003: Do paragraphs (c)(2)(i), (c)(2)(ii), (c)(2)(iii), and (c)(2)(iv) of this AD, as applicable.

(i) Rework the tail carbon box and the horizontal stabilizer by doing all the actions (including the inspection for delamination) in and per section 3.A. (Part I) or 3.F. (Part VI) of the Accomplishment Instructions of the service bulletin, as applicable. If any delamination is found that is outside the limits specified in the service bulletin, before further flight, repair per a method approved by either the FAA or the Departmento de Aviacao Civil (or its delegated agent).

(ii) Install wiring and electrical components by doing all the actions in and per section 3.B. (Part II) or 3.G. (Part VII) of the Accomplishment Instructions of the service bulletin, as applicable.

(iii) Install and activate the electromechanical gust lock system by doing all actions in section 3.D. (Part IV) or 3.I. (Part IX) of the Accomplishment Instructions of the service bulletin, as applicable. Where Part IV or IX of the Accomplishment Instructions of the service bulletin specifies to remove and "send the control stand to be reworked in a workshop," replace the control stand with a control stand reworked as specified in Part III or Part VIII of the service bulletin, as applicable.

(iv) Install a new spring cartridge and implement new logic for the electromechanical gust lock system by doing all actions in section 3.E. (Part V) of the Accomplishment Instructions of the service bulletin, as applicable.

Note 2: Part III and Part VIII of the Accomplishment Instructions of EMBRAER Service Bulletin 145–27–0086, Change 02, refer to EMBRAER Service Bulletin 145–22–0007 as an additional source of instructions for accomplishing the rework of the control stand.

Note 3: Part V of the Accomplishment Instructions of EMBRAER Service Bulletin 145–27–0086, Change 02, refers to EMBRAER Service Bulletins 145–27–0101 and 145–27–0102, both dated December 23, 2003, as additional sources of instructions for accomplishing the installation of a new spring cartridge and implementation of the new logic for the electromechanical gust lock system.

Alternative Methods of Compliance

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

Note 4: The subject of this AD is addressed in Brazilian airworthiness directive 2002–01–01R3, dated November 8, 2002.

Issued in Renton, Washington, on September 15, 2004.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04–21273 Filed 9–21–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF COMMERCE

International Trade Administration

19 CFR Part 351

[Docket No. 040722214–4214–01]

RIN 0625–AA66

Certification of Factual Information To Import Administration During Antidumping and Countervailing Duty Proceedings

AGENCY: International Trade Administration, Commerce.

ACTION: Notice of proposed rulemaking and request for comments.

SUMMARY: The Department of Commerce ("the Department") is proposing to amend a regulation, which governs the certification of factual information submitted to the Department by a person or their representative during antidumping and countervailing duty proceedings. The proposed amendments are intended to strengthen the current certification requirements, so that it is clear what has been certified, by whom and when, and so that parties and their counsel are aware of the potential consequences of false certifications.

DATES: Written comments must be received by November 22, 2004.

ADDRESSES: Address written comments to James J. Jochum, Assistant Secretary for Import Administration, U.S. Department of Commerce, Central Records Unit, Room 1870, 14th and Constitution Ave., NW., Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Elizabeth C. Seastrum, Senior Counsel, or Philip J. Curtin, Attorney-Advisor, Office of the General Counsel, Office of Chief Counsel for Import Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230, 202–482–0834 or 202–482–4224.

SUPPLEMENTARY INFORMATION:

Background: The Tariff Act of 1930, as amended, requires that any person who provides factual information to the Department during an antidumping or countervailing duty proceeding must certify to the accuracy and completeness of such information. *See* 19 U.S.C. 1677m(b). Department regulations set forth the specific content requirements for such certifications. *See* 19 CFR 351.303(g). The current language of the certification requirements does not address certain important issues. For example, the current language does not require the certifying official to specify the document or the proceeding for which the certification is submitted, or even the date on which the certification is submitted.

Therefore, on January 26, 2004, the Department published a Notice of Inquiry in the **Federal Register**, and asked whether the current certification requirements are sufficient to protect the integrity of Import Administration's ("IA") administrative processes and, if not, whether the current certification statements should be amended or strengthened and, if so, how. *Certification and Submission of False Statements to Import Administration During Antidumping and Countervailing Duty Proceedings—Notice of Inquiry* ("NOI"), 69 FR 3562. (The Department also solicited views on the broader question of submission of false statements to IA. The views received with regard to this question are not addressed here.) The Department received comments in response to the NOI through March 26, 2004. The comments which concerned the question of certifications provided general recommendations for amending the certification requirements, as well as comments suggesting specific adjustments to the certifications filed by company officials and their representatives.

General recommendations for amending the certification requirements: These suggestions include several comments proposing that the Department add language to the certification emphasizing the possible penalties for certification and submission of false statements. Suggested additions would include the fact that factual submissions may be verified, the possible use of adverse

facts available, the applicability of provisions of the criminal code concerning false claims made to the U.S. government (18 U.S.C. 1001; 31 U.S.C. 3729), and any sanctions which IA may develop under new enforcement regulations. Another commenter suggests that the Department remind parties and counsel prior to all *ex parte* meetings, verifications and hearings that their obligation to provide truthful factual information extends to those proceedings.

Department Position: The Department has adopted the first suggestion, to the extent that the proposed amendment states that criminal sanctions may be imposed for making false statements to the government. The Department has not included the second suggestion in the proposed amendment, but the Department agrees that parties and counsel have an obligation to provide truthful factual information in all proceedings before the Department, per 18 U.S.C. 1001.

Suggestions for specific adjustments to the certifications: Comments regarding the certifications filed by company officials include one comment proposing that the Department require that: the certification be executed on the basis of personal knowledge or reasonable inquiry regarding the underlying facts; the certifying official keep records demonstrating the extent of inquiry; and, the certifying official inform the Department if he or she later becomes aware that certified information is materially false or incorrect. Several other commenters suggest that the Department require the identification of the actual submission being certified by date and title. Another commenter states that each certification should correlate with each response, so that a generic photocopy may not be used, as is now often the case. One other commenter suggests that the certifications clarify that they apply to all parties that submit information in the proceeding. Of particular concern to this commenter is information submitted by third-parties—for example, in non-market economy (NME) cases, producers of subject merchandise submitting information related to factors of production. Another commenter suggests that the Department require certifications from supervisory personnel, as well as from the individuals who prepare specific portions of a submission. A comment regarding specific adjustments to the certifications filed by legal or other representatives proposes that the above-suggested changes made in the certification by company officials be incorporated into the certification by counsel. Another commenter suggests that certification for counsel should bind not just the individual lawyer but that lawyer's entire firm.

Department Position: The Department has attempted to incorporate each of these suggestions, to a certain extent, in this proposed amendment. First, certifying company officials would be required to have "a reasonable basis to formulate an informed judgment as to the accuracy and completeness of the information contained in this submission," consistent with the statute. Their legal or other representatives would be required to make "an inquiry reasonable under the circumstances" prior to certifying to the best of their knowledge that the submission is accurate and complete. Second, the company would be required to maintain the original certification and have it available for inspection upon verification of the questionnaire responses. Finally, the company officials and their legal or other representatives would certify that "this certification is deemed to be continuing in effect," thus requiring the certifying person to inform the Department if he or she possesses knowledge or has reason to know of a material misrepresentation or omission of fact in the submission or in any previously certified information upon which the submission relies.

In addition, the proposed amendment would establish that submissions of factual information be certified by date and title. Also, the proposed amendment has been set up so that each specific submission to the Department be certified separately. Next, the proposed amendment would require the name of the individuals with significant responsibility for preparing specific portions of each submission to the Department, in addition to the name and title of supervisory personnel. These changes have been incorporated into the certification by counsel. Finally, the Department has not adopted the suggestion that certification for counsel bind counsel's entire firm because that is an issue beyond the scope of this exercise.

Comments in favor of the status quo: Several commenters argue that the current certifications are adequate and effective, particularly since the existing rules of professional conduct for attorneys prevent the knowing submission of false evidence. Furthermore, one commenter argues that attorneys cannot be asked to certify either the completeness or accuracy of the factual submission, as to do so would be to impose on attorneys a standard of care that, as a practical matter, cannot be met.

Department Position: The Department has not adopted these suggestions. In its experience, the Department has not found the current certification requirements do not address certain important issues, notwithstanding the existing rules of professional conduct. Furthermore, while the Department understands that attorneys are in a difficult position when it comes to certifying the completeness and accuracy of a factual submission prepared by their client, the Department believes that the standard that would be established by the proposed amendment does not impose an unreasonable burden on attorneys. Specifically, the Department would require "an inquiry reasonable under the circumstances." The Department would expect that attorneys perform due diligence on factual submissions in AD/CVD proceedings in the same manner that they would perform due diligence on any other factual submission to which they are certifying as to its completeness and accuracy.

Proposed Amendment to Regulation: After analyzing the information collected from comments regarding the Notice of Inquiry, the Department proposes to amend the certification language in the regulation. New requirements in the proposed certifications would include the specific date on which the submitted information is certified. Further, the certifications would identify the specific material to which the person is certifying. The certification for the person's legal counsel or other representative would be amended to require certification that the information is accurate and complete to the best of legal counsel's or other representative's knowledge, after an inquiry reasonable under the circumstances.

The certifications would also list the individuals with significant responsibility for preparing the specific material (in the case of companies), and the individuals with significant responsibility for advising, preparing or reviewing the specific material (in the case of legal or other representatives). In addition, the certifications would emphasize that they continue to be in effect throughout the proceeding, and if the certifying person possesses knowledge or has reason to know of a material misrepresentation or omission of fact in the submission or in any previously certified information upon which the submission relies, that person must report such to the Department.

In addition, the certifications would remind certifying persons of the

possible sanctions that might be levied against them for making false statements to the government. The Department wishes to emphasize that the possible sanctions may eventually include those levied by the Department, including debarment from Department proceedings, if or when the Department implements procedures for investigating allegations, determining the degree of culpability, and leveling sanctions for making false statements to the Department.

The certifications would also require that company officials maintain the original certification in their records for Departmental inspection at verification. Their legal or other representatives must maintain a copy of their certification in their records during the pendency of the proceeding; they should file the original with the Department.

Classification

Regulatory Flexibility Act

In accordance with the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, the Chief Counsel for Regulation at the Department of Commerce has certified to the Chief Counsel for Advocacy, Small Business Administration, that the proposed rule, if promulgated as final, will not have a significant economic impact on a substantial number of small entities. The amendment would have little or no economic impact on the companies or their legal or other representatives since it only alters existing requirements. The amendment would have few, if any, new paperwork burdens since it only requires a small amount of additional supplemental information. IA possesses limited information regarding the number of entities that might be affected by this proposed rulemaking. In 2003, IA conducted 112 antidumping and countervailing duty investigations and reviews (excluding sunset reviews and suspension agreements), including initiation of 41 antidumping and countervailing duty investigations and completion of 71 antidumping and countervailing duty reviews. However, IA is unable to estimate the number of entities that participated in each of these investigations and reviews, and is therefore unable to estimate the number of entities affected by the proposed rulemaking. Furthermore, IA is unable to estimate the number of entities affected that may be considered small entities.

Paperwork Reduction Act

Notwithstanding any other provision of law, no person is required to respond to nor shall a person be subject to a collection of information subject to the requirements of the Paperwork Reduction Act of 1995 unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. This proposed rulemaking involves collection-of-information requirements subject to review and approval by the OMB under the Paperwork Reduction Act. Collection activities are currently approved by the OMB under control numbers 0625–0105, 0625–0148 and 0625–0200.

Executive Order 12866

It has been determined that the proposed rulemaking is not significant for purposes of Executive Order 12866.

Executive Order 12612

It has been determined that the proposed rulemaking does not contain federalism implications warranting the preparation of a federalism assessment.

List of Subjects in 19 CFR Part 351

Administrative practice and procedure, Antidumping duties, Business and industry, Confidential business information, Countervailing duties, Investigations, Reporting and recordkeeping requirements.

James J. Jochum,

Assistant Secretary for Import Administration, Department of Commerce.

For the reasons stated in the preamble, the Department of Commerce proposes to amend 19 CFR part 351 as follows:

PART 351—ANTIDUMPING AND COUNTERVAILING DUTIES

1. The authority citation for 19 CFR part 351 continues to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 1202 note; 19 U.S.C. 1303 note; 19 U.S.C. 1671 *et seq*; and 19 U.S.C. 3538.

2. Section 351.303 is proposed to be amended by revising paragraph (g) to read as follows:

§ 351.303 Filing, format, translation, service, and certification of documents.

* * * * *

(g) Certifications. A person must file with each submission containing factual information the certification in paragraph (g)(1) of this section and, in addition, if the person has legal counsel or another representative, the certification in paragraph (g)(2) of this section:

(1) For the person(s) officially responsible for presentation of the factual information:

COMPANY CERTIFICATION

On this___day of *(MONTH), (YEAR),* I, *(PRINTED NAME AND TITLE),* currently employed by *(COMPANY NAME),* certify that I prepared or otherwise supervised the preparation of the attached submission of *(IDENTIFY THE SPECIFIC SUBMISSION BY TITLE AND DATE)* pursuant to the *(INSERT ONE OF THE FOLLOWING: THE (ANTIDUMPING OR COUNTERVAILING DUTY) INVESTIGATION OF (PRODUCT) FROM (COUNTRY) or THE (DATES OF POR) (ADMINISTRATIVE or NEW SHIPPER) REVIEW UNDER THE (ANTIDUMPING OR COUNTERVAILING) DUTY ORDER ON (PRODUCT) FROM (COUNTRY).* I certify that I had sole or substantial responsibility for preparation (or supervision of the preparation) of this submission and have a reasonable basis to formulate an informed judgment as to the accuracy and completeness of the information contained in this submission. If I supervised the preparation of this submission, I list below those other individuals with significant responsibility for preparation of part or all of the submission. I certify that the information contained in this submission is, to the best of my knowledge, accurate and complete. I am aware that this certification is deemed to be continuing in effect, such that I must notify Import Administration, in writing, if at any point in this segment of the proceeding I possess knowledge or have reason to know of any material misrepresentation or omission of fact in this submission or in any previously certified information upon which this submission relies. I am aware that the information contained in this submission is subject to verification by the Department. I am also aware that U.S. law imposes criminal sanctions (including, but not limited to, 18 U.S.C. 1001) on individuals who knowingly make misstatements to the U.S. government. I also certify that the original of this signed certification will be maintained as part of my company's official records and will be available for inspection by Department of Commerce officials during any verification.

Signed: _____

Date: _____

I supervised the preparation of this submission. The following is a list of those other individuals with significant responsibility for preparation of part or all of the submission:

Printed Name : _____

Title: _____

Section: _____

Printed Name : _____

Title: _____

Section: _____

(2) For the person's legal counsel or other representative:

REPRESENTATIVE CERTIFICATION

On this___day of *(MONTH), (YEAR),* I, *(PRINTED NAME),* with *(LAW FIRM or OTHER FIRM),* counsel or representative to *(COMPANY OR PERSON),* certify that I have read the attached submission of *(IDENTIFY THE SPECIFIC SUBMISSION BY TITLE AND DATE)* pursuant to the *INSERT ONE OF THE FOLLOWING: THE (ANTIDUMPING OR*

COUNTERVAILING DUTY) INVESTIGATION OF (PRODUCT) FROM (COUNTRY) or THE (DATES OF POR) (ADMINISTRATIVE or NEW SHIPPER) REVIEW UNDER THE (ANTIDUMPING OR COUNTERVAILING) DUTY ORDER ON (PRODUCT) FROM (COUNTRY). Based on the information made available to me and knowledge acquired by me in my role as adviser, preparer or reviewer of the submission, and after an inquiry reasonable under the circumstances, I certify that to the best of my knowledge the submission is accurate and complete. If I supervised the advising, preparing or review of this submission, I list below those other individuals with significant responsibility for advising, preparing or reviewing part or all of the submission. I am aware that this certification is deemed to be continuing in effect, such that I must notify Import Administration, in writing, if at any point in this segment of the proceeding I possess knowledge or have reason to know of a material misrepresentation or omission of fact in this submission or in any previously certified information upon which this submission relies. I am aware that U.S. law imposes criminal sanctions (including, but not limited to, 18 U.S.C. 1001) on individuals who knowingly make misstatements to the U.S. government. I certify that I am filing the original of this signed certification with this submission to the Department of Commerce and that I will retain a copy during the pendency of this proceeding.

Signed: _____

Date: _____

I supervised the advising, preparing or review of this submission. The following is a list of those other individuals with significant responsibility for advising, preparing or reviewing part or all of the submission:

Printed Name : _____

Title: _____

Section: _____

Printed Name : _____

Title: _____

Section: _____

[FR Doc. 04–21209 Filed 9–21–04; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 635

[I.D. 072704A]

Atlantic Highly Migratory Species; Atlantic Commercial Shark Management Measures; Rescheduling of Public Hearings

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Rescheduling of public hearings.

SUMMARY: NMFS is concerned about a lack of participation by commercial shark fishermen in three public hearings for a proposed rule that was published in the **Federal Register** on September 17, 2004, because of an overlap between the dates of the hearings and the commercial shark fishing season. These hearings are being held to receive comments from fishery participants and other members of the public regarding proposed shark regulations.

DATES: The hearings scheduled for September 28, 2004, in Manteo, NC, September 29 in Cocoa Beach, FL, and September 30 in Madeira Beach, FL, are canceled. The public hearings are rescheduled for October 5, 2004, from 7–9 p.m. in Madeira Beach, FL; October 6, 2004, from 6:30–8:30 p.m. in Cocoa Beach, FL; and October 7, 2004, from 7–9 p.m. in Manteo, NC.

Written comments on the September 17, 2004, proposed rule (69 FR 56024) must be received no later than 5 p.m. on October 18, 2004.

ADDRESSES: The public hearings will be held at the following locations:

1. City of Madeira Beach, 300 Municipal Dr., Madeira Beach, FL 33708,

2. Cocoa Beach Public Library, 550 North Brevard Avenue, Cocoa Beach, FL 32931, and

3. North Carolina Aquarium, Roanoke Island, Airport Road, Manteo, NC 27954.

Written comments on the proposed rule or the Draft Environmental Assessment/Regulatory Impact Review/Initial Regulatory Flexibility Analysis (Draft EA/RIR/IRFA) may be submitted to Christopher Rogers, Chief, Highly Migratory Species Management Division:

- E-mail: *072704A@noaa.gov.*
- Mail: 1315 East-West Highway, Silver Spring, MD 20910. Please mark the outside of the envelope "Comments on Proposed Rule for LCS and SCS Quota Adjustments."
- Fax: 301–713–1917.
- Federal e-Rulemaking portal: *http://www.regulations.gov.* Include in the subject line the following identifier: I.D. 072704A.

Copies of the Draft EA/RIR/FRFA or Amendment 1 to the Fishery Management Plan for Atlantic Tunas, Swordfish, and Sharks or its implementing regulations, may be obtained by using the above mailing address, and are also available on the internet at *http://www.nmfs.noaa.gov/sfa/hms.*

FOR FURTHER INFORMATION CONTACT: Karyl Brewster-Geisz, Chris Rilling, or Mike Clark by phone: 301–713–2347 or by fax: 301–713–1917.

SUPPLEMENTARY INFORMATION: The Atlantic shark fishery is managed under the authority of the Magnuson-Stevens Fishery Conservation and Management Act. The Fisheries Management Plan for Atlantic Tunas, Swordfish, and Sharks (HMS FMP) and Amendment 1 to the HMS FMP are implemented by regulations at 50 CFR part 635. On September 17, 2004, NMFS published a proposed rule (69 FR 56024) that would adjust the regional and trimester quotas for Large Coastal Sharks (LCS) and Small Coastal Sharks (SCS) based on updated landings information, among other things. Complete descriptions of the measures, as well as the purpose and need for the proposed actions, are contained in the proposed rule and are not repeated here.

The September 17, 2004, proposed rule (69 FR 56024) specified, among other things, the dates, times, and locations of three public hearings. NMFS is concerned about a lack of participation by commercial shark fishermen because of an overlap between the dates of the hearings and the commercial shark fishing season that ends in the South Atlantic on September 30, 2004. Accordingly, NMFS is canceling and rescheduling the public hearings. The hearing previously scheduled for September 28, 2004, in Manteo, NC, has been canceled and rescheduled for October 7, 2004, in Manteo, NC. The hearing previously scheduled for September 29, 2004, in Cocoa Beach, FL, has been canceled and rescheduled for October 6, 2004, in Cocoa Beach, FL. The hearing previously scheduled for September 30, 2004, in Madeira Beach, FL, has been canceled and rescheduled for October 5, 2004, in Madeira Beach, FL (see **DATES** and **ADDRESSES**).

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Chris Rilling, (301) 713–2347, at least 7 days prior to the hearing in question.

Dated: September 16, 2004.

Bruce C. Morehead,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 04–21289 Filed 9–17–04; 2:38 pm]

BILLING CODE 3510–22–S

Notices

Federal Register
Vol. 69, No. 183
Wednesday, September 22, 2004

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

Office of the Secretary

Proposed Uniform Guidelines for Conducting Farm Service Agency County Committee Elections

AGENCY: Department of Agriculture.

ACTION: Notice with request for comments: reopening and extension of comment period.

SUMMARY: The Farm Service Agency (FSA) is reopening and extending the comment period for the notice with request for comments, Proposed Uniform Guidelines for Conducting Farm Service Agency County Committee Elections. The original comment period for the proposed rule closed on September 16, 2004 and FSA is reopening and extending it until October 16, 2004. The Agency will also consider any comments received from September 16, 2004 to the date of this notice. This action responds to requests from the public to provide more time to comment on the proposed guidelines.

DATES: Comments must be submitted by October 16, 2004 to be assured consideration. Comments received after that date will be considered to the extent practical.

ADDRESSES: The Agency invites interested persons to submit comments on this notice. Comments may be submitted by any of the following methods:

- E-Mail: Send comments to: *countyelectionguidelines@usda.gov*
- Mail: Send comments to: County Committee Election Reform Comments, Department of Agriculture, Room 3092–S, Mail Stop 0539, 1400 Independence Ave., SW., Washington, DC 20250–0539.
- Hand Delivery or Courier: Deliver comments to the above address.

All comments, including names and addresses, provided by respondents become a matter of public record. Comments may be inspected in the office of the Deputy Administrator for Field Operations, FSA, at the above address. Make inspection arrangements by calling (202) 720–7890.

SUPPLEMENTARY INFORMATION: On August 17, 2004, FSA published a notice with request for comments, Proposed Uniform Guidelines for Conducting Farm Service Agency County Committee Elections, in the **Federal Register** (69 FR 51052). The notice requested comments on the proposed guidelines to ensure that the County Committee election process is fair and transparent and that producers are fairly represented on FSA County Committees. The uniform guidelines make public the principles and procedures under which FSA will conduct such elections, thus contributing to the transparency and accountability of the process. FSA will be required to follow such guidelines in conducting County Committee elections, and FSA regulations and directives on conducting such elections must conform to these guidelines.

The Agency believes that the request for additional time to comment on the proposed guidelines is reasonable. As a result of the reopening and extension, the comment period for the proposed rule will close on October 16, 2004.

Signed in Washington, DC, September 16, 2004.

James R. Little,

Administrator, Farm Service Agency.

[FR Doc. 04–21292 Filed 9–21–04; 8:45 am]
BILLING CODE 3410–05–P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. 04–014N]

Availability of FSIS Form 10,240–1—Production Information on Post-Lethality Exposed Ready-to-Eat Products

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice of availability and request for comments.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing the availability of FSIS Form 10,240–1, Production Information on Post-Lethality Exposed Ready-to-Eat Products. This form will be used to collect information about the ready-to-eat products produced by establishments.

FOR FURTHER INFORMATION CONTACT: Dr. Arshad Hussain, Director, Data Analysis and Statistical Support Staff, Food Safety and Inspection Service, U.S. Department of Agriculture, (202) 720–3219.

Comments

FSIS invites interested persons to submit comments on the information required in this notice and the frequency of its collection. Comments may be submitted by any of the following methods:

- Mail, including floppy disks or CD–ROM's, and hand- or courier-delivered items: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 300 12th Street, SW., Room 102 Cotton Annex, Washington, DC 20250.

All submissions received must include the Agency name and docket number 04–014N. All comments submitted in response to this notice, as well as research and background information used by FSIS in developing this document, will be available for public inspection in the FSIS Docket Room at the address listed above between 8:30 a.m. and 4:30 p.m., Monday through Friday. The comments also will be posted on the Agency's Web site at *http://www.fsis.usda.gov/OPPDE/rdad/FRDockets.htm*.

SUPPLEMENTARY INFORMATION:

Background

FSIS is committed to developing strategies that address food safety hazards throughout the entire food production chain. Under the Federal Meat Inspection Act and the Poultry Products Inspection Act, FSIS has the authority and responsibility to provide for the safety of meat and poultry products during in-plant production and also through transportation, storage, and other handling.

On June 6, 2003, FSIS published an interim final rule (68 FR 34207) that amended its regulations to require that official establishments that produce certain ready-to-eat (RTE) meat and poultry products prevent product adulteration by the pathogen *Listeria monocytogenes* (*L. monocytogenes*). In this interim final rule, FSIS identified three alternative methods for addressing post-lethality contamination of RTE

products by *L. monocytogenes* and required that establishments adopt and implement one of these alternatives.

The use of FSIS Form 10,240–1, Production Information on Post-Lethality Exposed Ready-to-Eat Products, will facilitate collection of information about the RTE products produced by establishments. This information will be used in developing FSIS' annual sampling frequencies for establishments and RTE products. The annual collection of this information was addressed in the interim final rule (68 FR 34207) in 9 CFR 430.4(d). The Agency will use this information, along with the FSIS verification testing history of the establishment, to design a risk-based verification testing program, as stated in the preamble to the interim final rule and in FSIS Directive 10,240.4, Verification Procedures for the *Listeria monocytogenes* Regulation and Microbial Sampling of Ready-to-Eat (RTE) Products for the FSIS Verification Testing Program. In addition, FSIS will be issuing an FSIS notice to instruct FSIS inspection program personnel on how to verify that establishments are completing and submitting FSIS Form 10,240–1 to FSIS. At the first weekly meeting held after receipt of the FSIS notice, inspection program personnel are to inform plant management (1) about the availability of the form, (2) that the establishment is to complete and submit the form to meet the regulatory requirement at 9 CFR 430.4(d), and (3) that the establishment's failure to complete the form or to submit it to FSIS within 30 days from the date of the meeting may cause the Agency to seek appropriate enforcement actions against the establishment or responsible officials. The regulations at 9 CFR 430.4(d) state that "* * * an establishment that produces post-lethality exposed RTE product shall provide FSIS * * * with estimates of annual production volume and related information for the types of meat and poultry products processed * * *" under 9 CFR part 430—Requirements for Specific Classes of Product.

In a memorandum of interview, inspection program personnel are to document who was present at the meeting, the date and time of the meeting, what was discussed, and any documents that were shared with management. Inspection program personnel are to maintain a copy of the memorandum in the official government file and provide a copy to the plant management.

After 30 days from the meeting at which inspection program personnel notified the establishment about completing and submitting the form, inspection program personnel are to ask the establishment management whether it has completed FSIS Form 10,240–1 and submitted it to FSIS.

If an establishment has not completed the form, and does not indicate that it plans to do so in a timely manner, inspection program personnel are to notify the appropriate FSIS District Office through supervisory channels. The District Office will take the necessary follow-up actions.

FSIS Form 10,240–1 is available on the FSIS Web site at *www.fsis.usda.gov/Forms/index.asp* and is also available to FSIS employees in the FAIM forms library. The form can either be printed and filled out, signed and mailed to FSIS/USDA or filled out online, printed, signed and mailed to FSIS/USDA. The full address is FSIS/USDA, Data Analysis and Statistical Support Staff, Cotton Annex Building, 300 12th Street, SW., Room 201, Washington, DC 20250, or faxed to (202) 690–0824. (The form can also be requested from the FSIS Data Analysis and Statistical Support Staff at the address above).

Paperwork Reduction Act

The Office of Management and Budget has approved the information collection and recordkeeping requirements under approval number 0583–0132.

As establishments continue to adapt to the regulatory approach embodied in the interim final rule, FSIS will evaluate the need for the specific information required and the frequency of its collection. The Agency will consider, for example, whether establishments with no change in *Listeria* control methods or products affected could simply verify the fact and report production volume.

Copies of this information collection assessment can be obtained from John O'Connell, Paperwork Reduction Act Coordinator, FSIS, USDA, 112 Annex, 300 12th Street, SW., Washington, DC 20250–3700.

Government Paperwork Elimination Act (GPEA) Compliance

FSIS is committed to compliance with the 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.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to ensure that the public and in particular minorities, women, and persons with disabilities, are aware of this notice, FSIS will announce it on-line through the FSIS Web page located at *http://www.fsis.usda.gov*.

FSIS also will make copies of this **Federal Register** publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, recalls, and other types of information that could affect or would be of interest to our constituents and stakeholders. The update is communicated via Listserv, a free e-mail subscription service consisting of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals who have requested to be included. The update also is available on the FSIS Web page. Through Listserv and the Web page, FSIS is able to provide information to a much broader, more diverse audience.

Done at Washington, DC, on September 17, 2004.

Barbara J. Masters,

Acting Administrator.

[FR Doc. 04–21293 Filed 9–21–04; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF AGRICULTURE

Forest Service

Sierra National Forest, California, Kings River Project

AGENCY: Forest Service, USDA.

ACTION: Notice of intent to prepare an environmental impact statement.

SUMMARY: The Forest Service will prepare an environmental impact statement on a proposal to conduct a sustainable forest ecosystem study that examines the response of an array of ecosystem elements to uneven-aged, small group selection and prescribed fire. The intention is to implement these activities in suitable locations over time and to monitor and perform research studies on the response of physical, chemical, and biological features of the Big Creek and Dinkey Creek watersheds. The study is a collaborative effort between the Sierra National Forest and the Pacific Southwest Research Station.

DATES: A public field trip will be conducted on September 14, 2004 to provide further information about the Kings River Project. Comments concerning the scope of the analysis must be received by October 9, 2004. Mail comments to Kings River Project Coordinator, c/o High Sierra Ranger District, PO Box 559 (29688 Auberry

Road), Prather, CA 93651. The draft environmental impact statement is expected June 2005 and the final environmental impact statement is expected October 2005.

FOR FURTHER INFORMATION CONTACT: Ross Peckinpah, Acting Kings River Project Coordinator, (559) 855–5355 x3350.

SUPPLEMENTARY INFORMATION:

Purpose and Need for Action

The Kings River Project is a key part of the adaptive management program for the Sierra Nevada that is designed to address questions that relate to the uncertainties associated with management activities and their effects on wildlife habitat, watershed condition and modified wildlife behavior.

Proposed Action

The Sierra National Forest proposes to implement the Kings River Project that initially involves analyzing in detail eight management units for treatment between 2006 and 2008 (the ninth management unit, South of Shaver, already had NEPA completed and is scheduled for implementation in 2004). The remaining 71 management units (of which 10 are planned as no treatment-controls and the remaining 61 for implementation between 2011 and 2033) will be examined based on existing condition and the potential for cumulative effects on the Kings River Project. Thus the EIS will be programmatic for the entire project with a focused piece for the initial eight management units. The EIS will address the five planned research studies (Kings River experimental watershed, California spotted owl, fisher, air quality, and uneven-aged management) while incorporating the National Fire Plan objectives (April 2000), USDA Forest Service Strategic Plan and the Sierra Nevada Framework for Conservation and Collaboration Record of Decision (January 2001), as amended on January 21, 2004.

Lead and Cooperating Agencies

The Kings River Project is a collaborative effort between the Sierra National Forest and the Pacific Southwest Research Station (PSW). The Sierra National Forest is the lead agency.

Responsible Official

Ed Cole, Forest Supervisor, Sierra National Forest, 1600 Tollhouse Ave., Clovis, CA 93612.

Nature of Decision To Be Made

The decision to be made is whether to implement the planned treatment and associated studies, an alternative or select no action.

Scoping Process

The Sierra National Forest will conduct a 30-day public scoping period that coincides with this notice.

Comment Requested

This notice of intent initiates the scoping process which guides the development of the environmental impact statement. The scoping period will be conducted for 30 days from the date of this notice. The Sierra National Forest is seeking comments regarding this proposal to identify issues that may be presently unknown to the agency.

Early Notice of Importance of Public Participation in Subsequent Environmental Review

A draft environmental impact statement will be prepared for comment. The comment period of the draft environmental impact statement will be 60 days from the date the Environmental Protection agency publishes the notice of availability in the **Federal Register**.

The Forest Service believes, at this early stage, it is important to give reviewers notice of several court rulings related to public participation in the environmental review process. First, reviewers of draft environmental impact statements must structure their participation in the environmental review of the proposal so that it is meaningful and alerts an agency to the reviewer's position and contentions. *Vermont Yankee Nuclear Power Corp.* v. *NRDC*, 435 U.S. 519, 533 (1978). Also environmental objections that could be raised at the draft environmental impact statement stage but that are not raised until after completion of the final environmental impact statement may be waived or dismissed by the courts. *City of Angoon* v. *Hodel*, 803 F.2D 1016, 1022 (9th Cir. 1986) and *Wisconsin Heritages, Inc.* v. *Harris*, 490 F. Supp. 1334, 1338 (E.D. Wis. 1980). Because of these court rulings, it is very important that those interested in this proposed action participate by the close of the 60-day comment period so that substantive comments and objections are made available to the Forest Service at a time when it can meaningfully consider them and respond to them in the final environmental impact statement.

To assist the Forest Service in identifying and considering issues and concerns on the proposed action, comments on the draft environmental impact statement should be as specific as possible. It is also helpful if comments refer to specific pages or chapters of the draft statement. Comments may also address the adequacy of the draft environmental impact statement or the merits of the alternatives formulated and discussed in the statement. Reviewers may wish to refer to the Council on Environmental Quality Regulations for implementing the procedural provisions of the National Environmental Policy Act at 40 CFR 1503.3 in addressing these points.

Comments received, including the names and addresses of those who comment, will be considered part of the public record on this proposal and will be available for public inspection.

Authority: 40 CFR 1501.7 and 1508.22; Forest Service Handbook 1909.15, Section 21.

Dated: September 30, 2004.

Mark T. Smith,

Acting Forest Supervisor.

[FR Doc. 04–21291 Filed 9–21–04; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Order No. 1352]

Approval of Manufacturing Authority, Foreign-Trade Zone 134, Sofix Corporation (Colorformer Chemicals), Chattanooga, TN

Pursuant to its authority under the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a–81u), the Foreign-Trade Zones Board (the Board) adopts the following Order:

Whereas, the Chattanooga Chamber Foundation, grantee of FTZ 134, on behalf of Sofix Corporation, requesting authority to manufacture black colorformer chemicals under FTZ procedures within FTZ 134—Site 2 (FTZ Docket 58–2003, filed 11/04/03);

Whereas, notice inviting public comment has been given in the **Federal Register** (68 FR 64853, 11/17/03);

Whereas, the Board adopts the findings and recommendations of the examiner's report, and finds that the requirements of the FTZ Act and the Board's regulations are satisfied, and that approval of the request, is in the public interest;

Now, therefore, the Board hereby orders:

The application, on behalf of Sofix Corporation, requesting authority to manufacture black colorformer chemicals under FTZ procedures within FTZ 134—Site 2 is approved, subject to the FTZ Act and the Board's regulations, including § 400.28.

Signed at Washington, DC, this 13th day of September 2004.

James J. Jochum,

Assistant Secretary of Commerce for Import Administration, Alternate Chairman, Foreign-Trade Zones Board.

Attest:

Dennis Puccinelli,

Executive Secretary.

[FR Doc. 04–21284 Filed 9–21–04; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Initiation of Antidumping and Countervailing Duty Administrative Reviews and Request for Revocation in Part

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of initiation of antidumping and countervailing duty administrative reviews and request for revocation in part.

SUMMARY: The Department of Commerce (the Department) has received requests to conduct administrative reviews of various antidumping and countervailing duty orders and findings with August anniversary dates. In accordance with the Department's regulations, we are initiating those administrative reviews. The Department also received a request to revoke one antidumping duty order in part.

EFFECTIVE DATE: September 22, 2004.

FOR FURTHER INFORMATION CONTACT: Holly A. Kuga, Office of AD/CVD Enforcement, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230, telephone: (202) 482–4737.

SUPPLEMENTARY INFORMATION:

Background

The Department has received timely requests, in accordance with 19 CFR 351.213(b) (2002), for administrative reviews of various antidumping and countervailing duty orders and findings with August anniversary dates. The Department also received a timely request to revoke in part the antidumping duty order on Certain Small Diameter Carbon and Alloy Seamless Standard, Line and Pressure Pipe (Under 4½ Inches) from Romania.

Initiation of Reviews

In accordance with sections 19 CFR 351.221(c)(1)(i), we are initiating administrative reviews of the following antidumping and countervailing duty orders and findings. We intend to issue the final results of these reviews not later than August 31, 2005.

	Period to be reviewed
Antidumping Duty Proceedings	
Argentina: Oil Country Tubular Goods, A–357–810, Siderca, S.A.I.C	8/1/03–7/31/04
Brazil:	
Seamless Pipe, A–351–826, V & M do Brazil S.A	8/1/03–7/31/04
Silicon Metal [1], Companhia Ferroligas de Minas Gerais-Minasligas; Ligas de Aluminio S.A	7/1/03–6/30/04
Canada:	
Corrosion-Resistant Carbon Steel Flat Products, A–122–822, Impact Steel Canada, Ltd.; Dofasco Inc.; Stelco Inc	8/1/03–7/31/04
Pure Magnesium, A–122–814, Magnola Metallurgy Inc.; Norsk Hydo Canada, Inc	8/1/03–7/31/04
Italy: Granular Polytetrafluoroethylene (PTFE) Resin, A–475–703, Solvay Solexis, Inc	8/1/03–7/31/04
Japan:	
Corrosion-Resistant Carbon Steel Flat Products, A–588–824, Nippon Steel Corporation; Kawasaki Steel Corporation (and any alleged successor-in-interest including JFE Steel Corp.)	8/1/03–7/31/04
Granular Polytetrafluoroethylene Resin, A–588–707, Asahi Glass Fluoropolymers, Ltd	8/1/03–7/31/04
Oil Country Tubular Goods, A–588–835, JFE Steel Corporation; Nippon Steel Corporation; NKK Tubes; Sumitomo Metal Industries, Ltd	8/1/03–7/31/04
Mexico:	
Carbon and Alloy Seamless Standard, Line and Pressure Pipe (Over 4½ Inches), A–201–827, Tubos de Acero de Mexico, S.A	8/1/03–7/31/04
Gray Portland Cement and Clinker, A–201–802, CEMEX, S.A. de C.V.; GCC Cementos, S.A. de C.V	8/1/03–7/31/04
Oil Country Tubular Goods, A–201–817, Hylsa, S.A. de C.V.; Tubos de Acero de Mexico, S.A	8/1/03–7/31/04
Republic of Korea:	
Corrosion-Resistant Carbon Steel Flat Products, A–580–816, Dongbu Steel Co., Ltd.; Dongshin Special Steel Co., Ltd.; Hyundai HYSCO; Pohang Iron and Steel Co., Ltd./Pohang Coated Steel Co., Ltd./Pohang Steel Industries Co., Ltd.; SeAH Steel Corporation; Sunchon Works; Union Steel Manufacturing Co., Ltd	8/1/03–7/31/04
Oil Country Tubular Goods, A–580–825, Husteel Co., Ltd.; SeAH Steel Corporation	8/1/03–7/31/04
Romania	
Certain Small Diameter Carbon and Alloy Seamless Standard, Line and Pressure Pipe, A–485–805, S.C. Silcotub S.A	8/1/03–7/31/04
Cut-to-Length Carbon Steel Plate, A–485–803, Combinatul de Oteluri Speciali Tirgoviste; CSR SA Resita; Metanef, S.A.; Metalexportimport, S.A.; MINMET, S.A.; S.C. Ispat Sidex S.A	8/1/03–7/31/04
Socialist Republic of Vietnam: Frozen Fish Fillets, A–552–801, An Giang Fisheries Import and Export Joint Stock Company; An Giang Agriculture and Foods Import-Export Company (AFIEX); Can Tho Agricultural and Animal Products Import-Export Company (CATACO); Mekong Fisheries Joint Stock Company (MEKONIMEX); Phan Quan Company, Ltd.; Phu Thanh Company, Co.; QVD Food Co., Ltd.; Vinh Hoan Company, Ltd	1/31/03–7/31/04
The People's Republic of China:	
Persulfates [2], A–570–847, Shanghai AJ Import & Export Corporation [3]	7/1/03–6/30/04
Petroleum Wax Candles [4], A–570–504, Shanghai R&R Improt/Export Co., Ltd., Shangyu City Garden Candle Factory	8/1/03–7/31/04
Countervailing Duty Proceedings	
Canada:	
Alloy Magnesium, C–122–815, Magnola Metallurgy Inc.; Norsk Hydro Canada Inc	1/1/03–12/31/03
Pure Magnesium, C–122–815, Magnola Metallurgy Inc.; Norsk Hydro Canada Inc	1/1/03–12/31/03
Republic of Korea: Dynamic Random Access Memory Semiconductors, C–580–851, Hynix Semiconductor Inc. (formerly Hyundai Electronics Industries Co., Ltd.)	4/7/03–12/31/03

[1] The above listed companies were inadvertently omitted from the initiation notice that published on August 30, 2004 (69 FR 52857).

[2] This case was inadvertently omitted from the initiation notice that published on August 30, 2004 (69 FR 52857).

[3] If the above named company does not qualify for a separate rate, all other exporters of persulfates from the People's Republic of China who have not qualified for a separate rate are deemed to be covered by this review as part of the single PRC entity of which the named exporters are a part.

[4] If one of the above named companies does not qualify for a separate rate, all other exporters of petroleum wax candles from the People's Republic of China who have not qualified for a separate rate are deemed to be covered by this review as part of the single PRC entity of which the named exporters are a part.

Suspension Agreements

None.

During any administrative review covering all or part of a period falling between the first and second or third and fourth anniversary of the publication of an antidumping duty order under section 351.211 or a determination under section 351.218(f)(4) to continue an order or suspended investigation (after sunset review), the Secretary, if requested by a domestic interested party within 30 days of the date of publication of the notice of initiation of the review, will determine, consistant with *FAG Italia* v. *United States,* 291 F.3d 806 (Fed Cir. 202), as appropriate, whether antidumping duties have been absorbed by an exporter or producer subject to the review if the subject merchandise is sold in the United States through an importer that is affiliated with such exporter or producer. The request must include the name(s) of the exporter or producer for which the inquiry is requested.

Interested parties must submit applications for disclosure under administrative protective orders in accordance with 19 CFR 351.305.

These initiations and this notice are in accordance with section 751(a) of the Tariff Act of 1930, as amended (19 U.S.C. 1675(a)) and 19 CFR 351.221(c)(1)(i).

Dated: September 17, 2004.

Holly A. Kuga,

Senior Office Director, Office 4 for Import Administration.

[FR Doc. E4–2315 Filed 9–21–04; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

North Carolina State University; Notice of Decision on Application for Duty-Free Entry of Scientific Instrument

This decision is made pursuant to Section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89–651, 80 Stat. 897; 15 CFR part 301). Related records can be viewed between 8:30 a.m. and 5 p.m. in Suite 4100W, U.S. Department of Commerce, Franklin Court Building, 1099 14th Street, NW., Washington, DC.

Docket Number: 04–015. *Applicant:* North Carolina State University, Raleigh, NC 27695–7212. *Instrument:* Cryogen-Free Superconductive Magnet System. *Manufacturer:* Cryogen Limited, United Kingdom. *Intended Use:* See notice at 69 FR 51812, August 23, 2004. *Comments:* None received. *Decision:* Approved. No instrument of equivalent scientific value to the foreign instrument, for such purposes as it is intended to be used, is being manufactured in the United States. *Reasons:* The foreign instrument provides a magnetic field of 12 Tesla, without cryogen cooling, in order to achieve highly polarized spin states for study of spin polarization phenomena in novel magnetic materials and to exceed the local zero-field splitting field of single-molecule magnets to attain essentially pure quantum state for an ensemble of quantum dots in quantum computing experiments.

The Department of Energy advises that (1) these capabilities are pertinent to the applicant's intended purpose and (2) it knows of no domestic instrument or apparatus of equivalent scientific value to the foreign instrument for the applicant's intended use.

We know of no other instrument or apparatus of equivalent scientific value to the foreign instrument which is being manufactured in the United States.

Gerald A. Zerdy,

Program Manager, Statutory Import Programs Staff.

[FR Doc. E4–2316 Filed 9–21–04; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

University of Colorado Medical School; Notice of Decision on Application for Duty-Free Entry of Electron Microscope

This decision is made pursuant to Section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89–651, 80 Stat. 897; 15 CFR part 301). Related records can be viewed between 8:30 a.m. and 5 p.m. in Suite 4100W, Franklin Court Building, U.S. Department of Commerce, 1099 14th Street, NW., Washington, DC.

Docket Number: 04–016. Applicant: University of Colorado Medical School, Aurora, CO 80045. Instrument: Electron Microscope, Model Technai G[2] 12 BioTWIN. Manufacturer: FEI Company, The Netherlands. Intended Use: See notice at 69 FR 55143, September 13, 2004. Order Date: June 9, 2004.

Comments: None received.

Decision: Approved. No instrument of equivalent scientific value to the foreign instrument, for such purposes as the instrument is intended to be used, was being manufactured in the United States at the time the instrument was ordered. Reasons: The foreign instrument is a conventional transmission electron microscope (CTEM) and is intended for research or scientific educational uses requiring a CTEM. We know of no CTEM, or any other instrument suited to these purposes, which was being manufactured in the United States either at the time of order of the instrument or at the time of receipt of the application by U.S. Customs and Border Protection.

Gerald A. Zerdy,

Program Manager, Statutory Import Programs Staff.

[FR Doc. E4–2317 Filed 9–21–04; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Announcing a Meeting of the Information Security and Privacy Advisory Board

AGENCY: National Institute of Standards and Technology.

ACTION: Notice of meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act, 5 U.S.C. App., notice is hereby given that the Information Security and Privacy Advisory Board (ISPAB) will meet Tuesday, September 28, 2004, from 8:30 a.m. until 5 p.m., Wednesday, September 29, 2004, from 8:30 a.m. until 5 p.m., and Thursday, September 30, 2004, from 8:30 a.m. until 12 p.m. All sessions will be open to the public. The Advisory Board was established by the Computer Security Act of 1987 (Pub.

L. 100–235) and amended by the Federal Information Security Management Act of 2002 (Pub.L. 107–347) to advise the Secretary of Commerce and the Director of NIST on security and privacy issues pertaining to federal computer systems. Details regarding the Board's activities are available at *http://csrc.nist.gov/ispab/*.

DATES: The meeting will be held on September 28, 2004, from 8:30 a.m. until 5 p.m., September 29, 2004, from 8:30 a.m. until 5 p.m., and September 30, 2004, from 8:30 a.m. until 12 p.m.

ADDRESSES: The meeting will take place at the Hilton Hotel Washington, DC—North Gaithersburg, 620 Perry Parkway, Gaithersburg, Maryland.

Agenda

- Welcome and Overview
- Discussion of the Role of the Federal CISO
- Federal Enterprise Architecture Update
- Discussion of Federal IT Security Professional Credentials
- Department of Homeland Security Cyber Security Program Briefing
- Office of Management and Budget Cyber Security Update
- Department of Commerce Chief Privacy Officer Briefing
- NIST Development of the Federal Information Processing Standard for Common Identification of Federal Employees and Federal Contractors
- Agenda Development for September 2004 ISPAB Meeting
- Wrap-Up

Note that agenda items may change without notice because of possible unexpected schedule conflicts of presenters.

Public Participation

The Board agenda will include a period of time, not to exceed thirty minutes, for oral comments and questions from the public. Each speaker will be limited to five minutes. Members of the public who are interested in speaking are asked to contact the Board Secretariat at the telephone number indicated below. In addition, written statements are invited and may be submitted to the Board at any time. Written statements should be directed to the ISPAB Secretariat, Information Technology Laboratory, 100 Bureau Drive, Stop 8930, National Institute of Standards and Technology, Gaithersburg, MD 20899–8930. It would be appreciated if 25 copies of written material were submitted for distribution to the Board and attendees no later than September 24, 2004. Approximately 15 seats will be available for the public and media.

FOR FURTHER INFORMATION CONTACT: Ms. Joan Hash, Board Secretariat, Information Technology Laboratory, National Institute of Standards and Technology, 100 Bureau Drive, Stop 8930, Gaithersburg, MD 20899–8930, telephone: (301) 975–3357.

Dated: September 16, 2004.

Hratch G. Semerjian,

Acting Director.

[FR Doc. 04–21260 Filed 9–21–04; 8:45 am]

BILLING CODE 3510–CN–P

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Limitations of Duty- and Quota-Free Imports of Apparel Articles Assembled in Beneficiary Sub-Saharan African Countries From Regional and Third-Country Fabric

September 17, 2004.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Publishing the New 12-Month Cap on Duty- and Quota-Free Benefits.

EFFECTIVE DATE: October 1, 2004.

FOR FURTHER INFORMATION CONTACT: Anna Flaaten, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482-3400.

SUPPLEMENTARY INFORMATION:

Authority: Title I, Section 112(b)(3) of the Trade and Development Act of 2000, as amended by Section 3108 of the Trade Act of 2002 and Section 7(b)(2) of the AGOA Acceleration Act of 2004; Presidential Proclamation 7350 of October 4, 2000 (65 FR 59321); Presidential Proclamation 7626 of November 13, 2002 (67 FR 69459).

Title I of the Trade and Development Act of 2000 (TDA 2000) provides for duty- and quota-free treatment for certain textile and apparel articles imported from designated beneficiary sub-Saharan African countries. Section 112(b)(3) of TDA 2000 provides duty- and quota-free treatment for apparel articles wholly assembled in one or more beneficiary sub-Saharan African countries from fabric wholly formed in one or more beneficiary countries from yarn originating in the U.S. or one or more beneficiary countries. This preferential treatment is also available for apparel articles assembled in one or more lesser-developed beneficiary sub-Saharan African countries, regardless of the country of origin of the fabric used to make such articles. This special rule for lesser-developed countries applies through September 30, 2004. TDA 2000 imposed a quantitative limitation on imports eligible for preferential treatment under these two provisions.

The Trade Act of 2002 amended TDA 2000 to extend preferential treatment to apparel assembled in a beneficiary sub-Saharan African country from components knit-to-shape in a beneficiary country from U.S. or beneficiary country yarns and to apparel formed on seamless knitting machines in a beneficiary country from U.S. or beneficiary country yarns, subject to the quantitative limitation. The Trade Act of 2002 also increased the quantitative limitation but provided that this increase would not apply to apparel imported under the special rule for lesser-developed countries. Section 7(b)(2)(B) of the AGOA Acceleration Act extended the expiration of the quantitative limitations. It also further amended the percentages to be used in calculating the quantitative limitations for each twelve-month period, beginning on October 1, 2003. The AGOA Acceleration Act of 2004 provides that the quantitative limitation for the twelve-month period beginning October 1, 2004 will be an amount not to exceed 5.31025 percent of the aggregate square meter equivalents of all apparel articles imported into the United States in the preceding 12-month period for which data are available. See Section 112(b)(3)(A)(ii) of TDA 2000, as amended by Section 7(b)(2)(B) of the AGOA Acceleration Act. Of this overall amount, apparel imported under the special rule for lesser-developed countries is limited to an amount not to exceed 2.6428 percent of apparel imported into the United States in the preceding 12-month period. See Section 112(b)(3)(B)(ii) of TDA 2000, as amended by Section 7(b)(2)(B) of the AGOA Acceleration Act. For the purpose of this notice, the most recent 12-month period for which data are available is the 12-month period ending July 31, 2004.

Presidential Proclamation 7350 directed CITA to publish the aggregate quantity of imports allowed during each 12-month period in the **Federal Register**. Presidential Proclamation 7626, published on November 18, 2002, modified the aggregate quantity of imports allowed during each 12-month period.

For the one-year period, beginning on October 1, 2004, and extending through September 30, 2005, the aggregate quantity of imports eligible for preferential treatment under these provisions is 1,076,876,652 square meters equivalent. Of this amount, 535,938,914 square meters equivalent is available to apparel imported under the

special rule for lesser-developed countries. These quantities will be recalculated for each subsequent year. Apparel articles entered in excess of these quantities will be subject to otherwise applicable tariffs.

These quantities are calculated using the aggregate square meter equivalents of all apparel articles imported into the United States, derived from the set of Harmonized System lines listed in the Annex to the World Trade Organization Agreement on Textiles and Clothing (ATC), and the conversion factors for units of measure into square meter equivalents used by the United States in implementing the ATC.

D. Michael Hutchinson,

Acting Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. E4–2318 Filed 9–21–04; 8:45 am]

BILLING CODE 3510–DR–S

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Limitations of Duty- and Quota-Free Imports of Apparel Articles Assembled in Beneficiary ATPDEA Countries From Regional Country Fabric

September 17, 2004.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Publishing the New 12-Month Cap on Duty and Quota Free Benefits.

EFFECTIVE DATE: October 1, 2004.

FOR FURTHER INFORMATION CONTACT: Richard Stetson, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482-3400.

SUPPLEMENTARY INFORMATION:

Authority: Section 3103 of the Trade Act of 2002; Presidential Proclamation 7616 of October 31, 2002 (67 FR 67283).

Section 3103 of the Trade Act of 2002 amended the Andean Trade Preference Act (ATPA) to provide for duty and quota-free treatment for certain textile and apparel articles imported from designated Andean Trade Promotion and Drug Eradication Act (ATPDEA) beneficiary countries. Section 204(b)(3)(B)(iii) of the amended ATPA provides duty- and quota-free treatment for certain apparel articles assembled in ATPDEA beneficiary countries from regional fabric and components. More specifically, this provision applies to apparel articles sewn or otherwise assembled in one or more ATPDEA beneficiary countries from fabrics or from fabric components formed or from components knit-to-shape, in one or more ATPDEA beneficiary countries, from yarns wholly formed in the United States or one or more ATPDEA beneficiary countries (including fabrics not formed from yarns, if such fabrics are classifiable under heading 5602 and 5603 of the Harmonized Tariff Schedule (HTS) and are formed in one or more ATPDEA beneficiary countries). Such apparel articles may also contain certain other eligible fabrics, fabric components, or components knit-to-shape.

For the one-year period, beginning on October 1, 2004, and extending through September 30, 2005, preferential tariff treatment is limited under the regional fabric provision to imports of qualifying apparel articles in an amount not to exceed 3.5 percent of the aggregate square meter equivalents of all apparel articles imported into the United States in the preceding 12-month period for which data are available. For the purpose of this notice, the 12-month period for which data are available is the 12-month period that ended July 31, 2004. In Presidential Proclamation 7616, (published in the **Federal Register** on November 5, 2002, 67 FR 67283), the President directed CITA to publish in the **Federal Register** the aggregate quantity of imports allowed during each 12-month period.

For the one-year period, beginning on October 1, 2004, and extending through September 30, 2005, the aggregate quantity of imports eligible for preferential treatment under the regional fabric provision is 709,772,286 square meters equivalent. This quantity will be recalculated for each subsequent year, under Section 204(b)(3)(B)(iii). Apparel articles entered in excess of this quantity will be subject to otherwise applicable tariffs.

This quantity is calculated using the aggregate square meter equivalents of all apparel articles imported into the United States, derived from the set of Harmonized System lines listed in the Annex to the World Trade Organization Agreement on Textiles and Clothing (ATC), and the conversion factors for units of measure into square meter equivalents used by the United States in implementing the ATC.

D. Michael Hutchinson,

Acting Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. E4–2319 Filed 9–21–04; 8:45 am]

BILLING CODE 3510–DR–S

COMMODITY FUTURES TRADING COMMISSION

Sunshine Act Meetings

TIME AND DATE: 10:30 a.m., Wednesday, September 29, 2004.

PLACE: 1155 21st St., NW., Washington, DC, 9th Floor Commission Conference Room.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Rule Enforcement Review.

CONTACT PERSON FOR MORE INFORMATION: Jean A. Webb, 202–418–5100.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 04–21349 Filed 9–20–04; 10:24 am]

BILLING CODE 6351–01–M

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Availability of Government-Owned Inventions; Available for Licensing

AGENCY: Department of the Navy, DoD.

ACTION: Notice.

SUMMARY: The inventions listed below are assigned to the United States Government as represented by the Secretary of the Navy and are available for licensing by the Department of the Navy. U.S. Patent Application Serial No. 10/863,850: Biological Laser Printing Via Indirect Laser-Biomaterial Interaction, Navy Case No. 84,621.//U.S. Patent Application Serial No. 10/863,833: Biological Laser Printing Via Indirect Laser-Biomaterial Interaction, Navy Case No. 96,075.

ADDRESSES: Requests for copies of the inventions cited should be directed to the Naval Research Laboratory, Code 1004, 4555 Overlook Avenue, SW., Washington, DC 20375–5320, and must include the Navy Case number.

FOR FURTHER INFORMATION CONTACT: Jane F. Kuhl, Head, Technology Transfer Office, NRL Code 1004, 4555 Overlook Avenue, SW., Washington, DC 20375–5320, telephone (202) 767–3083. Due to temporary U.S. Postal Service delays, please fax (202) 404–7920, E-Mail: *kuhl@utopia.nrl.navy.mil* or use courier delivery to expedite response.

(Authority: 35 U.S.C. 207, 37 CFR part 404)

Dated: September 15, 2004.

J.H. Wagshul,

Commander, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. 04–21266 Filed 9–21–04; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Availability of Government-Owned Inventions; Available for Licensing

AGENCY: Department of the Navy, DoD.

ACTION: Notice.

SUMMARY: The inventions listed below are assigned to the United States Government as represented by the Secretary of the Navy and are available for domestic and foreign licensing by the Department of the Navy.

The following patents are available for licensing:

U.S. Patent No. 6,665,582: STANDARDIZED CONTAINER PAYLOAD DELIVERY AND CONTROL SYSTEM.//U.S. Patent No. 6,669,408: SELF-ORIENTING PILING, FLUID–FLOW REDUCTION DEVICE.//U.S. Patent No. 6,697,715: INSTINCTIVE STEERING SYSTEM AND METHOD FOR REDUCING OPERATOR ERROR IN CONTROLLING A VEHICLE REMOTELY.//U.S. Patent No. 6,694,911 B1: ENHANCED DISPLAY UNDERWATER COMBAT SWIM BOARD.//U.S. Patent No. 6,695,068: TEXTILE AND CORDAGE NET FIRE EXTINGUISHER SYSTEM.//U.S. Patent No. 6,704,618: CONTAINER BASED SYSTEM FOR GENERATION AND DISPERSAL OF PRINTED MATERIALS.//U.S. Patent No. 6,711,095: EXPENDABLE/RECOVERABLE VOICE AND DATA COMMUNICATIONS SYSTEM BUOY.// 6,712,312: RECONNAISSANCE USING UNMANNED SURFACE VEHICLES AND UNMANNED MICRO-AERIAL VEHICLES.//U.S. Patent No. 6,730,917 B2: MINIATURE HIGH INTENSITY LED ILLUMINATION SOURCE.//U.S. Patent No. 6,748,609: CLOSURE DEVICE FOR A PROTECTIVE SUIT.//U.S. Patent No. 6,754,390: FUSING OUTPUTS FROM MULTIPLE DETECTION/CLASSIFICATION SCHEMES.//

ADDRESSES: Requests for copies of the patents cited should be directed to Naval Surface Warfare Center Panama City, 110 Vernon Ave, Panama City, FL 32407–7001.

FOR FURTHER INFORMATION CONTACT: Mr. James Shepherd, Patent Counsel, Naval Surface Warfare Center Panama City, 110 Vernon Ave, Panama City, FL 32407–7001, telephone (850) 234–4646.

(Authority: 35 U.S.C. 207, 37 CFR Part 404).

Dated: September 15, 2004.

J.H. Wagshul,

Commander, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. 04–21267 Filed 9–21–04; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF ENERGY

Office of Science; DOE/NSF Nuclear Science Advisory Committee

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the DOE/NSF Nuclear Science Advisory Committee (NSAC). Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770) requires that public notice of these meetings be announced in the **Federal Register**.

DATES: Thursday, October 7, 2004, 9 a.m. to 4 p.m.

ADDRESSES: Quality Suites, 3 Research Court, Rockville, Maryland 20850.

FOR FURTHER INFORMATION CONTACT: Brenda L. May, U.S. Department of Energy; SC–90/Germantown Building, 1000 Independence Avenue, SW., Washington, DC 20585–1290; Telephone: 301–903–0536.

SUPPLEMENTARY INFORMATION:

Purpose of Meeting: To provide advice and guidance on a continuing basis to the Department of Energy and the National Science Foundation on scientific priorities within the field of basic nuclear science research.

Tentative Agenda: Agenda will include discussions of the following:

Thursday, October 7, 2004

- Perspectives from Department of Energy and National Science Foundation.
- Presentation and discussion on the interim report from the Relativistic Heavy Ion Sub-Committee.
- Discussion of NSAC response and transmittal letter on the Relativistic Heavy Ion Report.
- Public comment (10-minute rule).

Public Participation: The meeting is open to the public. If you would like to file a written statement with the Committee, you may do so either before or after the meeting. If you would like to make oral statements regarding any of these items on the agenda, you should contact Brenda L. May, 301–903–0536 or *Brenda.May@science.doe.gov* (e-mail). You must make your request for an oral statement at least 5 business days before the meeting. Reasonable provision will be made to include the scheduled oral statements on the agenda. The Chairperson of the Committee will conduct the meeting to facilitate the orderly conduct of business. Public comment will follow the 10-minute rule.

Minutes: The minutes of the meeting will be available for public review and copying within 30 days 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 September 17, 2004.

Rachel Samuel,

Deputy Advisory Committee, Management Officer.

[FR Doc. 04–21263 Filed 9–21–04; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Energy Information Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Energy Information Administration (EIA), Department of Energy (DOE).

ACTION: Agency information collection activities: submission for OMB review; comment request.

SUMMARY: The EIA has submitted the form EIA–886, "Annual Survey of Alternative Fueled Vehicle Suppliers and Users" to the Office of Management and Budget (OMB) for review and a three-year extension under section 3507(h)(1) of the Paperwork Reduction Act of 1995 (Pub. L. 104–13) (44 U.S.C. 3501 *et seq.*).

DATES: Comments must be filed by October 22, 2004. If you anticipate that you will be submitting comments but find it difficult to do so within that period, you should contact the OMB Desk Officer for DOE listed below as soon as possible.

ADDRESSES: Send comments to John A. Asalone, OMB Desk Officer for DOE, Office of Information and Regulatory Affairs, Office of Management and Budget. To ensure receipt of the comments by the due date, submission by FAX (202–395–7285) is recommended. The mailing address is 726 Jackson Place, NW., Washington, DC 20503. (A copy of your comments should also be provided to EIA's Statistics and Methods Group at the address below.)

FOR FURTHER INFORMATION CONTACT: Requests for additional information

should be directed to Herbert Miller. To ensure receipt of the comments by the due date, submission by FAX (202–287–1705) or e-mail (*herbert.miller@eia.doe.gov*) is recommended. The mailing address is Statistics and Methods Group (EI–70), Forrestal Building, U.S. Department of Energy, Washington, DC 20585–0670. Mr. Miller may be contacted by telephone at (202) 287–1711.

SUPPLEMENTARY INFORMATION: This section contains the following information about the energy information collection submitted to OMB for review: (1) The collection numbers and title; (2) the sponsor (*i.e.*, the Department of Energy component); (3) the current OMB docket number (if applicable); (4) the type of request (*i.e.*, new, revision, extension, or reinstatement); (5) response obligation (*i.e.*, mandatory, voluntary, or required to obtain or retain benefits); (6) a description of the need for and proposed use of the information; (7) a categorical description of the likely respondents; and (8) an estimate of the total annual reporting burden.

1. EIA–886, "Annual Survey of Alternative Fueled Vehicle Suppliers and Users."
2. Energy Information Administration.
3. OMB Number 1905–0191.
4. Revision.
5. Mandatory.
6. Form EIA–886 is an annual survey of the number of Alternative Fuel Vehicles. (AFVs) made available on a calendar year basis and the amount and distribution of each type of Alternative Transportation Fuel (ATF) consumed. The data will be used to track the AFV supply situation available for the Federal Government, State Governments, and the fuel providers, and the consumption of ATFs. Respondents are manufacturers, importers, and conversion companies of AFV vehicles, and ATF providers and users.
7. Business or other for-profit; Not-for-profit institutions; Federal Government; State, Local or Tribal Government.
8. 10,853 hours.

Please refer to the supporting statement as well as the proposed forms and instructions for more information about the purpose, who must report, when to report, where to submit, the elements to be reported, detailed instructions, provisions for confidentiality, and uses (including possible nonstatistical uses) of the information. For instructions on obtaining materials, see the **FOR FURTHER INFORMATION CONTACT** section.

Statutory Authority: Section 3507(h)(1) of the Paperwork Reduction Act of 1995 (Pub. L. 104–13) (44 U.S.C. 3501 *et seq.*).

Issued in Washington, DC, September 16, 2004.

Jay H. Casselberry,

Agency Clearance Officer, Statistics and Methods Group, Energy Information Administration.

[FR Doc. 04–21264 Filed 9–21–04; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC04–511–000 FERC–511]

Commission Collection Activities, Proposed Collection; Comment Request; Extension & Reinstatement

September 15, 2004.

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Notice.

SUMMARY: In compliance with the requirements of Section 3506(c)(2)(a) of the Paperwork Reduction Act of 1995 (Pub. L. 104–13), the Federal Energy Regulatory Commission (Commission) is soliciting public comment on the specific aspects of the information collection described below.

DATES: Comments on the collection of information are due by November 19, 2004.

ADDRESSES: Copies of the proposed collection of information can be obtained from Michael Miller, Office of the Executive Director, ED–30, 888 First Street NE., Washington, DC 20426. Comments on the proposed collection of information may be filed either in paper format or electronically. Those parties filing electronically do not need to make a paper filing. For paper filings, the original and 14 copies of such comments should be submitted to the Office of the Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426 and should refer to Docket No. IC 04–511–000.

Documents filed electronically via the Internet can be prepared in a variety of formats, including WordPerfect, MS Word, Portable Document Format, Rich Text Format, or ASCII format. To file the document, access the Commission's Web site at *http://www.ferc.gov* and click on "Make an E-filing," and then follow the instructions for each screen. First time users will have to establish a user name and password. The Commission will send an automatic acknowledgment to the sender's e-mail address upon receipt of comments. User assistance for electronic filings is available at (202) 502–8258 or by e-mail to *efiling@ferc.gov*. Comments should not be submitted to this e-mail address.

All comments may be viewed, printed or downloaded remotely via the Internet through FERC's homepage using the eLibrary link. For user assistance, contact *FERCOnlineSupport@ferc.gov* or toll free at (866) 208–3676 or for TTY, contact (202) 502–8659.

FOR FURTHER INFORMATION CONTACT: Michael Miller may be reached by telephone at (202) 502–8415, by fax at (202) 273–0873, and by e-mail at *michael.miller@ferc.gov*.

SUPPLEMENTARY INFORMATION: The information collected under the requirements of FERC–511, "Application for Transfer of License" (OMB No. 1902–0069) is used by the Commission to implement the statutory refund provisions of Part I, Sections 4(e) and 8 of the Federal Power Act (FPA) 16 U.S.C. 792–828c. Section 4(e) authorizes the Commission to issue licenses for the construction, operation and maintenance of Reservoirs, power houses, and transmission lines or other facilities necessary for development, transmission, and utilization of power from bodies of water Congress has jurisdiction over. Section 8 of the FPA provides that the voluntary transfer of any license can only be made with the written approval of the Commission. Any successor to the licensee may assign the rights of the original licensee but is subject to all of the conditions of the license. The information filed with the Commission is a mandatory requirement contained in the format of a written application for transfer of license, executed jointly by the parties to the proposed transfer. The transfer of a license may be occasioned by the sale or merger of a licensed hydropower project. The information is used by Commission staff to determine the qualifications of the proposed transferee to hold the license, and to prepare the transfer of the license order. The Commission implements these filing requirements in the Code of Federal Regulations (CFR) under 18 CFR Part 9.

Action: The Commission is requesting a three-year extension of the current expiration date, with no changes to the existing collection of data.

Burden Statement: Public reporting burden for this information collection is estimated as:

Number of respondents annually (1)	Number of responses per respondent (2)	Average burden (Number of hours per response) (3)	Total annual burden (total number of hours) (1) × (2) × (3)
15	1	40	600

Estimated cost to respondents: 600 hours ÷ 2,080 per year × $107,185 = $30,919. The cost per respondent = $2,061 (rounded off). The reporting burden includes the total time, effort, or financial resources to generate, maintain, retain, disclose, or provide the information including: (1) Reviewing instructions; (2) developing, acquiring, installing, and utilizing technology and systems for the purpose of collecting, validating, verifying, processing, maintaining, disclosing and providing information; (3) adjusting the existing ways to comply with any previously applicable instructions and requirements; (4) training personnel to respond to a collection of information; (5) searching data sources; (6) completing and reviewing the collection of information; and (7) transmitting, or otherwise disclosing the information.

The estimate of cost for respondents is based upon salaries for professional and clerical support as well as direct and indirect overhead costs. Direct costs include all costs directly attributable to providing this information, such as administrative costs and the cost for information technology. Indirect or overhead costs are costs incurred by an organization in support of its mission. These costs apply to activities which benefit the whole organization rather than any one particular function or activity.

Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) 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) 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 those who are to respond, including 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.

Linda Mitry,

Acting Secretary.

[FR Doc. E4–2302 Filed 9–21–04; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP04–591–000]

National Fuel Gas Supply Corporation; Notice of Proposed Changes in FERC Gas Tariff

September 15, 2004.

Take notice that on September 14, 2004, National Fuel Gas Supply Corporation (National Fuel) tendered for filing as part of its FERC Gas Tariff, Fourth Revised Volume No. 1, the tariff sheets listed on Appendix A to its filing, with a proposed effective date of October 14, 2004.

National Fuel states that the purpose of this filing is to prepare for the implementation of Section 358.5(c)(4) of the Commission's new Standards of Conduct for Transmission Providers by revising its tariff to remove certain discretionary language. National Fuel indicates that its filing also makes a number of corrections and clarifications.

National Fuel states that copies of this filing were served upon its customers and interested State commissions.

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 and 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 in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not 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.

Linda Mitry,

Acting Secretary.

[FR Doc. E4–2297 Filed 9–21–04; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP04–589–000]

Pine Needle LNG Company, LLC; Notice of Proposed Changes in FERC Gas Tariff

September 15, 2004.

Take notice that on September 10, 2004, Pine Needle LNG Company, LLC ("Pine Needle") tendered for filing as part of its FERC Gas Tariff, Original Volume No. 1, Fourth Revised Sheet No. 40 and Second Revised Sheet No. 88 to become effective October 10, 2004.

Pine Needle states that the purpose of this filing is to set forth in its tariff, in a new Section 27 of the General Terms and Conditions, provisions under which customers may, at their option and subject to certain conditions, consolidate multiple service agreements under a rate schedule into a single service agreement under that rate

schedule. Pine Needle is proposing these provisions to provide its customers the opportunity to simplify the administration of multiple service agreements under a rate schedule.

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 and 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 in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not 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.

Linda Mitry,

Acting Secretary.

[FR Doc. E4–2300 Filed 9–21–04; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP04–590–000]

Trunkline Gas Company, LLC; Notice of Annual Report of Flow Through of Cash Out and Penalty Revenues

September 15, 2004.

Take notice that, on September 13, 2004 Trunkline Gas Company, LLC (Trunkline) tendered for filing its Annual Report of Flow Through of Cash Out and Penalty Revenues.

Trunkline states that this filing is made in accordance with Section 23 of the General Terms and Conditions in Trunkline's FERC Gas Tariff, Third Revised Volume No. 1.

Trunkline further states that copies of this filing were served on all affected customers and applicable State regulatory agencies.

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 Procedures (18 CFR 385.211 and 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 date as indicated below. Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not 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.

Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room. This filing is also assessable on-line at *http://www.ferc.gov*, using the "eLibrary" link. 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.

Intervention and Protest Date: 5 p.m. eastern standard time September 22, 2004.

Linda Mitry,

Acting Secretary.

[FR Doc. E4–2301 Filed 9–21–04; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EC04–92–000, et al.]

UniSource Energy Corporation, et al.; Electric Rate and Corporate Filings

September 15, 2004.

The following filings have been made with the Commission. The filings are listed in ascending order within each docket classification.

1. UniSource Energy Corporation; Tucson Electric Power Company; UNS Electric, Inc.; Saguaro Utility Group I Corp.; Saguaro Acquisition Corp.; Saguaro Utility Group L.P.

[Docket No. EC04–92–000]

Take notice that on September 15, 2004, UniSource Energy Corporation (UniSource Energy), Tucson Electric Power Company (TEP), UNS Electric, Inc., Saguaro Utility Group I Corp., Saguaro Acquisition Corp., and Saguaro Utility Group, L.P. (collectively Applicants) submitted an amendment to their joint application seeking all authorizations and approvals necessary for an indirect disposition of jurisdictional facilities pursuant to section 203 of the Federal Power Act in connection with the acquisition of UniSource Energy Corporation by Saguaro Utility Group I Corp. The amendment modifies Applicants' proposed market monitoring plan.

Comment Date: 5 p.m. eastern standard time on September 27, 2004.

2. Alabama Power Company

[Docket No. ER04–815–000]

Take notice that on September 1, 2004, Alabama Power Company (APC), filed a withdrawal of its May 5, 2004 filing in ER04–815–000.

Comment Date: 5 p.m. eastern standard time on September 22, 2004.

3. California Independent System Operator Corporation

[Docket No. ES04–49–000]

Take notice that on September 3, 2004, California Independent System

Operator Corporation (California ISO) submitted an application pursuant to section 204 of the Federal Power Act seeking authorization to issue long-term debt in the form of bonds, notes and guarantees in an amount not to exceed $130 million.

California ISO also requests a waiver from the Commission's competitive bidding and negotiated placement requirements at 18 CFR 34.2.

Comment Date: 5 p.m. eastern standard time on September 28, 2004.

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 and 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. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant and all parties to this proceeding.

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. E4–2303 Filed 9–21–04; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Settlement Agreement and Soliciting Comments

September 15, 2004.

Take notice that the following settlement agreement has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Settlement Agreement.

b. *Project No.:* 2105–089.

c. *Date filed:* April 30, 2004.

d. *Applicant:* Pacific Gas and Electric Company.

e. *Name of Project:* Upper North Fork Feather River Project.

f. *Location:* On the North Fork Feather River, in the vicinity of the community of Chester, Plumas County, California, T28N, R7E. The project occupies 1,500 acres of land administered by the Forest Supervisors of the Lassen and Plumas National Forests.

g. *Filed Pursuant to:* Rule 602 of the Commission's Rules of Practice and Procedure, 18 CFR 385.602.

h. *Applicant Contact:* Mr. Randal Livingston, Lead Director, Hydro Generation Department, Pacific Gas and Electric Company, P.O. Box 770000, N11C, San Francisco, CA 94177, (415) 973–6950.

i. *FERC Contact:* Any questions concerning this notice should be addressed to John Mudre, e-mail address *john.mudre@ferc.gov*, or telephone (202) 502–8902.

j. *Deadline for Filing Comments:* The deadline for filing comments on the settlement agreement is November 1, 2004.[1] Reply comments are due December 1, 2004.

All documents (original and eight copies) should be filed with: Magalie R. Salas, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

The Commission's Rules of Practice require all intervenors filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

[1] Comments on the settlement agreement may be combined or filed jointly with comments on the Commission's September 2004 draft Environmental Impact Statement for this proceeding, which presents staff's analysis of the settlement agreement. Those comments are also due on November 1, 2004.

Comments may be filed electronically via the Internet in lieu of paper. The Commission strongly encourages electronic filings. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site (*http://www.ferc.gov*) under the "e-Filing" link.

k. Pacific Gas and Electric Company filed the Settlement Agreement on behalf of itself and the U.S. Department of Agriculture Forest Service (FS), the California Department of Fish and Game, American Whitewater, Plumas County, Chico Paddleheads, Shasta Paddlers, Mountain Meadows Conservancy, and the California Sportfishing Protection Alliance. The purpose of the Settlement Agreement is to resolve among the signatories all lake level and streamflow issues for ecological purposes, river-based recreational uses, and other resolved subjects in support of FS issuing its recommended conditions and the Commission issuing a new project license. Water temperature issues and the term of license were not resolved by the Settlement Agreement.

l. A copy of the settlement agreement is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the "eLibrary" link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at 1–866–208–3676, or for TTY, (202) 502–8659. A copy is also available for inspection and reproduction at the address in item h above.

Register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via e-mail of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

m. *Procedural Schedule:* The application will be processed according to the following Hydro Licensing Schedule. Revisions to the schedule will be made as appropriate.

Comments on DEIS and Settlement Agreement: November 1, 2004.

Notice of the Availability of the FEIS: April 2005.

Linda Mitry,

Acting Secretary.

[FR Doc. E4–2299 Filed 9–21–04; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 11841–002—Alaska]

Energy Northwest; Notice of Site Visit

September 15, 2004.

Ketchikan Public Utility (KPU), applicant for the proposed Whitman Lake Hydroelectric Project (FERC No. 11841–002), will be hosting a site visit for the proposed project on November 4, 2004. The site visit is being conducted to provide all parties interested in the proposed project's licensing, an opportunity to view the location of existing project facilities and surrounding area and the proposed locations of project facilities to be constructed. Commission staff will be attending the site visit.

The Commission encourages all interested parties to participate. Details of the site visit follow:

Date and Time: November 4, 2004 at 11 a.m.

Location: Ketchikan Public Utilities Offices, 2930 Tongass Avenue, Ketchikan, AK 99901.

Due to the remote location of the reservoir, some hiking will be involved. Please dress accordingly. For further information or directions please contact Jennifer Soderstrom of KPU at (907) 225–1000.

Linda Mitry,

Acting Secretary.

[FR Doc. E4–2298 Filed 9–21–04; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[OECA–2004–0045; FRL–7817–3]

Agency Information Collection Activities: Proposed Collection; Comment Request; Region 7 Lead Education and Awareness Project in St. Louis, MO (Agency Information Collection), EPA ICR Number 2161.01

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) This notice announces that the EPA is planning to submit the following proposed Information Collection Request (ICR) to the Office of Management and Budget (OMB): Compliance Assistance Surveys for the Lessors and Lessees Sectors, EPA ICR Number 2161.01. This is a request for a new collection and this information request has no prior OMB Control Number. Before submitting the ICR to OMB for review and approval, the EPA is soliciting comments on specific aspects of the proposed information collection as described below.

DATES: Comments must be submitted on or before November 22, 2004.

ADDRESSES: Submit your comments, referencing docket ID number OECA–2004–0045, to EPA online using EDOCKET (our preferred method), by e-mail to *docket.oeca@epa.gov*, or by mail to: EPA Docket Center, Environmental Protection Agency, OECA Docket, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: Carolyn Scully, OECA Docket Center, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (202) 566–1752; e-mail address: *CarolynScully/DC/USEPA/US.*

SUPPLEMENTARY INFORMATION: EPA has established a public docket for this ICR under Docket ID number OECA–2004–0045, which is available for public viewing at the OECA Docket in the EPA Docket Center (EPA/DC), EPA West, Room B102, 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 Reading Room is (202) 566–1744, and the telephone number for the OECA Docket is (202) 566–1752. An electronic version of the public docket is available through EPA Dockets (EDOCKET) at *http://www.epa.gov/edocket.* Use EDOCKET to obtain a copy of the draft collection of information, submit or view public comments, access the index listing of the contents of the public 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 above.

Any comments related to this ICR should be submitted to EPA within 60 days of this notice. EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EDOCKET as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose public disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EDOCKET. The entire printed comment, including the copyrighted material, will be available in the public docket. Although identified as an item in the official docket, information claimed as CBI, or whose disclosure is otherwise restricted by statute, is not included in the official public docket, and will not be available for public viewing in EDOCKET. For further information about the electronic docket, see EPA's **Federal Register** notice describing the electronic docket at 67 FR 38102 (May 31, 2002), or go to *http://www.epa.gov/edocket.*

Affected Entities: Entities potentially affected by this action are the following:

- Lessors located in areas of high risk for lead poisoning in St. Louis, Missouri
- Lessees located in areas of high risk for lead poisoning in St. Louis, Missouri

Title: Region 7 Lead Education and Awareness Project in St. Louis, Missouri (Agency Information Collection); EPA ICR Number 2161.01.

Abstract: EPA Region 7 and the Office of Compliance (OC) within the Office of Enforcement and Compliance Assurance (OECA) are planning to conduct a performance baseline survey and follow-up survey for the Lessors and Lessees sectors. The OC is interested in having a baseline performance survey conducted and compliance assistance needs assessed for the Lessors sector. In addition, OC is interested in assessing the awareness and behavioral change of Lessees through a survey. There are three main purposes for these Lessor and Lessee surveys:

(1) To determine a baseline level of regulatory awareness of and compliance with the "Residential Lead-Based Paint Hazard Reduction Act of 1992" (Title X) and the "Requirements for Disclosure of Known Lead-Based Paint and/or Lead-Based Paint Hazards in Housing" rule (Disclosure Rule), from which to measure the success of the Agency's compliance outreach efforts for reporting under the Government Performance and Results Act (GPRA). For key sectors for which EPA is planning to initiate compliance assistance, a baseline level of compliance and regulatory awareness is needed from which to measure future progress.

(2) To determine the effectiveness of the Department of Housing and Urban Development's (HUD) education and outreach efforts.

(3) To determine whether lessees are reading and understanding the *Protect Your Family From Lead In Your Home* pamphlet and whether they are implementing methods to reduce lead exposure as a result.

The EPA Region 7 is planning targeted Disclosure Rule inspections in high risk areas of St. Louis, Missouri during FY2005 and/or FY2006. The activities planned under the Statistically Valid Compliance Assistance Rate study are designed to determine the baseline rate of lessors' compliance with the Disclosure Rule and whether lessees are reading and understanding the *Protect Your Family From Lead In Your Home* pamphlet and implementing methods to reduce exposure to lead. The EPA would like to conduct statistically valid voluntary surveys with a sample size of approximately 150 respondents. These surveys will be used to establish a performance baseline at the start of the study. A follow-up survey will then be conducted to determine progress against the baseline.

The OECA has adopted a sector approach for many of its compliance assistance activities. The lessor sector is an example of a sector for which EPA has focused many of its compliance assistance activities. There is considerable debate as to the extent of regulatory compliance, the need for additional compliance assistance, and the effectiveness of compliance assistance methods and materials developed for this sector. The OECA would like to conduct a statistically valid voluntary survey and site-visit survey of a sample of lessor venues in areas of high risk for lead poisoning in St. Louis, Missouri to determine a performance snapshot of this sector which reflects current sector performance with respect to the Disclosure Rule. The surveys will be conducted as a voluntary blind sample (*i.e.*, the lessors' identities will be unknown to EPA and the lessors will participate voluntarily). The results of the survey will provide OECA with information on compliance assistance applicable to this sector and information from which to measure the success of OECA's compliance assistance programs for Government Performance and Results Act (GPRA) reporting purposes.

The EPA Region 7 will evaluate the need for educational outreach for an additional sector: lessees in areas of St. Louis, Missouri at high risk for lead poisoning. Sufficient data are not available in EPA's databases to evaluate the current rate at which lessees are reading the EPA pamphlet, *Protect Your Family From Lead In Your Home*, and are implementing behavioral changes to reduce lead exposure as a result. Therefore, OECA is interested in determining:

- The level of regulatory awareness and compliance in the lessor sector;
- Areas of noncompliance and root causes of noncompliance;
- The need for compliance assistance for the lessor sector; and
- The need for educational outreach for the lessee sector.

The OECA is soliciting comment on whether to conduct a statistically valid voluntary survey and site-visit survey of a sample of lessors and a site-visit survey of a sample of lessees in high risk areas of St. Louis.

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 are listed in 40 CFR part 9 and 48 CFR chapter 15.

The EPA would like to solicit comments 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).

Burden Statement: The baseline surveys being requested are one-time information collections. The public reporting burden for this collection of information is estimated to average:

- 1.5 hours per respondent.

"Burden" means the total time, effort, or financial resources expended by persons to generate, maintain, retain, and 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.

Respondents/Affected Entities: Lessors conducting business in areas of high risk for lead poisoning in St. Louis, Missouri; Lessees living in areas of high risk for lead poisoning in St. Louis, Missouri.

Estimated Number of Respondents: Approximately 150 respondents in areas of high risk for lead poisoning in St. Louis, Missouri.

Frequency of Response: Twice (EPA Region 7 will conduct a follow-up survey in FY 2007).

Estimated Total Annual Hour Burden: 225 hours.

Estimated Total Annualized Cost Burden: $10,715.

Dated: September 10, 2004.

William A. Spratlin,

Director, Air, RCRA, and Toxics Division, U.S. Environmental Protection Agency, Region 7.

Draft List of Data Elements To Be Included in Collection of Information

Landlord Questions

- Did you provide the tenant with a copy of the pamphlet, *Protect Your Family From Lead In Your Home* before you rented the housing unit to them?
- Did you provide the tenant with a copy of the Lead Warning Statement before you rented the housing unit to them?
- Do you have records and/or reports regarding lead-based paint for the housing unit rented to the tenant? **If yes,** did you provide the tenants with a copy of the records and/or reports regarding lead-based paint for the housing unit rented to the tenant before you rented the housing unit to them?
- Did you complete a disclosure form and have the tenants sign and date it before you rented the housing unit to them?

Tenant Questions

- Did you receive the pamphlet, *Protect Your Family From Lead In Your Home* from the landlord before you rented the housing unit? **If yes,** did you read the pamphlet, *Protect Your Family From Lead In Your Home?* **If yes,** did you make behavior changes because of reading the pamphlet, *Protect Your Family From Lead In Your Home?*

[FR Doc. 04–21285 Filed 9–21–04; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7816–4]

Protection of Stratospheric Ozone: Letter of Clarification on Request for Information on Existing and Available Stocks of Methyl Bromide

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability of letter of clarification and extension of deadline.

SUMMARY: With this notice, EPA is informing individuals or legal entities that produce, import, distribute, sell, apply, or buy methyl bromide of a letter available on EPA's Web site at *http://www.epa.gov/ozone/mbr* that clarifies that nature and scope of information sought by the Agency in the Section 114 Information Request published in the **Federal Register** on August 25, 2004 (69 FR 52403). As a result of the clarifications provided by the Agency, EPA has agreed to extend the deadline for submission of the required data to October 14, 2004.

The request is for information on the amount of methyl bromide material held in inventory for sale or transfer. EPA needs this information to promulgate a rule to allow for the continued production, consumption, and use of methyl bromide for proposed critical uses exempted from the January 1, 2005 phaseout of methyl bromide. This exemption for critical uses is allowed under section 604 of the Clean Air Act (CAA) and the *Montreal Protocol on Substances that Deplete the Ozone Layer* ("Montreal Protocol").

DATES: The deadline for submission of the required data is October 14, 2004.

FOR FURTHER INFORMATION CONTACT: For further information about this information request, contact Hodayah Finman by telephone at (202) 343–9246, or by e-mail at *finman.hodayah@epa.gov*, or by mail at Hodayah Finman, U.S. Environmental Protection Agency, Stratospheric Protection Division, Stratospheric Program Implementation Branch (6205J), 1200 Pennsylvania Avenue, NW., Washington, DC, 20460. Overnight or courier deliveries should be sent to 1310 L Street, NW., Washington, DC, 20005, Attn: Hodayah Finman at 343–9410. You may also visit the Methyl Bromide Phaseout web site of EPA's Stratospheric Protection Division at *http://www.epa.gov/ozone/mbr* for further information about this request for information.

Dated: September 14, 2004.

Drusilla Hufford,

Director, Stratospheric Protection Division.

[FR Doc. 04–21188 Filed 9–21–04; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2004–0033; FRL–7675–4]

Rodenticides; Availability of Revised Comparative Ecological Risk Assessment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notices announces the availability of the revised comparative ecological risk assessment and related documents for nine rodenticides, which includes those addressed in the Reregistration Eligibility Decisions (REDs) for zinc phosphide and the rodenticide cluster (brodifacoum, bromadiolone, bromethalin, chlorophacinone, and diphacinone), as well as three other rodenticides, warfarin, difethialone, and cholecalciferol. This notice also opens a 60–day public participation period during which the public is encouraged to submit risk management ideas or proposals. These actions are designed to further efforts to engage stakeholders in a dialogue on risk reduction and risk management.

DATES: Comments, identified by docket identificationnumber OPP–2004–0033, must be received by EPA on or before November 22, 2004.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Kelly White, Special Review and Reregistration Division (7508C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–8401; e-mail address: *white.kelly@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. Nevertheless, a wide range of stakeholders will be interested in obtaining the revised risk assessments and submitting risk management comments on these nine rodenticides, including environmental, human health, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the use of pesticides. As such, the Agency has not attempted to specifically describe all of the entities potentially affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket ID number OPP–2004–0033. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing 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.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at *http://www.epa.gov/fedrgstr/*. In addition, copies of the revised comparative ecological risk assessment for nine rodenticides may also be accessed at *http://www.epa.gov/rodenticidecluster/*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select "search," then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing

in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the Docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

C. How and to Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked "late." EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically.* If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. 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.

i. *EPA Dockets.* Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at *http://www.epa.gov/edocket/*, and follow the online instructions for submitting comments. Once in the system, select "search," andthen key in docket ID number OPP–2004–0033. The system is an "anonymous access" system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail.* Comments may be sent by e-mail to *opp-docket@epa.gov*, Attention: Docket ID number OPP–2004–0033. In contrast to EPA's electronic public docket, EPA's e-mail system is not an "anonymous access" system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM.* You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail.* Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001, Attention: Docket ID number OPP–2004–0033.

3. *By hand delivery or courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA, Attention: Docket ID number OPP–2004–0033. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

D. How Should I Handle CBI Information that I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any 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 version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

E. What Should I Consider as 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.

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. Provide specific examples to illustrate your concerns.

6. Offer alternative ways to improve the notice or collection activity.

7. Make sure to submit your comments by the deadline in this document.

8. 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.

II. What Action is EPA Taking in this Notice?

EPA is making available for public viewing the revised comparative ecological risk assessment and related documents for nine rodenticides, which includes those addressed in the Reregistration Eligibility Decisions (REDs) for zinc phosphide and the rodenticide cluster (brodifacoum, bromadiolone, bromethalin, chlorophacinone, diphacinone), as well as three other rodenticides, warfarin, difethialone, and cholecalciferol. Included among the documents being released to the public through this notice is EPA's response to comments on the preliminary comparative ecological risk assessment. The preliminary assessment was released to the public through a notice in the **Federal Register** on January 29, 2003 (FR 68 4468)(FRL–7280–6). Also being published is a memorandum summarizing the revisions to the preliminary comparative ecological risk assessment that are reflected in the revised assessment, and a document that details the use patterns of the nine rodenticide active ingredients.

The Agency notes that the comparative ecological risk assessment for the rodenticides is revised; however, further refinements may be appropriate. Risk assessment documents reflect only the work and analysis conducted as of the time they were produced and it is appropriate that, as new information becomes available and/or additional analyses are performed, the conclusions they contain may change.

This notice begins a 60–day public participation period during which the public is encouraged to submit risk management proposals or otherwise comment on risk management for the nine rodenticides listed in this notice. Such comments and proposals could address ideas about how to manage ecological risks associated with particular uses of any of the nine rodenticides. For example, commenters may suggest ways to reduce environmental exposure, e.g., exposure to birds, fish, mammals, and other non-target organisms. During the comment period, stakeholders are also encouraged to comment on the document titled "Analysis of Rodenticide Bait Use" and/or to provide additional information related to the use and importance of these nine rodenticide products. The Agency recongnizes that there are public health and other benefits associated with the use of rodenticide baits, and will consider those benefits in reaching a risk management decision.

During the public comment period, EPA plans to work with the United States Department of Agriculture, the Centers for Disease Control and Prevention, the United States Fish and Wildlife Service, the National Marine Fisheries Service, the United States Department of Defense, and other interested stakeholders to identify and propose mitigation measures to reduce risks while maintaining the key benefits of the rodenticides. If you wish to participate in this process, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**. Failure to participate or comment as part of this opportunity will in no way prejudice or limit a commenter's opportunity to participate fully in later notice and comment processes. All comments and proposals must be received by EPA on or before November 22, 2004 at the addresses given under the **ADDRESSES** section. Comments and proposals will become part of the Agency record for each rodenticide to which it pertains.

List of Subjects

Environmental protection, Chemicals, Pesticides and pests.

Dated: August 25, 2004.

Debra Edwards,

Director, Special Review and Reregistration Division, Office of Pesticide Programs.

[FR Doc. 04–21068 Filed 9–21–04; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2004–0261; FRL–7678–5]

Desmedipham; Tolerance Reassessment Decision for Low Risk Pesticide; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the availability of EPA's Tolerance Reassessment Decision (TRED) for desmedipham, and opens a public comment period on this document, related risk assessments, and other support documents. EPA has reviewed the low risk pesticide desmedipham through a modified, highly streamlined version of the public participation process that the Agency uses to involve the public in developing pesticide tolerance reassessment and reregistration decisions. Through the tolerance reassessment program, EPA is ensuring that all pesticides meet current health and food safety standards.

DATES: Comments, identified by docket ID number OPP–2004–0261, must be received on or before November 22, 2004.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Nathan Mottl, Special Review and Reregistration Division (7508C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–0208; fax number: (703) 308–7042; e-mail address: *mottl.nathan@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including environmental, human health, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP–2004–0261. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing 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.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at*http://www.epa.gov/fedrgstr/.*

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select "search," then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

C. How and to Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked "late." EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically.* If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. 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.

i. *EPA Dockets.* Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at*http://www.epa.gov/edocket/*, and follow the online instructions for submitting comments. Once in the system, select "search," and then key in docket ID number OPP–2004–0261. The system is an "anonymous access" system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail.* Comments may be sent by e-mail to*opp-docket@epa.gov*, Attention: Docket ID Number OPP–2004–0261. In contrast to EPA's electronic public docket, EPA's e-mail system is not an "anonymous access" system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM.* You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail.* Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001, Attention: Docket ID Number OPP–2004–0261.

3. *By hand delivery or courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA, Attention: Docket ID Number OPP–2004–0261. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

D. How Should I Submit CBI to the Agency?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, 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 CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

In addition to one complete version of the comment that includes any 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 and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

E. What Should I Consider as 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.
2. Describe any assumptions that you used.
3. Provide 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 your estimate.
5. Provide specific examples to illustrate your concerns.
6. Offer alternatives.
7. Make sure to submit your comments by the comment period deadline identified.
8. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your response. It would also be helpful if you provided the name, date, and **Federal Register** citation related to your comments.

II. Background

A. What Action is the Agency Taking?

EPA has reassessed the uses of desmedipham, reassessed two existing tolerances or legal residue limits, and reached a tolerance reassessment decision for the low risk pesticide. The Agency is issuing for comment the resulting Report on Food Quality Protection Act (FQPA) Tolerance Reassessment Progress and Risk Management Decision for Desmedipham, known as a TRED, as well as related risk assessments and technical support documents.

Desmedipham is currently registered for use as a selective post-emergence herbicide on sugar beets. Desmedipham is formulated only as an active ingredient in emulsifiable concentrates and wettable powders. Permanent tolerances are established for desmedipham residues in/on sugar beet roots and tops under 40 CFR 180.353(a). Time-limited tolerances established in conjunction with a section 18 emergency exemption had been established for desmedipham residues in red beet roots and tops under 40 CFR 180.353(b).

EPA developed the Desmedipham TRED through a modified, streamlined version of its public process for making tolerance reassessment and reregistration eligibility decisions. Through these programs, the Agency is ensuring that pesticides meet current standards under the Federal Food, Drug, and Cosmetic Act (FFDCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended by FQPA. EPA must review tolerances and tolerance exemptions that were in effect when the FQPA was enacted, to ensure that these existing pesticide residue limits for food and feed commodities meet the safety standard established by the new law. Tolerances are considered reassessed once the safety finding has been made or a revocation occurs. EPA has reviewed and made the requisite safety finding for the desmedipham tolerances included in this notice.

EPA is applying the principles of public participation to all pesticides undergoing reregistration and tolerance reassessment. The Agency's Pesticide Tolerance Reassessment and Reregistration; Public Participation Process, published in the **Federal Register** of May 14, 2004 (FR 68 26819) (FRL–7357–9), explains that in conducting these programs, the Agency is tailoring its public participation process to be commensurate with the level of risk, extent of use, complexity of issues, and degree of public concern associated with each pesticide. EPA can expeditiously reach decisions for pesticides like desmedipham, which pose no risk concerns, have low use, affect few if any stakeholders, and require no risk mitigation. Once EPA assesses uses and risks for such pesticides, the Agency may go directly to a decision and prepare a document summarizing its findings. The Agency therefore is issuing the low risk Desmedipham TRED, risk assessments, and related documents simultaneously for public comment.

The tolerance reassessment program is being conducted under Congressionally mandated time frames, and EPA recognizes the need both to make timely decisions and to involve the public in finding ways to effectively mitigate pesticide risks. Desmedipham, however, poses no risks that require mitigation. The Agency therefore is issuing the Desmedipham TRED, its risk assessments, and related support documents simultaneously for public comment. The comment period is intended to provide an opportunity for public input and a mechanism for initiating any necessary amendments to the TRED. All comments should be submitted using the methods in Unit I. of the **SUPPLEMENTARY INFORMATION**, and must be received by EPA on or before the closing date. These comments will become part of the Agency Docket for desmedipham. Comments received after the close of the comment period will be marked "late." EPA is not required to consider these late comments.

EPA will carefully consider all comments received by the closing date and will provide a Response to Comments Memorandum in the Docket and electronic docket. If any comment significantly affects the document, EPA also will publish an amendment to the TRED in the **Federal Register**. In the absence of substantive comments requiring changes, the decisions reflected in the TRED will be implemented as presented.

B. What is the Agency's Authority for Taking this Action?

Section 408(q) of the FFDCA, 21 U.S.C. 346a(q), requires EPA to review tolerances and exemptions for pesticide residues in effect as of August 2, 1996, to determine whether the tolerance or exemption meets the requirements of section 408(b)(2) or (c)(2) of FFDCA. This review is to be completed by August 3, 2006.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: September 8, 2004.

Debra Edwards,

Director, Special Review and Reregistration Division, Office of Pesticide Programs.

[FR Doc. 04–21190 Filed 9–21–04; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7817–2]

Final National Pollutant Discharge Elimination System (NPDES) General Permit for Offshore Oil and Gas Exploration, Development and Production Operations Off Southern California

AGENCY: Environmental Protection Agency (EPA), Region 9.

ACTION: Notice of final permit issuance.

SUMMARY: EPA, Region 9 is today issuing a final general NPDES permit (permit No. CAG280000) for discharges from offshore oil and gas exploration, development and production facilities located in Federal waters off the coast of Southern California. The general permit establishes effluent limitations, prohibitions, and other conditions for discharges from platforms that engage in such operations within the geographic coverage area of the general permit. The general permit applies to 22 existing development and production platforms as well as to any new exploratory drilling operations located in and discharging to specified lease blocks on the Pacific Outer Continental Shelf offshore Southern California.

EPA is issuing this general permit to replace existing permits for the 22 platforms, some of which have been in place for many years. Today's general permit will achieve significant environmental benefits compared to the existing permits. In particular, the permit incorporates effluent limitation guidelines promulgated by EPA in 1993 for this industry, which have already been implemented for other offshore oil and gas platforms in the United States. In addition, the permit provides for a one-year study which will be used by EPA to determine whether additional limits are necessary in the future to ensure compliance with water quality standards.

DATES: The permit is being issued pursuant to 40 CFR 124.15 on September 22, 2004. The effective date of the permit is December 1, 2004, which is the first day of the month that begins at least 45 days after the date of the **Federal Register** notice of final permit issuance.

ADDRESSES: The final general permit and other related documents in the administrative record are on file and may be inspected any time between 8:30 a.m. and 4 p.m., Monday through Friday, excluding legal holidays, at the following address: U.S. EPA, Region 9, CWA Standards and Permits Office (WTR–5), 75 Hawthorne Street, San Francisco, CA 94105–3901.

FOR FURTHER INFORMATION CONTACT: Eugene Bromley, EPA, Region 9, CWA Standards and Permits Office (WTR–5), 75 Hawthorne Street, San Francisco, California 94105–3901, or telephone (415) 972–3510. Copies of the final general permit, Addendum to Fact Sheet and the Response to Public Comments will be provided upon request and are also available at EPA, Region 9's Web site at *http://www.epa.gov/region09/water/*.

SUPPLEMENTARY INFORMATION:

A. Proposed General Permit

On July 20, 2000, EPA proposed to issue a general permit for discharges from oil and gas exploration, development, and production operations in Federal waters offshore of the State of California. The proposed permit contained effluent limitations based on EPA's 1993 effluent limitation guidelines for the offshore subcategory of the oil and gas extraction point source category (40 CFR part 435) as well as other terms and conditions, including a provision that would require permittees to sample produced water discharges for purposes of a future determination whether the discharges had the reasonable potential to cause or contribute to an exceedance of Federal water quality criteria (adopted under Clean Water Act section 304(a)) applied 100 meters from the platform's point of discharge. As required by the Coastal Zone Management Act (CZMA), EPA submitted a certification to the California Coastal Commission (CCC) that the general permit was consistent with the California Coastal Management Plan (CMP) approved by the National Oceanic and Atmospheric Administration (NOAA) in 1978.

After reviewing the proposal and EPA's consistency determination, the CCC requested that, for purposes of analyzing samples of produced water discharges to determine reasonable potential to exceed a water quality standard, dilution be calculated based on Federal water quality criteria and California Ocean Plan (COP) objectives (both applied at the boundary of the 100-meter mixing zone). Additionally, the CCC requested that EPA revise the scope and timing of the study requirements in the permit for alternative disposal for certain discharges and include in the fact sheet a description of a commitment by EPA regarding third party monitoring. On the condition that EPA made these changes in the final general permit and fact sheet, the CCC concurred that the permit was consistent with the CMP.

On December 10, 2003, EPA submitted a revised proposed general permit to the CCC, along with a certification by EPA that the revised proposed permit was consistent with the CMP. For produced water discharges, EPA proposed a revision to the requirement that each permittee sample produced water discharges for certain, specified constituents in order to determine whether the discharges cause, have the reasonable potential to cause, or contribute to an exceedance above the applicable water quality criteria. For each constituent, EPA proposed that the facility include a determination of the minimum dilution limit required for each discharge location to ensure no reasonable potential to cause or contribute to an exceedance of the Federal water quality criteria at a point 100 meters from the platform's point of discharge or the California Ocean Plan (COP) criteria (adopted by California under Clean Water Act section 303(c)) at the seaward boundary of California's territorial seas. EPA would then review the results of each facility's sampling, evaluate the information for the potential to cause an exceedance of the applicable water quality criteria, and propose any appropriate new limits for the general permit pursuant to the procedures in 40 CFR part 124. On March 17, 2004, the CCC objected to EPA's consistency certification. On April 8, 2004, EPA proposed a revised general permit consistent with the December 10, 2003, certification to the CCC.

The CCC objected to EPA's proposed revision of the reasonable potential study provision and recommended that, after EPA received and reviewed the results of the study, the permit should be modified to require produced water discharges to comply with either the COP criteria or EPA's CWA section 304(a) criteria, whichever was determined to be more stringent, at a point of compliance located 100 meters from each platform's point of discharge. In today's action, EPA is issuing the general permit with the changes requested by the CCC, for the reasons described in this notice.

B. Final Permit Provisions

EPA proposed the general permit on July 20, 2000 (65 FR 45063), and solicited public comment from July 20, 2000, through September 5, 2000. In addition, EPA held a public hearing on the proposed permit on August 23, 2000. On April 8, 2004, EPA proposed certain modifications to the July 2000 proposed permit and sought public

comment on such modifications (69 FR 18570). EPA has included additional relevant documents in the administrative record for this permit, including responses to comments received on the July 20, 2000, proposed permit as well as the revisions proposed in April 2004.

1. Reasonable Potential Study/Point of Compliance

EPA is revising the reasonable potential study provisions proposed in April 2004. Specifically, today's permit requires each permittee to sample produced water discharges for certain, specified constituents in order to determine whether the discharges cause, have the reasonable potential to cause, or contribute to an exceedance above the more stringent of the Federal and COP criteria, compared at a point of compliance 100 meters from each facility's point of discharge. For each constituent, the minimum dilution must be calculated for each discharge location to ensure no reasonable potential to cause or contribute to a water quality standard exceedance and submit the results to EPA.

EPA will then review the results of each facility's sampling and evaluate the information, and following such review, EPA intends to propose appropriate modifications to the general permit pursuant to the procedures in 40 CFR part 124 to establish new effluent limitations based on the review of the study results.[1] EPA is including this reasonable potential study point of compliance provision in the general permit as a consequence of the CCC's March 17, 2004, objection to EPA's proposed decision to apply the COP criteria at the seaward boundary of State waters for purposes of the reasonable potential study dilution calculation.

EPA will, at the time of permit modification after completion of the study, consider new information relevant to the provision in the final general permit for produced water discharges which requires that each permittee use a point 100 meters from its platform's point of discharge to determine whether there is reasonable potential to cause or contribute to exceedances of either EPA or COP criteria. The final permit provides that EPA will reopen the permit after completion of the reasonable potential study and will modify the permit to establish permit conditions based on the outcome of that study. EPA will provide the public with notice and an opportunity to comment on any such modification, as required by 40 CFR 124.5. If, as a result of the study, or for other reasons, there is new information relevant to the new limits proposed at that time, EPA will consider such information and determine whether and how the general permit should be modified.

The CZMA prohibits Federal agencies from granting a license or permit that is subject to the CZMA consistency certification requirement until the State has concurred with the certification. CZMA section 307(c)(3). Even though EPA continues to believe the permit proposed in April 2004 was fully consistent with the enforceable policies of the CMP, as described in our comments on the CCC Staff Report of March 2004, the CCC's objection to EPA's consistency certification effectively prevented EPA from issuing the permit under CZMA section 307(c)(3). Further, for the reasons described below, EPA is concerned that issuing the permit under CZMA section 307(c)(1) with a delayed effective date, as proposed in April 2004, could result in considerable delay in implementing the new permit. Moreover, issuing the permit under CZMA section 307(c)(3) is consistent with EPA's long-standing practice and the NOAA regulations.[2] As described in more detail below, EPA is including the requirement requested by the CCC in order to issue the permit now, make it effective on December 1, 2004, and thus ensure that the environmental benefits of the new permit are achieved as soon as possible.

EPA is including this provision in the permit in order to implement the more stringent permit limits as soon as possible. However, EPA continues to believe that the permit proposed in April 2004 would be consistent with the California CMP. EPA recognizes that the Federal consistency provisions of the CZMA apply to licenses for activities outside State waters, such as those addressed by today's General Permit, if it is reasonably foreseeable that such activities will affect the uses or resources of the State's coastal zone. However, EPA disagrees that the CZMA authorizes California to require that the discharges at issue in this General Permit comply with the COP criteria at the point of discharge in Federal waters. Moreover, EPA continues to believe that the permit proposed in April 2004 would be fully protective of California's coastal resources. As described in more detail in EPA's December 2003 consistency certification, EPA concluded that the proposed discharges would not cause unreasonable degradation of the marine environment, including its biological resources, or other adverse effects in California's coastal zone. *See* "Demonstration of Consistency of the Revised Draft General Permit with the California CMP," Enclosure D (enclosure with letter from Alexis Strauss, Water Division Director, EPA Region 9, to Peter Douglas, Executive Director, California Coastal Commission) Dec. 10, 2003.

EPA notes that the Agency cannot at this time predict whether any particular permittee's discharges will be found to have reasonable potential to cause or contribute to an exceedance of the applicable water quality criterion, nor can it predict the specific nature of any potential future permit modifications based on the results of the reasonable potential analysis described in today's permit, including whether the COP criteria or the Federal criteria will apply for any particular constituent. EPA will provide public notice of and seek public comment on any proposed permit modification, including permit limitations based on the Federal water quality criteria or COP criteria. 40 CFR 124.5 and 124.6.

2. Effective Date

Today's general permit will be effective on December 1, 2004, which is the first day of the month that begins at least 45 days after the date of the **Federal Register** notice of final permit issuance. Because of the significant and important environmental benefits that will be achieved by the general permit, EPA has determined that it is critical to make the permit effective as soon as possible and therefore is not finalizing the delayed effective date proposed on April 8, 2004. Instead, EPA is issuing the permit with an effective date of December 1, 2004.

In April 2004, EPA proposed to treat the permit as a Federal agency activity under CZMA Section 307(c)(1) and to modify the proposed effective date to allow the Agency to issue the permit but delay its effectiveness for a given facility until the facility sought and obtained from the CCC concurrence with the facility's certification that its discharges pursuant to the permit would be consistent with the CMP. As described above, the CCC objected to the permit as

[1] Part I.A.4 of the final permit provides that the permit may be modified at any time if new data would have justified different permit conditions at the time of issuance. Any permit modification would be conducted in accordance with 40 CFR 122.62 and 122.63 and 40 CFR part 124.

[2] The regulations governing Federal consistency review under the CZMA provide that general permit programs proposed by Federal agencies are subject to the regulations governing review of Federal agency activities, unless a Federal agency chooses to subject its general permit program to review under the regulations governing license or permit activities. *See* 15 CFR 930.31(d).

proposed at that time. Thus, pursuant to regulations implementing the CZMA, the permit would not have become effective for a particular discharger until after a considerable delay. Under the proposed approach, each facility would first prepare an individual certification that its discharges under the general permit would be consistent with the CMP. Each facility would then seek concurrence with its certification from the CCC. The CCC would consider each certification and, under the requirements of the State law governing the CCC's procedures, would hold a public hearing on each certification. *See* California Public Resources Code sections 30315 and 30320. After considering comments received, the CCC would decide whether to concur with or object to each certification. If the CCC objected to a facility's certification, the facility could appeal the objection to the Secretary of Commerce. *See* 15 CFR part 930, subpart H. In that event, the Secretary of Commerce would hear and decide the appeal under the procedures described at 15 CFR 930.125–930.130. The entire process described above, including a potential appeal to the Secretary of Commerce, could take as long as two to three years. In the meantime, the terms and conditions of the existing permits would continue in effect and the environmental benefits of the new permit conditions would be further postponed.

After considering the time involved in such a process and the potential delay in implementing the new general permit, EPA concludes that the approach proposed on April 8, 2004, would delay significant environmental benefits that will be achieved by the effluent limitations in today's general permit. In particular, the permit implements technology-based effluent limitations for conventional, non-conventional, and toxic pollutants based on EPA's effluent guidelines promulgated in March 1993, and EPA wants to avoid any further delay in achieving the environmental benefits of these effluent limitations. *See* 58 FR 12504 (March 4, 1993). Today's general permit offers substantial improvements over the present discharge requirements for the 22 platforms because it incorporates the more stringent 1993 EPA effluent limitations guidelines. For example, the 1993 guidelines reduce allowable discharges of oil and grease in produced water to 42 mg/l (daily maximum) and 29 mg/l (monthly average). In comparison the existing general permit includes a daily maximum limit of 72 mg/l and no monthly average limit.

The CCC has concurred with EPA's determination that today's general permit is consistent with the CMP. The CCC Executive Director confirmed in a letter to EPA dated July 19, 2004, that the January 9, 2001, CCC concurrence is still valid as long as EPA includes in the permit and the addendum to the fact sheet all the changes which EPA agreed to in 2001. Today's permit includes those changes. Therefore, permittees need not seek and obtain the CCC's concurrence with individual consistency certifications under 15 CFR 930.31(d) before applying for coverage under the general permit.

3. Other Issues

The April 8, 2004, proposed permit included a number of other proposed changes from the July 20, 2000, permit. These changes have been retained with no significant changes in the final permit. As proposed on April 8, 2004, today's final permit accelerates the schedule for produced water sampling for determining reasonable potential to exceed applicable water quality criteria. The final permit requires a total of 12 samples taken during the first year of the permit rather than 10 samples taken during the first 2½ years, as was required by the proposed permit of July 20, 2000. The final permit also retains the revised maximum discharge volumes for Platforms Harvest, Hermosa and Hidalgo (based on updated information from the operator) which had been proposed on April 8, 2004. Further, the final permit uses EPA's revised CWA 304(a) water quality criteria found in "National Recommended Water Quality Criteria: 2002 (EPA–822–R–02–047) and 68 FR 75507 (December 31, 2003) for purposes of the reasonable potential study's dilution calculation. The April 8, 2004, proposed permit also included a number of minor editorial changes, clarifications and other revisions based on comments which had been received since the proposal of July 20, 2000. These revisions have been retained in the final permit.

C. Permit Appeal Procedures

Within 120 days following notice of EPA's final decision for the general permit under 40 CFR 124.15, any interested person may appeal the permit in the federal Court of Appeals in accordance with section 509(b)(1) of the Clean Water Act (CWA). Persons affected by a general permit may not challenge the conditions of a general permit as a right in further Agency proceedings. They may instead either challenge the general permit in court, or apply for an individual permit as specified at 40 CFR 122.21 (and authorized at 40 CFR 122.28), and then petition the Environmental Appeals Board to review any condition of the individual permit (40 CFR 124.19).

D. Executive Order 12866

Under Executive Order 12866 (58 FR 51735 (October 4, 1993)) the Agency must determine whether the regulatory action is "significant" and therefore subject to Office of Management and Budget (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. OMB has exempted review of NPDES general permits under the terms of Executive Order 12866.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act (APA) or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

Issuance of an NPDES general permit is not subject to rulemaking requirements, under APA section 553 or any other law, and is thus not subject to the RFA requirements. The APA defines two broad, mutually exclusive categories of agency action—"rules" and "orders." Its definition of "rule" encompasses "an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency * * *" APA section 551(4). Its definition of "order" is residual: "a final disposition * * * of an agency in a

matter other than rule making but including licensing" APA section 551(6). The APA defines "license" to "include * * * an agency permit * * *" APA section 551(8). The APA thus categorizes a permit as an order, which by the APA's definition is not a rule. Section 553 of the APA establishes "rule making" requirements. The APA defines "rule making" as "the agency process for formulating, amending, or repealing a rule" APA section 551(5). By its terms, then, section 553 applies only to "rules" and not also to "orders," which include permits.

F. 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. UMRA uses the term "regulatory actions" to refer to regulations. (*See, e.g.*, UMRA section 201, "Each agency shall * * * assess the effects of Federal regulatory actions * * * (other than to the extent that such regulations incorporate requirements specifically set forth in law)"). UMRA section 102 defines "regulation" by reference to 2 U.S.C. 658 which in turn defines "regulation" and "rule" by reference to section 601(2) of the Regulatory Flexibility Act (RFA). That section of the RFA defines "rule" as "any rule for which the agency publishes a notice of proposed rulemaking pursuant to section 553(b) of the Administrative Procedure Act (APA)[we only need parentheses around APA], or any other law * * *."

As discussed in the RFA section of this notice, NPDES general permits are not "rules" under the APA and thus not subject to the APA requirement to publish a notice of proposed rule making. NPDES general permits are also not subject to such a requirement under the CWA. While EPA publishes a notice to solicit public comment on draft general permits, it does so pursuant to the CWA section 402(a) requirement to provide "an opportunity for a hearing." Thus, NPDES general permits are not "rules" for RFA or UMRA purposes.

G. Paperwork Reduction Act

The information collection required by this permit has been approved by Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, in submissions made for the NPDES permit program and assigned OMB control numbers 2040–0086 (NPDES permit application) and 2040–0004 (discharge monitoring reports).

Authority: Clean Water Act, 33 U.S.C. 1251 *et seq.*

Dated: September 15, 2004.

Alexis Strauss,

Director, Water Division, EPA Region 9.

[FR Doc. 04–21286 Filed 9–21–04; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL ACCOUNTING STANDARDS ADVISORY BOARD

Notice of Meetings for 2005

Board Action: Pursuant to 31 U.S.C. 3511(d), the Federal Advisory Committee Act (Pub. L. No. 92–463), as amended, and the FASAB Rules of Procedure, as amended in April, 2004, notice is hereby given that the Federal Accounting Standards Advisory Board (FASAB) will meet on the following dates in room 7C13 of the U.S. Government Accountability Office (GAO) Building (441 G Street NW) unless otherwise noted:

—Wednesday and Thursday, March 2 and 3, 2005
—Wednesday and Thursday, May 4 and 5, 2005
—Wednesday and Thursday, June 22 and 23, 2005
—Wednesday and Thursday, August 17 and 18, 2005
—Wednesday and Thursday, October 5 and 6, 2005
—Wednesday and Thursday, December 7 and 8, 2005

The purposes of the meetings are to discuss issues related to:

—FASAB's conceptual framework,
—Stewardship Reporting,
—Social Insurance,
—Natural Resources,
—Inter-entity Costs,
—Fiduciary Activities,
—Technical Agenda, and
—Any other topics as needed.

A more detailed agenda can be obtained from the FASAB Web site (*http://www.fasab.gov*) one week prior to each meeting.

Any interested person may attend the meetings as an observer. Board discussion and reviews are open to the public. GAO Building security requires advance notice of your attendance. Please notify FASAB of your planned attendance by calling 202–512–7350 at least one day prior to the respective meeting.

FOR FURTHER INFORMATION CONTACT: Wendy M. Comes, Executive Director, 441 G St., NW., Mail Stop 6K17V, Washington, DC 20548, or call (202) 512–7350.

Authority: Federal Advisory Committee Act. Pub. L. 92–463.

Dated: September 17, 2004.

Charles Jackson,

Federal Register Liaison Officer.

[FR Doc. 04–21251 Filed 9–21–04; 8:45 am]

BILLING CODE 1610–01–M

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Reviewed by the Federal Communications Commission, Comments Requested

September 14, 2004.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as required by the Paperwork Reduction Act (PRA) of 1995, Public Law No. 104–13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act that does not display a valid control number. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

DATES: Written Paperwork Reduction Act (PRA) comments should be submitted on or before November 22, 2004. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all Paperwork Reduction Act (PRA) comments to Les Smith, Federal Communications Commission, Room 1–A804, 445 12th Street, SW., Washington, DC 20554 or via the Internet to *Leslie.Smith@fcc.gov*.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection(s), contact Les

Smith at (202) 418–0217 or via the Internet at *Leslie.Smith@fcc.gov*.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0057.

Title: Application for Equipment Authorization, 47 CFR Sections 2.911, 2.913, 2.925, 2.926, 2.929, 2.932, 2.944, 2.960, 2.1033(a), and 2.1043.

Form Number: FCC 731.

Type of Review: Revision of currently approved collection.

Respondents: Business or other for profit entities.

Estimated Number of Respondents: 5,619.

Estimated Time per Response: 18 to 30 hours (average 24 hours).

Frequency of Response: Recordkeeping; On occasion reporting requirements.

Total Annual Burden: 134,856 hours.

Total Annual Costs: $1,124,000.

Privacy Act Impact Assessment: N.A.

Needs and Uses: On July 8, 2004, the Commission adopted a *Report and Order,* Modification of Parts 2 and 15 of the Commission's Rules for Unlicensed Devices and Equipment Approval, ET Docket No. 03–201, FCC 04–165. The change requires that all paper filings required in 47 CFR Sections 2.913(c), 2.926(c), 2.929(c), and 2.929(d) of the rules are outdated and now must be filed electronically via the Internet on FCC Form 731. The Commission believes that electronic filing speeds up application processing and supports the Commission in further streamlining to reduce cost and increase efficiency. Information on the procedures for electronically filing equipment authorization applications can be obtained from the Commission's rules, and from the Internet at: *https://gullfoss2.fcc.gov/prod/oet/cf/eas/index.cfm.*

Designated Telecommunications Certification Body (TCB). The number of responses and the response time is not expected to change, since the basic authorization process will not change. Respondents are only being required to file the same information electronically.

OMB Control Number: 3060–0934.

Title: Application for Equipment Authorization, 47 CFR Sections 2.913, 2.925, 2.926, 2.929, 2.932, 2.944, 2.960, 2.962, 2.1043, 68.160 and 68.162.

Form Number: FCC 731–TC.

Type of Review: Revision of currently approved collection.

Respondents: Business or other for profit entities.

Estimated Number of Respondents: 25.

Estimated Time per Response: 4 hours.

Frequency of Response: On occasion reporting requirements; Third party disclosure.

Total Annual Burden: 6,400 hours.

Total Annual Costs: $175,000.

Privacy Act Impact Assessment: N.A.

Needs and Uses: Under 47 CFR parts 2 and 15 of FCC Rules, certain equipment must comply with FCC technical standards before it can be marketed. Equipment that operates in the licensed service requires FCC Authorization under 47 CFR parts 2 and 68. Since its 1999 *Report and Order,* ET Docket No. 98–68, the FCC has permitted private sector firms or "Telecommunications Certification Body" (TCB) to approve equipment for marketing. TCBs are accredited by FCC recognized accrediting bodies, and then designated by the FCC to act on behalf of the Commission. TCBs may be designated based on the terms of established Mutual Recognition Agreements with foreign trade partners. TCBs may accept FCC Form 731–TC filings and evaluate the equipment's compliance with FCC Rules and technical standards. TCBs submit this information to the FCC via the Internet. On July 8, 2004, the Commission adopted a *Report and Order,* Modification of Parts 2 and 15 of the Commission's Rules for Unlicensed Devices and Equipment Approval, ET Docket No. 03–201, FCC 04–165. The change requires that all paper filings required in Sections 2.913(c), 2.926(c), 2.929(c), and 2.929(d) of the rules are outdated and now must be filed electronically via the Internet on FCC Form 731–TC. The Commission believes that electronic filing speeds up application processing and supports the Commission in further streamlining to reduce cost and increase efficiency. The number of responses and the response time is not expected to change, since the basic authorization process will not change. Respondents are only being required to file the same information electronically.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 04–21296 Filed 9–21–04; 8:45 am]

BILLING CODE 6712–10–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at *www.ffiec.gov/nic/.*

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than October 15, 2004.

A. Federal Reserve Bank of Dallas (W. Arthur Tribble, Vice President) 2200 North Pearl Street, Dallas, Texas 75201–2272:

1. First Financial Bankshares, Inc., Abilene, Texas; to acquire 100 percent of the voting shares of Southwestern Bancshares, Inc., Glen Rose, Texas, and thereby indirectly acquire voting shares of Southwestern Delaware Financial Corporation, Wilmington, Delaware, and First National Bank, Glen Rose, Texas.

2. First National Bank Group, Inc., Edinburg, Texas; to acquire 14.99 percent of the voting shares of Alamo Corporation of Texas, Alamo, Texas, and Alamo Corporation of Delaware, Wilmington, Delaware, and thereby indirectly acquire voting shares of Alamo Bank of Texas, Alamo, Texas.

Board of Governors of the Federal Reserve System, September 16, 2004.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 04–21294 Filed 9–21–04; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at *www.ffiec.gov/nic/*.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than October 15, 2004.

A. Federal Reserve Bank of St. Louis (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63166–2034:

1. The Peoples Holding Company, Tupelo, Mississippi; to merge with Heritage Financial Holding Corporation, Decatur, Alabama, and thereby indirectly acquire Heritage Bank, Decatur, Alabama.

B. Federal Reserve Bank of Kansas City (Donna J. Ward, Assistant Vice President) 925 Grand Avenue, Kansas City, Missouri 64198–0001:

1. Wilber Co., Wilber, Nebraska; to acquire 100 percent of the voting shares of Hickman Corporation, Hickman, Nebraska, and thereby indirectly acquire First State Bank, Lincoln, Nebraska, and to acquire 100 percent of the voting shares of Yutan Bancorp., Inc., Yutan, Nebraska, and thereby indirectly acquire Bank of Yutan, Yutan, Nebraska. In addition, Wilber Co., Wilber, Nebraska, has applied to engage in insurance agency activities in a town of less than 5,000 in population through the acquisition of Yutan Insurance Agency, Yutan, Nebraska, pursuant to section 225.28(b)(11)(iii)(A) of Regulation Y.

2. SSB Management LLC, Wilber, Nebraska; to acquire additional shares, for a total of 45.2 percent of the voting shares, of Wilber Co., Wilber, Nebraska, and thereby indirectly acquire Hickman Corporation, Hickman, Nebraska, and thereby indirectly acquire First State Bank, Lincoln, Nebraska; Yutan Bancorp., Inc., Yutan, Nebraska, and thereby indirectly acquire Bank of Yutan, Yutan, Nebraska. SSB Management LLC, also has applied to acquire Yutan Insurance Agency, Inc., Yutan, Nebraska, and thereby to indirectly engage in insurance activities in a town of less than 5,000 in population, pursuant to section 225.28(b)(iii)(A) of Regulation Y.

3. First National Johnson Bancshares, Inc. Johnson, Nebraska; to acquire additional voting shares, for a total of 12.9 percent of the voting shares of Wilber Co., Wilber, Nebraska, and thereby acquire shares of Hickman Corporation, Hickman, Nebraska, and First State Bank, Lincoln, Nebraska; Yutan Bancorp., Inc., Yutan, Nebraska, and thereby indirectly acquire Bank of Yutan, Yutan, Nebraska. First National Johnson Bancshares, Inc., also has applied to indirectly engage in insurance activities through the acquisition of Yutan Insurance Agency, Inc., Yutan, Nebraska, by Wilber Co., and thereby engage in insurance activities in a town of less than 5,000 in population, pursuant to section 225.28(b)(11)(iii)(A) of Regulation Y.

Board of Governors of the Federal Reserve System, September 16, 2004.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 04–21295 Filed 9–21–04; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL TRADE COMMISSION

[File No. 041 0106]

General Electric Company; Analysis To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair or deceptive acts or practices or unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the draft complaint that accompanies the consent agreement and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before October 14, 2004.

ADDRESSES: Comments should refer to "General Electric Company, File No. 041 0106," to facilitate the organization of comments. A comment filed in paper form should include this reference both in the text and on the envelope, and should be mailed or delivered to the following address: Federal Trade Commission/Office of the Secretary, Room H–159, 600 Pennsylvania Avenue, NW., Washington, DC 20580. Comments containing confidential material must be filed in paper form, as explained in the Supplementary Information section. The FTC is requesting that any comment filed in paper form be sent by courier or overnight service, if possible, because U.S. postal mail in the Washington area and at the Commission is subject to delay due to heightened security precautions. Comments filed in electronic form (except comments containing any confidential material) should be sent to the following email box: *consentagreement@ftc.gov*.

FOR FURTHER INFORMATION CONTACT: Sean Dillon, FTC, Bureau of Competition, 600 Pennsylvania Avenue, NW., Washington, DC 20580, (202) 326–3575.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46(f), and Section 2.34 of the Commission's Rules of Practice, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for September 15, 2004), on the World Wide Web, at *http://www.ftc.gov/os/2004/09/index.htm*. A paper copy can be obtained from the FTC Public Reference Room, Room 130–H, 600 Pennsylvania Avenue, NW., Washington, DC 20580, either in person or by calling (202) 326–2222.

Public comments are invited, and may be filed with the Commission in either paper or electronic form. Written comments must be submitted on or before October 14, 2004. Comments should refer to "General Electric Company, File No. 041 0106," to facilitate the organization of comments. A comment filed in paper form should include this reference both in the text and on the envelope, and should be mailed or delivered to the following address: Federal Trade Commission/ Office of the Secretary, Room H–159, 600 Pennsylvania Avenue, NW., Washington, DC 20580. If the comment contains any material for which confidential treatment is requested, it must be filed in paper (rather than electronic) form, and the first page of the document must be clearly labeled "Confidential." [1] The FTC is requesting that any comment filed in paper form be sent by courier or overnight service, if possible, because U.S. postal mail in the Washington area and at the Commission is subject to delay due to heightened security precautions. Comments filed in electronic form should be sent to the following email box: *consentagreement@ftc.gov*.

The FTC Act and other laws the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. All timely and responsive public comments, whether filed in paper or electronic form, will be considered by the Commission, and will be available to the public on the FTC Web site, to the extent practicable, at *http://www.ftc.gov*. As a matter of discretion, the FTC makes every effort to remove home contact information for individuals from the public comments it receives before placing those comments on the FTC Web site. More information, including routine uses permitted by the Privacy Act, may be found in the FTC's privacy policy, at *http://www.ftc.gov/ftc/privacy.htm*.

Analysis of Agreement Containing Consent Orders To Aid Public Comment

I. Introduction

The Federal Trade Commission has accepted, subject to final approval, an Agreement Containing Consent Orders from General Electric Company, which is designed to remedy the anticompetitive effects resulting from GE's acquisition of InVision Technologies, Inc. Under the terms of the Consent Agreement, GE will be required to divest InVision's nondestructive testing ("NDT") business, including InVision's YXLON NDT subsidiaries, within six months after the date GE signed the Consent Agreement. The Consent Agreement also includes an Order to Hold Separate and Maintain Assets that requires GE to preserve the YXLON NDT business as a viable, competitive, and ongoing operation until the divestiture is achieved.

The proposed Consent Agreement has been placed on the public record for thirty (30) days to solicit comments from interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the proposed Consent Agreement and the comments received and will decide whether it should withdraw from the proposed Consent Agreement or make it final.

Pursuant to a stock purchase agreement dated March 15, 2004, GE proposes to acquire InVision ("Proposed Acquisition"). The total value of the Proposed Acquisition is approximately $900 million. The Commission's Complaint alleges that the Proposed Acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. 45, by lessening competition in the U.S. market for the research, development, manufacture, and sale of certain types of x-ray NDT and inspection equipment, specifically: (1) Standard x-ray cabinets, (2) x-ray NDT and inspection systems equipped with automated defect recognition software ("ADR-capable x-ray systems"), and (3) x-ray generators capable of producing energy levels higher than 350 kilovolts ("high-energy x-ray generators").

II. The Parties

GE is a diversified technology and services company headquartered in Fairfield, Connecticut. GE is made up of a broad range of primary business units, each with its own divisions. GE Infrastructure, the business unit that proposes to acquire InVision, oversees the operations of GE's security and sensing, water technologies, and automation enterprises. Another business unit of GE, GE Inspection Technologies, designs, manufactures, and sells various NDT and inspection equipment, including x-ray, ultrasound and eddy current equipment under the Seifert, Pantak, Krautkramer and Hocking brand names. GE Inspection Technologies is headquartered in Hürth, Germany. The company's NDT and inspection products serve customers in the aerospace, energy, petrochemical and automotive industries.

Headquartered in Newark, California, InVision is the leading supplier of explosive detection systems ("EDS") to the U.S. government for civil aviation security. InVision's EDS devices are used at airports for screening checked passenger baggage. InVision also offers industrial NDT and inspection equipment through its YXLON subsidiary. YXLON, headquartered in Hamburg, Germany, was acquired by InVision in 2003. YXLON designs, manufactures and sells x-ray NDT and inspection equipment for use in a wide range of industries, including the aerospace, automotive, and security industries.

III. X-Ray NDT and Inspection Equipment

GE and InVision, through its YXLON subsidiary, are the two largest suppliers of x-ray NDT and inspection equipment in the United States. X-ray NDT and inspection equipment includes, among other products: (1) Standard x-ray cabinets; (2) ADR-capable x-ray systems; and (3) high-energy x-ray generators. X-ray NDT and inspection equipment is used to inspect the structure and tolerance of materials, or identify objects inside materials, without damaging the materials or impairing their future usefulness.

Standard x-ray cabinets are x-ray NDT and inspection systems with generic configurations and uniform prices. Standard x-ray cabinets are multi-purpose inspection systems, as opposed to customized systems that are designed for particular customer needs, or application-specific x-ray systems utilized for specific tasks such as tire or airbag inspection. A single standard x-ray cabinet is capable of inspecting a variety of products as diverse as, for example, metal die-castings, turbine engine parts, steel components, plastics and ceramics.

ADR-capable x-ray systems are inspection systems that utilize automated defect recognition, or ADR, software that completely automates the inspection process. Unlike traditional x-ray NDT and inspection systems that require a manual operator, ADR-capable x-ray systems eliminate the need to make subjective human decisions regarding the objects being inspected. The benefits of ADR-capable x-ray systems for customers are improved

[1] Commission Rule 4.2(d), 16 CFR 4.2(d). The comment must be accompanied by an explicit request for confidential treatment, including the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. The request will be granted or denied by the Commission's General Counsel, consistent with applicable law and the public interest. *See* Commission Rule 4.9(c), 16 CFR 4.9(c).

inspection quality, increased throughput and decreased labor costs.

High-energy x-ray generators are components of x-ray NDT and inspection systems that generate the power needed to produce an x-ray beam and display an x-ray image. There are different categories of x-ray generators that are distinguished by the amount of power they can produce. High-energy x-ray generators produce levels of power sufficient for x-rays to penetrate dense materials, such as steel, that other types of x-ray generators cannot produce.

Manufacturers and end users in a variety of industries use standard x-ray cabinets, ADR-capable x-ray systems, and high-energy x-ray generators for quality control and safety purposes. Purchasers of these products purchase the type of x-ray NDT and inspection equipment that is best-suited for their application and, because of the unique performance characteristics of each type of equipment, there is little opportunity to switch to alternative equipment. In fact, even a price increase of five to ten percent for standard x-ray cabinets, ADR-capable x-ray systems, or high-energy x-ray generators would not likely cause a significant number of customers for these products to switch to any alternative product.

The United States is the appropriate geographic market for standard x-ray cabinets, ADR-capable x-ray systems, and high-energy x-ray generators in which to analyze the competitive effects of the Proposed Acquisition. Because x-ray NDT and inspection equipment frequently needs to be serviced and repaired to ensure proper operation, customers purchase from suppliers with local service and support networks. Furthermore, customers purchase from companies with a proven reputation for accurate and reliable equipment, and are reluctant to switch to a new company that does not have a proven track record for providing such service and support. Foreign suppliers that have not established the necessary service and support networks, brand reputation, and customer acceptance in the United States are not effective competitors for U.S. customers and would not be able to constrain a price increase for standard x-ray cabinets, ADR-capable x-ray systems, or high-energy x-ray generators in the United States.

The U.S. markets for standard x-ray cabinets, ADR-capable x-ray systems, and high-energy x-ray generators are all highly concentrated. GE and InVision are the two largest suppliers in each of these markets. If the Proposed Acquisition is consummated, GE would become the dominant supplier in each of these markets. For many customers, GE and InVision are the top two choices when considering a supplier of standard x-ray cabinets, ADR-capable x-ray systems, or high-energy x-ray generators. By eliminating competition between these two leading suppliers, the Proposed Acquisition would allow GE to unilaterally exercise market power, thereby increasing the likelihood that purchasers of standard x-ray cabinets, ADR-capable x-ray systems, and high-energy x-ray generators would be forced to pay higher prices and that innovation in these markets would decrease.

Significant impediments to new entry exist in the U.S. markets for x-ray NDT and inspection equipment. First, a new entrant would need to devote significant time and expense researching and developing a product. Second, a new entrant must undertake the lengthy and costly process of establishing a track record of reliability for its product. This track record is critical to customers because x-ray NDT and inspection equipment is relied upon to ensure the quality, performance, and safety of their products. Finally, a new supplier of standard x-ray cabinets, ADR-capable x-ray systems, and high-energy x-ray generators would have to spend a great deal of time and money to develop a broad service and support network upon which customers can rely. For these reasons, new entry into the markets for standard x-ray cabinets, ADR-capable x-ray systems, and high-energy x-ray generators is not likely to occur in a timely manner even if prices increased substantially after the Proposed Acquisition. Additionally, new entry into these markets is unlikely because the costs of entering these markets are too high relative to the limited sales opportunities available to new entrants.

IV. The Consent Agreement

The Consent Agreement effectively remedies the Proposed Acquisition's anticompetitive effects in the U.S. markets for the research, development, manufacture, and sale of standard x-ray cabinets, ADR-capable x-ray systems, and high-energy x-ray generators by requiring GE to divest InVision's YXLON NDT business. Pursuant to the Consent Agreement, GE is required to divest the YXLON NDT business, including the YXLON NDT subsidiaries, to a buyer, at no minimum price, within six (6) months from the date GE signed the Consent Agreement. The acquirer of the YXLON NDT business must receive the prior approval of the Commission. The Commission's goal in evaluating possible purchasers of divested assets is to ensure that the competitive environment that existed prior to the acquisition is maintained. A proposed acquirer of divested assets must not itself present competitive problems.

Should GE fail to accomplish the divestiture within the time and in the manner required by the Consent Agreement, the Commission may appoint a trustee to divest these assets. If approved, the trustee would have the exclusive power and authority to accomplish the divestiture within six (6) months of being appointed, subject to any necessary extensions by the Commission. The Consent Agreement requires GE to provide the trustee with access to information related to the YXLON NDT business as necessary to fulfill his or her obligations.

The Order to Hold Separate and Maintain Assets that is included in the Consent Agreement requires that GE hold separate and maintain the viability of the YXLON NDT business as a competitive operation until the business is transferred to the Commission-approved acquirer. Furthermore, it contains measures designed to ensure that no material confidential information is exchanged between GE and the YXLON NDT business (except as otherwise provided in the Consent Agreement) and provisions designed to prevent interim harm to competition in each x-ray NDT and inspection equipment market pending divestiture. The Order to Hold Separate and Maintain Assets provides that the Commission may appoint a Hold Separate Trustee who is charged with the duty of monitoring GE's compliance with the Consent Agreement. Pursuant to that Order, the Commission has appointed Hartmut G. Grossmann of H. Grossmann Consulting LLC as Hold Separate Trustee to oversee the YXLON NDT business prior to its divestiture and to ensure that GE complies with its obligations under the Consent Agreement. Mr. Grossmann, who holds law degrees from both the United States and Germany, has more than 25 years of experience advising and managing companies both inside and outside of Germany. He has held several key management positions, including chief counsel, managing director, and chief operating officer, and during his professional career has developed experience related to corporate governance, litigation, business integration and restructuring, and regulatory compliance matters.

In order to ensure that the Commission remains informed about the status of the YXLON NDT business pending divestiture, and about the efforts being made to accomplish the divestiture, the Consent Agreement requires GE to file periodic reports with

the Commission until the divestiture is accomplished.

The purpose of this analysis is to facilitate public comment on the Consent Agreement, and is not intended to constitute an official interpretation of the proposed Decision and Order or the Order to Maintain Assets, or to modify their terms in any way.

By direction of the Commission, Commissioner Harbour recused, and Commissioner Leibowitz not participating.

Donald S. Clark,

Secretary.

[FR Doc. 04–21262 Filed 9–21–04; 8:45 am]

BILLING CODE 6750–01–P

GENERAL SERVICES ADMINISTRATION

[OMB Control No. 3090–0200]

General Services Administration Acquisition Regulation; Information Collection; Sealed Bidding

AGENCY: Office of the Chief Acquisition Officer, GSA.

ACTION: Notice of request for comments regarding a renewal to an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the General Services Administration will be submitting to the Office of Management and Budget (OMB) a request to review and approve a renewal of a currently approved information collection requirement regarding sealed bidding.

Public comments are particularly invited on: Whether this collection of information is necessary and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected.

DATES: Submit comments on or before: November 22, 2004.

FOR FURTHER INFORMATION CONTACT: Ms. Linda Nelson, Procurement Analyst, Contract Policy Division, at telephone (202) 501–1900 or via e-mail to *linda.nelson@gsa.gov.*

ADDRESSES: Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to the Regulatory Secretariat (V), General Services Administration, Room 4035, 1800 F Street, NW., Washington, DC 20405. Please cite OMB Control No. 3090–0200, Sealed Bidding, in all correspondence.

SUPPLEMENTARY INFORMATION:

A. Purpose

The General Services Administration is requesting that the Office of Management and Budget (OMB) review and approve information collection, 3090–0200, Sealed Bidding. The information requested regarding an offeror's monthly production capability is needed to make progressive awards to ensure coverage of stock items.

B. Annual Reporting Burden

Respondents: 10
Responses Per Respondent: 1
Hours Per Response: .5
Total Burden Hours: 5
Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat (V), 1800 F Street, NW., Room 4035, Washington, DC 20405, telephone (202) 208–7312. Please cite OMB Control No. 3090–0200, Sealed Bidding, in all correspondence.

Dated: September 9, 2004

Ralph DeStefano,

Acting Director, Contract Policy Division.

[FR Doc. 04–21228 Filed 9–21–04; 8:45 am]

BILLING CODE 6820–61–S

GENERAL SERVICES ADMINISTRATION

[OMB Control No. 3090–0007]

General Services Administration Acquisition Regulation; Information Collection; GSA Form 527, Contractor's Qualifications and Financial Information

AGENCY: Office of the Chief Finance Officer, GSA.

ACTION: Notice of request for comments regarding a renewal to an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the General Services Administration will be submitting to the Office of Management and Budget (OMB) a request to review and approve a renewal of a currently approved information collection requirement regarding GSA Form 527, Contractor's Qualifications and Financial Information.

Public comments are particularly invited on: Whether this collection of information is necessary and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected.

DATES: Submit comments on or before: November 22, 2004.

FOR FURTHER INFORMATION CONTACT: Michael J. Kosar, Accountant, Office of the Chief Financial Officer, Office of Finance, at (202) 501–2029 or via email at *mike.kosar@gsa.gov.*

ADDRESSES: Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to the Regulatory Secretariat (V), General Services Administration, Room 4035, 1800 F Street, NW., Washington, DC 20405. Please cite OMB Control No. 3090–0007, GSA Form 527, Contractor's Qualifications and Financial Information, in all correspondence.

SUPPLEMENTARY INFORMATION:

A. Purpose

The General Services Administration will be requesting the Office of Management and Budget to extend information collection 3090–0007, concerning GSA Form 527, Contractor's Qualifications and Financial Information. This form is used to determine the financial capability of prospective contractors as to whether they meet the financial responsibility standards in accordance with the Federal Acquisition Regulation (FAR) and the General Services Administration Acquisition Manual (GSAM).

B. Annual Reporting Burden

Respondents: 2,940
Responses Per Respondent: 1.2
Total Responses: 3,528
Hours Per Response: 2.5
Total Burden Hours: 8,820
Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat (V), 1800 F Street, NW., Room 4035, Washington, DC 20405, telephone (202) 208–7312. Please cite OMB Control No. 3090–0007, GSA Form 527, Contractor's Qualifications and Financial Information, in all correspondence.

Dated: September 15, 2004

Michael W. Carleton,

Chief Information Officer.

[FR Doc. 04–21229 Filed 9–21–04; 8:45 am]

BILLING CODE 6820–34–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Blood Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Blood Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on October 21, 2004, from 8 a.m. to 5:30 p.m. and on October 22, 2004, from 8:30 a.m. to 12:45 p.m.

Location: Holiday Inn Gaithersburg, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Linda A. Smallwood, Center for Biologics Evaluation and Research (HFM–302), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–3514, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014519516. Please call the Information Line for up-to-date information on this meeting.

Agenda: On October 21, 2004, the committee will hear updates on the following topics: Summary of the Transmissible Spongiform Encephalopathies Advisory Committee (TSEAC) meeting discussion of new variant Creutzfeldt-Jacob disease (vCJD) transmission by transfusion in the United Kingdom and supplemental testing for human immunodeficiency virus (HIV) and hepatitis C virus (HCV). In the morning, the committee will also discuss and provide recommendations on the agency's current thinking on re-entry of donors previously deferred for anti-HBc reactivity. In the afternoon, the committee will discuss and provide recommendations on the potential risk of transmission of Simian Foamy Virus (SFV) by blood transfusions. On October 22, 2004, the committee will hear updates on these topics: a summary of the Plasma Workshop held on August 31 through September 1, 2004, draft uniform donor health questionnaire acceptance guidance: review of public comments, and FDA current thinking on monitoring weight in source plasma donors. The committee will also hear presentations, discuss and provide recommendations on the agency's current thinking on donor deferral for potential or documented infection with West Nile Virus (WNV).

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by October 8, 2004. Oral presentations from the public will be scheduled between approximately 10:30 a.m. and 11 a.m., 4 p.m. and 4:30 p.m. on October 21, 2004, and between approximately 11 a.m. and 11:45 a.m. on October 22, 2004. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 8, 2004, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Linda A. Smallwood, or Pearline K. Muckelvene at 301–827–1281 at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 13, 2004.

Sheila Dearybury Walcoff,

Associate Commissioner for External Relations.

[FR Doc. 04–21283 Filed 9–21–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Measuring the Effectiveness of the Nation's Foodservice and Retail Food Protection System; Notice of Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; satellite downlink public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting (via satellite downlink) entitled "Measuring the Effectiveness of the Nation's Foodservice and Retail Food Protection System." The purpose of the meeting is to discuss the report entitled "FDA Report on the Occurrence of Foodborne Illness Risk Factors Within Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (2004)" (the 2004 Report) and to provide information to the public to improve food preparation practices and food employee behaviors at institutional food service establishments, restaurants, and retail food stores. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the 2004 Report.

DATES: The satellite downlink public meeting will be held on Wednesday, October 13, 2004, from 1 p.m. to 3 p.m., eastern standard time.

ADDRESSES: The public meeting will be broadcast nationwide from FDA's broadcast studio at the Center for Devices and Radiological Health (HFZ–260), 16071–B Industrial Dr., Gaithersburg, MD. Satellite coordinates for the broadcast will be posted on FDA's Web site at *http://www.fda.gov/cdrh/ocer/dcm/html/program_calendar.html* beginning September 15, 2004. See **SUPPLEMENTARY INFORMATION** for locations where the satellite downlink may be viewed.

FOR FURTHER INFORMATION CONTACT: Lakesha Abbey, Center for Food Safety and Applied Nutrition (HFS–625), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2440, FAX: 301–436–2672, e-mail: *Labbey@cfsan.fda.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA advises other Federal agencies, State, local, and tribal governments on food safety standards for institutional food service establishments, restaurants, retail food stores, and other retail food establishments. In this advisory role, FDA works closely with these agencies to provide guidance and assistance that will enhance the regulatory programs of Federal, State, local, and tribal jurisdictions.

The purpose of the 2004 Report is to present data on foodborne illness risk factors in institutional foodservice establishments, restaurants, and retail food stores. The results contained in the 2004 Report provide insight into the effectiveness of current industry management systems and food safety regulatory programs in controlling

foodborne illness risk factors in retail and foodservice operations. Using the data from multiple collection periods, FDA hopes to evaluate trends and determine if progress is being made toward the goals of reducing the occurrence of foodborne illness risk factors.

FDA will discuss the 2004 Report during the public meeting. The presentation will be available on FDA's Web site at *http://www.fda.gov* on the day of the satellite broadcast.

II. Registration

Persons interested in attending the satellite downlink public meeting as a member of the studio audience should send their registration information (including name, title, business affiliation, address, and telephone and fax numbers) to the contact person (see **FOR FURTHER INFORMATION CONTACT**). Due to space limitations, we recommend that you register at least 5 days prior to the meeting. Seating capacity is limited to 75 persons. Registration will be accepted on a first-come-first-served basis. There is no registration fee for this public meeting, but early registration is encouraged because space is limited, and it will expedite entry into the building and its parking area. If you are interested in attending as a member of the studio audience and need any reasonable accommodations due to a disability, including a sign language interpreter, please contact Lakesha Abbey by October 6, 2003.

III. Sites for Viewing the Downlink Public Meeting

The satellite broadcast can be received at any place that has access to a steerable C-ban satellite dish. Contact your state retail food protection office or local FDA office for locations where the satellite broadcast will be available.

A videotape copy of the satellite broadcast may be available at the location where it was viewed or through the contact person listed in this document (see **FOR FURTHER INFORMATION CONTACT**). You may also borrow a copy of the videotape through FDA's ORA–U Lending Library by sending your name and mailing address along with the name, title, and date of the broadcast to *ORADLT@ora.fda.gov*.

IV. Electronic Access

The 2004 report will be available electronically on FDA's Web site at *http://www.cfsan.fda.gov/~dms/retrsk2.html*.

Dated: September 16, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–21314 Filed 9–17–04; 4:06 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Transmissible Spongiform Encephalopathies Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Transmissible Spongiform Encephalopathies Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on October 14, 2004, from 8 a.m. to 5:30 p.m.

Location: Hilton Hotel, 8727 Colesville Rd., Silver Spring, MD 20910.

Contact Person: William Freas or Sheila D. Langford, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512392. Please call the Information Line for up-to-date information on this meeting.

Agenda: On October 14, 2004, the committee will hear updates on the following issues: USDA-licensed tests for the diagnosis of bovine spongiform encephalopathy (BSE) and other transmissible spongiform encephalopathies (TSE), review of the worldwide BSE situation, new FDA/Center for Food Safety and Applied Nutrition BSE-food safety rules, and labeling claims for TSE clearance studies for plasma derivative products. The committee will then discuss and make recommendations regarding presumptive transfusion transmissions of variant Creutzfeldt Jakob Disease (vCJD) and current FDA-recommended safeguards.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by October 5, 2004. Oral presentations from the public will be scheduled between approximately 9.20 a.m. and 9:50 a.m., and 2:45 p.m. and 3:15 p.m. on October 14, 2004. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 7, 2004, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact William Freas or Sheila D. Langford at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 15, 2004.

Sheila Dearybury Walcoff,

Associate Commissioner for External Relations.

[FR Doc. 04–21282 Filed 9–21–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Food and Drug Administration Report on the Occurrence of Foodborne Illness Risk Factors Within Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (2004); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a report entitled "FDA Report on the Occurrence of Foodborne Illness Risk Factors Within Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (2004)" (the 2004 Report). The 2004 Report summarizes results from a data collection conducted in 2003 on risk factors which have been identified as

contributing to foodborne illness in institutional foodservice establishments, restaurants, and retail food stores: food from unsafe sources; inadequate cooking; improper holding temperature; contaminated equipment; and poor personal hygiene.

DATES: Limited paper copies of the 2004 Report will be available beginning September 30, 2004.

ADDRESSES: Submit written requests for single copies of the 2004 Report to Lakesha Abbey, Center for Food Safety and Applied Nutrition (HFS–625), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the 2004 Report.

FOR FURTHER INFORMATION CONTACT: Lakesha Abbey, Center for Food Safety and Applied Nutrition (HFS–625), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2440, FAX: 301–436–2672, e-mail: *Labbey@cfsan.fda.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of the 2004 Report. The 2004 Report is the subject of a public meeting (via satellite downlink) which will be held on Wednesday, October 13, 2004, from 1 p.m. to 3 p.m., eastern standard time. Elsewhere in this issue of the **Federal Register**, FDA is announcing the satellite downlink public meeting. The 2004 Report summarizes results from a data collection conducted in 2003 on risk factors which have been identified as contributing to foodborne illness in institutional foodservice establishments, restaurants, and retail food stores; food from unsafe sources; inadequate cooking; improper holding temperature; contaminated equipment; and poor personal hygiene. A previous report presented data from a 1998 data collection on the same risk factors in institutional food-service establishments, restaurants, and retail food stores.

The two reports are FDA's response to a 1996 report entitled "Reinventing Food Regulations" issued under the National Performance Review, which concluded that foodborne illness caused by harmful bacteria and other pathogenic microorganisms in meat, poultry, seafood, dairy products, and a host of other foods is a significant public health problem in the United States. This 1996 report required Federal agencies to develop performance plans that included measurable goals and performance indicators which resulted in the study being reported.

In order to assess information associated with the occurrence of foodborne outbreaks and improve risk assessment capabilities, the level at which risky practices and behaviors occur had to be identified first. The 1998 data collection established a national baseline on the occurrence of foodborne disease risk factors within the retail segment of the food industry. The risk factors identified by the Centers for Disease Control and Prevention as contributing to foodborne illness that are being tracked are as follows: Food from unsafe sources, inadequate cooking, improper holding temperature, contaminated equipment, and poor personal hygiene.

The purpose of the 2004 Report is to present the second set of data from the 2003 data collection on risk factors in institutional foodservice establishments, restaurants, and retail food stores.

The 2004 Report is most useful when read and the data interpreted, as a separate stand alone report. As such, the 2004 report makes no attempt to draw comparisons between the results of the 1998 and 2003 data collections. Additional data are needed before any meaningful assessments of trends can be made for each of the facility types.

The results contained in the 2004 Report provide insight into the effectiveness of current industry management systems and food safety regulatory programs in controlling foodborne illness risk factors in retail and foodservice operations.

The data from the 1998 study, this project, and future studies planned for 2008 are expected to provide input into the Healthy People 2010's Food Safety Objective 10.6. This objective is designed to improve food preparation practices and food employee behaviors at institutional food-service establishments, restaurants, and retail food stores. Healthy People 2010 is a national health promotion and disease prevention initiative with the objective to improve the health of all Americans.

II. Electronic Access

The 2004 Report is available electronically on FDA's Web site at *http://www.cfsan.fda.gov/~dms/retrsk2.html.*

III. Satellite Downlink to Discuss the Report's Results

A satellite downlink public meeting will be held October 13, 2004, from 1 p.m. to 3 p.m., eastern standard time to discuss results in the report. The satellite broadcast can be received at any place that has access to a steerable C-band satellite dish. Satellite coordinates with instructions on how to downlink will be posted on FDA's Web site at *http://www.fda.gov/cdrh/ocer/dcm/html/program_calendar.html* beginning September 15, 2004.

Dated: September 16, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–21315 Filed 9–17–04; 4:06 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Progress Reports for Continuation Training Grants (OMB No. 0915–0061)—Extension

The HRSA Progress Reports for Continuation Training Grants are used for the preparation and submission of continuation applications for Titles VII and VIII health professions and nursing education and training programs. The Uniform Progress Report measures grantee success in meeting (1) the objectives of the grant project and (2) the cross-cutting outcomes developed for the Bureau's education and training programs. The progress report is designed to collect information to determine whether sufficient progress has been made on the approved project objectives, as grantees must demonstrate satisfactory progress to warrant continuation of funding. Information is also collected on activities specific to a given program as well as data on overall project performance related to the Bureau of Health Profession's strategic goals, objectives, outcomes and indicators. Progress will be measured based on the objectives of the grant project and outcome measures and

indicators developed by the Bureau to meet requirements of the Government Performance and Results Act (GPRA).

Estimates of annualized reporting burden are as follows:

Type of respondent	Number of respondents	Responses per respondent	Total responses	Minutes per response	Total burden hours
Grantees	1,550	1	1,550	21.5	33,325

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: John Kraemer, Health Resources and Services Administration, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: September 15, 2004.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 04–21221 Filed 9–21–04; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

[CFDA #93.926]

Maternal and Child Health Federal Set-Aside Program; Healthy Start Initiative, Closing the Health Gap Initiative on Infant Mortality: African American-Focused Risk Reduction

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of grant award.

SUMMARY: The Maternal and Child Health Bureau (MCHB), Health Resources and Services Administration (HRSA), awarded four cooperative agreements of $562,500 each, (for a total of $2.25 million) in fiscal year (FY) 2004, to four States: Illinois, Michigan, Mississippi, and South Carolina. The grants support the creation of evidence-based interventions and strategies to lower infant mortality among African Americans. The award was made from funds appropriated under Public Law 108–199 (Consolidated Appropriations Act, 2004). As part of HHS's overall appropriation, monies have been designated to support the Closing the Health Gap on Infant Mortality Initiative, under HRSA Guidance HRSA–04–097. The African American Initiative, to reduce low birthweight and SDS, was developed jointly by HRSA and the Acting Assistant Secretary for Health to address health disparities in States experiencing the highest mortality rates for African Americans.

Limited Competition Justification: The HRSA is providing Federal funds to lower infant mortality among African Americans in these four States based on their high rates of African American infant mortality; significant number of births to African Americans; their rank among the top States for highest percentage of African American births that are low birth weight (LBW); and their disproportionately high percentage of Sudden Infant Death Syndrome (SIDS) deaths among African Americans.

The funds are awarded to these four States so that they may work within a community that is committed to bring evidence-based practices to bear on the problem of high African American infant mortality rates caused by preterm birth (PTB), LBW, and SIDS. The cooperative agreements support strategies in each State that are culturally competent, represent a partnership between the State Title V agency and the local community; build on existing HHS or other funded programs; and employ one or more science-based approaches to African American infant mortality risk reduction. These agreements will also support the projects' evaluation of their progress according to specific goals and objectives.

Other Award Information: The Catalog of Federal Domestic assistance number is 93.926; HRSA Activity Code U–19.

FOR FURTHER INFORMATION CONTACT: Maribeth Badura, M.S.N., R.N., Division of Perinatal Systems and Women's Health, Maternal and Child Health Bureau, HRSA, 5600 Fishers Lane, Room 10–C–16, Rockville, MD 20857, (301) 443–0543.

Dated: September 15, 2004.

Elizabeth M. Duke,

Administrator.

[FR Doc. 04–21222 Filed 9–21–04; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program; List of Petitions Received

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) is publishing this notice of petitions received under the National Vaccine Injury Compensation Program ("the Program"), as required by Section 2112(b)(2) of the Public Health Service (PHS) Act, as amended. While the Secretary of Health and Human Services is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.

FOR FURTHER INFORMATION CONTACT: For information about requirements for filing petitions, and the Program in general, contact the Clerk, United States Court of Federal Claims, 717 Madison Place, NW., Washington, DC 20005, (202) 219–9657. For information on HRSA's role in the Program, contact Joyce Somsak, Acting Director, Division of Vaccine Injury Compensation Program, Special Programs Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Room 16C–17, Rockville, MD 20857; telephone number (301) 443–6593.

SUPPLEMENTARY INFORMATION: The Program provides a system of no-fault compensation for certain individuals who have been injured by specified childhood vaccines. Subtitle 2 of Title XXI of the PHS Act, 42 U.S.C. 300aa–10 *et seq.*, provides that those seeking compensation are to file a petition with the U.S. Court of Federal Claims and to serve a copy of the petition on the Secretary of Health and Human Services, who is named as the respondent in each proceeding. The Secretary has delegated his

responsibility under the Program to HRSA. The Court is directed by statute to appoint special masters who take evidence, conduct hearings as appropriate, and make initial decisions as to eligibility for, and amount of, compensation.

A petition may be filed with respect to injuries, disabilities, illnesses, conditions, and deaths resulting from vaccines described in the Vaccine Injury Table (the Table) set forth at Section 2114 of the PHS Act or as set forth at 42 CFR 100.3, as applicable. This Table lists for each covered childhood vaccine the conditions which will lead to compensation and, for each condition, the time period for occurrence of the first symptom or manifestation of onset or of significant aggravation after vaccine administration. Compensation may also be awarded for conditions not listed in the Table and for conditions that are manifested outside the time periods specified in the Table, but only if the petitioner shows that the condition was caused by one of the listed vaccines.

Section 2112(b)(2) of the PHS Act, 42 U.S.C. 300aa–12(b)(2), requires that the Secretary publish in the **Federal Register** a notice of each petition filed. Set forth below is a list of petitions received by HRSA on January 5, 2004, through March 30, 2004.

Section 2112(b)(2) also provides that the special master "shall afford all interested persons an opportunity to submit relevant, written information" relating to the following:

1. The existence of evidence "that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition," and

2. Any allegation in a petition that the petitioner either:

(a) "Sustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Table but which was caused by" one of the vaccines referred to in the Table, or

(b) "Sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table the first symptom or manifestation of the onset or significant aggravation of which did not occur within the time period set forth in the Table but which was caused by a vaccine" referred to in the Table.

This notice will also serve as the special master's invitation to all interested persons to submit written information relevant to the issues described above in the case of the petitions listed below. Any person choosing to do so should file an original and three (3) copies of the information with the Clerk of the U.S. Court of Federal Claims at the address listed above (under the heading **FOR FURTHER INFORMATION CONTACT**), with a copy to HRSA addressed to Joyce Somsak, Acting Director, Division of Vaccine Injury Compensation Program, Special Programs Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Room 16C–17, Rockville, MD 20857. The Court's caption (Petitioner's Name v. Secretary of Health and Human Services) and the docket number assigned to the petition should be used as the caption for the written submission.

Chapter 35 of title 44, United States Code, related to paperwork reduction, does not apply to information required for purposes of carrying out the Program.

List of Petitions

1. Krystyna Kane on behalf of Miriam Labib, Somers Point, New Jersey, Court of Federal Claims Number 04–0002V.

2. Lynette and Joseph Hasson on behalf of Izzy Jack Hasson, Washington, District of Columbia, Court of Federal Claims Number 04–0003V.

3. Robert C. Blair, III, Bluefield, Virginia, Court of Federal Claims Number 04–0004V.

4. Diane and Craig Arpino on behalf of Joseph Craig Arpino, Somers Point, New Jersey, Court of Federal Claims Number 04–0005V.

5. Kelley Tomczak and Christopher Sarli on behalf of Megan Sarli, Chicago, Illinois, Court of Federal Claims Number 04–0006V.

6. Shana and Allen Denenberg on behalf of Chase Denenberg, Philadelphia, Pennsylvania, Court of Federal Claims Number 04–0014V.

7. Hieu T. Doan and Phuoc H. Nguyen on behalf of Douglas Duc Nguyen, Temecula, California, Court of Federal Claims Number 04–0015V.

8. Ivy and Nathaniel Seeds on behalf of Evan Seeds, Temecula, California, Court of Federal Claims Number 04–0016V.

9. Christy and Eric Crider on behalf of Dylan Scott Crider, Temecula, California, Court of Federal Claims Number 04–0017V.

10. Brenda and Garth Bachman on behalf of Parker Allen Bachman, Temecula, California, Court of Federal Claims Number 04–0018V.

11. Amots Grosvirt-Dramen and Sigal Dramen on behalf of Adam Dramen, Temecula, California, Court of Federal Claims Number 04–0019V.

12. Dale Sader on behalf of Garrett Sader, Temecula, California, Court of Federal Claims Number 04–0020V.

13. Rosemarie Dombrowski on behalf of Brendan Wagner, Vienna, Virginia, Court of Federal Claims Number 04–0022V.

14. Erika Cababe, Las Vegas, Nevada, Court of Federal Claims Number 04–0024V.

15. Norieta and George Stephanos on behalf of Tanner Michael Stephanos, Houston, Texas, Court of Federal Claims Number 04–0025V.

16. Teotimo and Eleuteria Sosa on behalf of Joshua Alejandro Sosa, Houston, Texas, Court of Federal Claims Number 04–0026V.

17. Deanne Palmer, Sharon, Pennsylvania, Court of Federal Claims Number 04–0029V.

18. Shannon and William Albright on behalf of Taylor Albright, Pine Bluff, Arkansas, Court of Federal Claims Number 04–0030V.

19. Debbie and Michael Graves on behalf of Haley Graves, Dallas, Texas, Court of Federal Claims Number 04–0031V.

20. Denise and Todd Glover on behalf of Chance Glover, Dallas, Texas, Court of Federal Claims Number 04–0032V.

21. Randi and Craig Garfinkel on behalf of Jaden Garfinkel, Lake Success, New York, Court of Federal Claims Number 04–0039V.

22. Chrissy and Matt McNair on behalf of Luke McNair, Lake Success, New York, Court of Federal Claims Number 04–0040V.

23. Jill Robinson, Lexington, Kentucky, Court of Federal Claims Number 04–0041V.

24. Kimberlee and Glenn Leuz on behalf of Logan Leuz, Deceased, Meadowbrook, Pennsylvania, Court of Federal Claims Number 04–0042V.

25. Carmen Gail and Rodney Lee Phillips on behalf of Carson Anthony Phillips, Van Nuys, California, Court of Federal Claims Number 04–0043V.

26. Julianne Colon on behalf of Sierra Kendall Colon, Deceased, Perrysburg, Ohio, Court of Federal Claims Number 04–0044V.

27. Charmane Collins on behalf of Sharmarie Simmons, Holtsville, New York, Court of Federal Claims Number 04–0047V.

28. Roslyn Ewah on behalf of Bryant Akeiti, Holtsville, New York, Court of Federal Claims Number 04–0048V.

29. Roslyn Ewah on behalf of Brittany Akeiti, Holtsville, New York, Court of Federal Claims Number 04–0049V.

30. Laura Orozco-Cordero on behalf of Kevin Cordero, Decatur, Texas, Court of Federal Claims Number 04–0051V.

31. Marissa and David Leal on behalf of Daniel Leal, Decatur, Texas, Court of Federal Claims Number 04–0052V.

32. Nina Fabella on behalf of Lisa Maria Arellano, Decatur, Texas, Court of Federal Claims Number 04–0053V.

33. Luisa Salinas on behalf of Joseph Anthony Guitierrez, Decatur, Texas, Court of Federal Claims Number 04–0054V.

34. Julie Fuentes on behalf of Robbye Lea Ivey, Decatur, Texas, Court of Federal Claims Number 04–0055V.

35. Joe Fuentes on behalf of Brittany Fuentes, Decatur, Texas, Court of Federal Claims Number 04–0056V.

36. Martha and Francisco Luna on behalf of Sergio Enrique Luna, Decatur, Texas, Court of Federal Claims Number 04–0057V.

37. Alma Lozano on behalf of Pierre Lozano, Decatur, Texas, Court of Federal Claims Number 04–0058V.

38. Mathal Vasquez on behalf of Rafael Vasquez, Decatur, Texas, Court of Federal Claims Number 04–0059V.

39. Veronica and Francisco Perez on behalf of Luis Angel Perez, Decatur, Texas, Court of Federal Claims Number 04–0060V.

40. Karnella McMillan on behalf of Christopher White, Houston, Texas, Court of Federal Claims Number 04–0061V.

41. Vicki Kirby on behalf of Destiny Kirby, Chicago, Illinois, Court of Federal Claims Number 04–0062V.

42. Alejandro Villalobos on behalf of Rodolfo Villalobos, Boston, Massachusetts, Court of Federal Claims Number 04–0064V.

43. Ada Sepulveda on behalf of Darian Sepulveda, Brooklyn, New York, Court of Federal Claims Number 04–0066V.

44. Joanna and Marcus Kerner on behalf of Daniel Lewis Kerner, Trabuco Canyon, California, Court of Federal Claims Number 04–0072V.

45. Mary Ann and Keiffer Markley on behalf of Noah Markley, Reisterstown, Maryland, Court of Federal Claims Number 04–0073V.

46. Michelle Weaver on behalf of William Weaver, Boston, Massachusetts, Court of Federal Claims Number 04–0076V.

47. Stewart West on behalf of Jackson West, Boston, Massachusetts, Court of Federal Claims Number 04–0077V.

48. Melissa Hartman on behalf of Julia Hartman, Boston, Massachusetts, Court of Federal Claims Number 04–0078V.

49. Marianne Lasseigne on behalf of James Lasseigne, Boston, Massachusetts, Court of Federal Claims Number 04–0079V.

50. Luanne Helms on behalf of Jake Helms, Boston, Massachusetts, Court of Federal Claims Number 04–0080V.

51. Christine and Joseph Bolander on behalf of Katlyn Bolander, New York, New York, Court of Federal Claims Number 04–0081V.

52. Teresa and Irvin Stepp on behalf of Cammi Jo Stepp, Baton Rouge, Louisiana, Court of Federal Claims Number 04–0086V.

53. Kimberly Kelly and Mark Edmonds on behalf of Blake Edwards, Philadelphia, Pennsylvania, Court of Federal Claims Number 04–0087V.

54. Melanie Hewitt on behalf of Brandan Michael Hewitt, Houston, Texas, Court of Federal Claims Number 04–0089V.

55. Patricia and Howard Alperin on behalf of Courtney Alperin, Santa Monica, California, Court of Federal Claims Number 04–0092V.

56. Laura Harris on behalf of Valarie Harris, Decatur, Georgia, Court of Federal Claims Number 04–0105V.

57. Kara and Alan Brodeur on behalf of Arlen Brodeur, Hoffman Estates, Illinois, Court of Federal Claims Number 04–0110V.

58. John Cordts, Fullerton, California, Court of Federal Claims Number 04–0111V.

59. Leslie Richards and Terrell Sheppard on behalf of Victoria Ann Sheppard, Deceased, Fort Walton Beach, Florida, Court of Federal Claims Number 04–0112V.

60. Rebecca and Kevin Peck on behalf of Spencer Peck, Overland Park, Kansas, Court of Federal Claims Number 04–0113V.

61. Delores Legros on behalf of Emile Legros, Great Neck, New York, Court of Federal Claims Number 04–0114V.

62. Sherrie Kjar on behalf of Dillon Christopher Kjar, Decatur, Texas, Court of Federal Claims Number 04–0115V.

63. Keisha and Thomas Miller on behalf of Isaiah Miller, Deceased, New Orleans, Louisiana, Court of Federal Claims Number 04–0122V.

64. Michelle Hartis on behalf of Garrett Hartis, Deceased, Boston, Massachusetts, Court of Federal Claims Number 04–0128V.

65. Brenda and Charlie Steele on behalf of Mason Steele, Vienna, Virginia, Court of Federal Claims Number 04–0136V.

66. Allison Wastak on behalf of Ashlynn Wastak, Vienna, Virginia, Court of Federal Claims Number 04–0137V.

67. Carol Sojka, Brattleboro, Vermont, Court of Federal Claims Number 04–0138V.

68. Virginia and Peter Violas on behalf of Peter Violas, Houston, Texas, Court of Federal Claims Number 04–0139V.

69. Kenneth Ulappa on behalf of Theodore Graham Ulappa, Portland, Oregon, Court of Federal Claims Number 04–0140V.

70. Darlene Crosby on behalf of Hugh Paul Dyson, Portland, Oregon, Court of Federal Claims Number 04–0141V.

71. Kellie Cirone on behalf of Stevan Cirone, Portland, Oregon, Court of Federal Claims Number 04–0142V.

72. Lisa and Timothy Thompson on behalf of Patricia Thompson, Lake Success, New York, Court of Federal Claims Number 04–0143V.

73. Bill Hoffman on behalf of Matthew Hoffman, Houston, Texas, Court of Federal Claims Number 04–0144V.

74. Joyce and Greg Wiatt on behalf of Weston Wiatt, Temecula, California, Court of Federal Claims Number 04–0147V.

75. Carla and Kenneth Sizemore on behalf of Sean Sizemore, Temecula, California, Court of Federal Claims Number 04–0148V.

76. Jeanne Ferrucci on behalf of Joseph Anthony Ferrucci, Somers Point, New Jersey, Court of Federal Claims Number 04–0151V.

77. Cynthia and James Reiners on behalf of James Robert Reiners, III, Houston, Texas, Court of Federal Claims Number 04–0152V.

78. Marianne and Anthony Salemi on behalf of Anthony Salemi, Houston, Texas, Court of Federal Claims Number 04–0153V.

79. Susan Spund on behalf of Alexandra Spund, Boston, Massachusetts, Court of Federal Claims Number 04–0156V.

80. Susan Spund on behalf of Jennifer Spund, Boston, Massachusetts, Court of Federal Claims Number 04–0157V.

81. Dorothy Young on behalf of Daniel Young, Boston, Massachusetts, Court of Federal Claims Number 04–0158V.

82. Laura Martinez on behalf of Charles Martinez, Boston, Massachusetts, Court of Federal Claims Number 04–0159V.

83. James Bryan Quattlebaum on behalf of Grant Quattlebaum, Sacramento, California, Court of Federal Claims Number 04–0160V.

84. Ana and Randy Tillim on behalf of Ryan Tillim, Sterling, Virginia, Court of Federal Claims Number 04–0162V.

85. Lona Maker on behalf of McKinley Maker, Minneapolis, Minnesota, Court of Federal Claims Number 04–0164V.

86. Ellen Schneider and Sam Alexander on behalf of Benjamin Alexander, New Orleans, Louisiana, Court of Federal Claims Number 04–0168V.

87. Nancy Cobb on behalf of Tasmin Mosby, New Orleans, Louisiana, Court of Federal Claims Number 04–0169V.

88. Sharon Muse on behalf of Drexel Muse, Jr., New Orleans, Louisiana,

Court of Federal Claims Number 04–0170V.

89. Kimberly Ngo on behalf of Joanh Nguyen, New Orleans, Louisiana, Court of Federal Claims Number 04–0171V.

90. Sabrina Slattery on behalf of Kyle Baham, New Orleans, Louisiana, Court of Federal Claims Number 04–0172V.

91. Cassandra Thomas on behalf of Ryan Thomas, New Orleans, Louisiana, Court of Federal Claims Number 04–0173V.

92. Ikona Traylor on behalf of Michael Brown, New Orleans, Louisiana, Court of Federal Claims Number 04–0174V.

93. J. Danyele and Danny Tutt on behalf of Kaleb Tutt, New Orleans, Louisiana, Court of Federal Claims Number 04–0176V.

94. Traneice Victor on behalf of Malaysia Victor, New Orleans, Louisiana, Court of Federal Claims Number 04–0177V.

95. Marilyn and John Warr on behalf of John E. Warr, III, New Orleans, Louisiana, Court of Federal Claims Number 04–0178V.

96. Scott Devinney on behalf of Garret Devinney, Vienna, Virginia, Court of Federal Claims Number 04–0179V.

97. Patricia Brockman on behalf of Hannah Jacobson, Vienna, Virginia, Court of Federal Claims Number 04–0180V.

98. Susan Sexton and Michael Smith on behalf of Spencer Ryan Smith, Vienna, Virginia, Court of Federal Claims Number 04–0181V.

99. Jennifer and Joshua Mazer on behalf of Maximilian Mazer, Vienna, Virginia, Court of Federal Claims Number 04–0182V.

100. Michele Akmon on behalf of Taya Akmon, Vienna, Virginia, Court of Federal Claims Number 04–0183V.

101. Katrina and Lance Ray on behalf of Elise Victoria Ray, Saginaw, Michigan, Court of Federal Claims Number 04–0184V.

102. Rosann Landry on behalf of David Landry, Vienna, Virginia, Court of Federal Claims Number 04–0185V.

103. Jennifer Jean and Marvin Robert Oskey on behalf of Elijah Maurice Oskey, Portland, Oregon, Court of Federal Claims Number 04–0186V.

104. Denise and Scott Corbin on behalf of William Corbin, Philadelphia, Pennsylvania, Court of Federal Claims Number 04–0189V.

105. Wendy and Pausanias Alexander on behalf of Christos Alexander, Richmond, Virginia, Court of Federal Claims Number 04–0191V.

106. Miriam and James Owens on behalf of Sarah Christina Owens, Richmond, Virginia, Court of Federal Claims Number 04–0193V.

107. Katherine and Seymour Young on behalf of Anna Young, Houston, Texas, Court of Federal Claims Number 04–0194V.

108. Jade and Andrea Trahan on behalf of Dominic Trahan, Miami, Florida, Court of Federal Claims Number 04–0195V.

109. Doris and Abdel Brown on behalf of Sharif Brown, Miami, Florida, Court of Federal Claims Number 04–0196V.

110. Kerri and Robert Helmick on behalf of Kameron William Helmick, Melbourne, Florida, Court of Federal Claims Number 04–0197V.

111. Genett and Nathan Reed on behalf of Adam Reed, Philadelphia, Pennsylvania, Court of Federal Claims Number 04–0198V.

112. Joanne Patsis on behalf of Alec Jonathan Patsis, Bala Cynwyd, Pennsylvania, Court of Federal Claims Number 04–0199V.

113. Laurie and George Curry on behalf of Thomas Curry, Philadelphia, Pennsylvania, Court of Federal Claims Number 04–0200V.

114. Jeff Rousseau on behalf of Hunter Rousseau, Houston, Texas, Court of Federal Claims Number 04–0201V.

115. Jennifer and Erik Boergesson on behalf of Brigham Boergesson, Houston, Texas, Court of Federal Claims Number 04–0202V.

116. Jesus Camero on behalf of Jesus A. Camero, Houston, Texas, Court of Federal Claims Number 04–0203V.

117. Darlene and Charles DiRico on behalf of Derek DiRico, Houston, Texas, Court of Federal Claims Number 04–0204V.

118. Dana Everette, Tarboro, North Carolina, Court of Federal Claims Number 04–0205V.

119. Kathryn Moffatt on behalf of Patrick Moffatt, Somers Point, New Jersey, Court of Federal Claims Number 04–0206V.

120. Lisa and Richard Richardson on behalf of Megan Richardson, Hanover, Massachusetts, Court of Federal Claims Number 04–0208V.

121. Laura and Dan Clarke on behalf of Daniel Joseph Clarke, II, Covington, Kentucky, Court of Federal Claims Number 04–0209V.

122. Patricia Schrum, Melbourne, Florida, Court of Federal Claims Number 04–0210V.

123. Penn Schwartzenburg on behalf of Connor Schwartzenburg, Vienna, Virginia, Court of Federal Claims Number 04–0211V.

124. Lisa Gutierrez on behalf of David Gutierrez, Boston, Massachusetts, Court of Federal Claims Number 04–0215V.

125. Anne and Dean Moore on behalf of Andrew Moore, Philadelphia, Pennsylvania, Court of Federal Claims Number 04–0217V.

126. Monica and Clifton Hoffman on behalf of Clifton Hoffman, Philadelphia, Pennsylvania, Court of Federal Claims Number 04–0218V.

127. Eileen DiMarino on behalf of Drew DiMarino, Philadelphia, Pennsylvania, Court of Federal Claims Number 04–0219V.

128. Mattie and Gilbert Hattier on behalf of Fionn Hattier, Philadelphia, Pennsylvania, Court of Federal Claims Number 04–0220V.

129. Melissa and Jonathan Garner on behalf of Joshua Garner, Philadelphia, Pennsylvania, Court of Federal Claims Number 04–0221V.

130. Debra Coviak on behalf of Alexander Coviak, Somers Point, New Jersey, Court of Federal Claims Number 04–0222V.

131. Linda Tutza on behalf of Peter Leal, Boston, Massachusetts, Court of Federal Claims Number 04–0223V.

132. Lori and Scott Cox on behalf of Tyler Austin Cox, Decatur, Texas, Court of Federal Claims Number 04–0224V.

133. Sarita and Peter Lang on behalf of Talan Lang, Houston, Texas, Court of Federal Claims Number 04–0227V.

134. Martha and Paul Brach on behalf of Sam Brach, Houston, Texas, Court of Federal Claims Number 04–0228V.

135. Maria and Mario Ramirez on behalf of Andre Ramirez, Houston, Texas, Court of Federal Claims Number 04–0229V.

136. Sarita and Peter Lang on behalf of Trevan Lang, Houston, Texas, Court of Federal Claims Number 04–0230V.

137. Michelle Bennett on behalf of Brandon Derrick Hernandez, Sandusky, Michigan, Court of Federal Claims Number 04–0232V.

138. Christine and Jeffrey Sanders on behalf of Matthew Serget Sanders, Richmond, Virginia, Court of Federal Claims Number 04–0234V.

139. Diane and Peter Tenore on behalf of Haley Morgan Tenore, Richmond, Virginia, Court of Federal Claims Number 04–0235V.

140. Ember Plumlee, Little Rock, Arkansas, Court of Federal Claims Number 04–0241V.

141. Jennifer and Troy Armstrong on behalf of Bryant Armstrong, Cleveland, Mississippi, Court of Federal Claims Number 04–0242V.

142. Amy and Stephen Pincus on behalf of Mark Gregory Pincus, Baton Rouge, Louisiana, Court of Federal Claims Number 04–0243V.

143. Linda Tutza on behalf of Peter Leal, Huntington, Vermont, Court of Federal Claims Number 04–0244V.

144. Susan Goewey and William Carey on behalf of Luke Owen Carey, Richmond, Virginia, Court of Federal Claims Number 04–0245V.

145. Jennifer Deoliveira on behalf of Isaiah Deoliviera, Boston,

Massachusetts, Court of Federal Claims Number 04–0246V.

146. Jennifer Landau on behalf of Caleb Landau, Boston, Massachusetts, Court of Federal Claims Number 04–0247V.

147. Kristin and Jeffrey Morrison on behalf of Wade Morrison, Alexandria, Virginia, Court of Federal Claims Number 04–0251V.

148. Moses Lacy on behalf of Rachel Lacy, Deceased, Fort McCoy, Wisconsin, Court of Federal Claims Number 04–0253V.

149. Cindy Bramblett on behalf of Tiffany Bramblett, Vienna, Virginia, Court of Federal Claims Number 04–0255V.

150. Suihua Zhu and Bin Zhao on behalf of Fiona Zhao, Houston, Texas, Court of Federal Claims Number 04–0257V.

151. Eva J. Coiro-Lorusso and Nicola Lorusso on behalf of Umberto Lorusso, Melbourne, Florida, Court of Federal Claims Number 04–0258V.

152. Tammy and Joseph Hodges on behalf of Joseph Christopher Hodges, Houston, Texas, Court of Federal Claims Number 04–0259V.

153. Jenell and Randall Bailey on behalf of Joel Bailey, Portland, Oregon, Court of Federal Claims Number 04–0260V.

154. Jenell and Randall Bailey on behalf of David Bailey, Portland, Oregon, Court of Federal Claims Number 04–0261V.

155. Jenell and Randall Bailey on behalf of James Bailey, Portland, Oregon, Court of Federal Claims Number 04–0262V.

156. Stephanie James on behalf of Nicholas James, Portland, Oregon, Court of Federal Claims Number 04–0263V.

157. Kelly Ray and Leslie Duncan on behalf of Zachary Duncan, Portland, Oregon, Court of Federal Claims Number 04–0264V.

158. Carla and William Whiteside on behalf of Lauren Whiteside, Deceased, Lincolnton, North Carolina, Court of Federal Claims Number 04–0266V.

159. Arkadiusz and Bozena Zarzycka on behalf of Alan Victor Zarzycka, Houston, Texas, Court of Federal Claims Number 04–0268V.

160. Francine and Bennett Zuck on behalf of Adin Jacob Zuck, Houston, Texas, Court of Federal Claims Number 04–0269V.

161. Carolyn Proper and Gary Wimbish on behalf of Nicholas Wimbish, Norcross, Georgia, Court of Federal Claims Number 04–0271V.

162. Edie and William Nale on behalf of William Nale, Dallas, Texas, Court of Federal Claims Number 04–0272V.

163. Janis Talebizadeh, Valencia, California, Court of Federal Claims Number 04–0273V.

164. Wasfi Meshagbeh on behalf of Karam Al-Meshagbeh, Troy, Michigan, Court of Federal Claims Number 04–0274V.

165. Julie and Mark Hutton on behalf of Caleb Hutton, Portland, Oregon, Court of Federal Claims Number 04–0275V.

166. Anna Smith on behalf of Ryan Smith, Portland, Oregon, Court of Federal Claims Number 04–0276V.

167. Amanda and Richard Coe on behalf of Colton Coe, Alexandria, Virginia, Court of Federal Claims Number 04–0278V.

168. Karen and David Zwemer on behalf of Andrew Zwemer, Vero Beach, Florida, Court of Federal Claims Number 04–0281V.

169. Aydin Rza on behalf of Camilla Rza, Lake Success, New York, Court of Federal Claims Number 04–0282V.

170. Cynthia and David Emminger on behalf of David Thomas Emminger, Lake Success, New York, Court of Federal Claims Number 04–0283V.

171. Heather and Aaron Bostic on behalf of Colin Bostic, Portland, Oregon, Court of Federal Claims Number 04–0285V.

172. Cheryl and Timothy Lozon on behalf of Christopher Lozon, Gaithersburg, Maryland, Court of Federal Claims Number 04–0286V.

173. Deana Orth on behalf of Nicholas Orth, Boston, Massachusetts, Court of Federal Claims Number 04–0292V.

174. Katrina Dyer-Alexander on behalf of Amya Alexander, Boston, Massachusetts, Court of Federal Claims Number 04–0293V.

175. Corina Ianculovici on behalf of Christopher Ianculovici, Boston, Massachusetts, Court of Federal Claims Number 04–0294V.

176. Beth Schmied on behalf of William Schmied, Portland, Oregon, Court of Federal Claims Number 04–0298V.

177. Ellen and Paul Mazzie on behalf of Eric Mazzie, North Reading, Massachusetts, Court of Federal Claims Number 04–0305V.

178. Susan and Mike Killiany on behalf of Dominic Killiany, Dover, New Hampshire, Court of Federal Claims Number 04–0306V.

179. Debbie and Terrence Kavanagh on behalf of Julia Kavanagh, Dover, New Hampshire, Court of Federal Claims Number 04–0307V.

180. Beverly and Edward Messina on behalf of Harrison Messina, Peabody, Massachusetts, Court of Federal Claims Number 04–0308V.

181. Beverly and Edward Messina on behalf of Charles Messina, Peabody, Massachusetts, Court of Federal Claims Number 04–0309V.

182. Kelly and Guido Melo on behalf of Lindsey Melo, North Dartmouth, Massachusetts, Court of Federal Claims Number 04–0310V.

183. Joanna Callinan on behalf of Patrick Callinan, Sommerville, Massachusetts, Court of Federal Claims Number 04–0311V.

184. Gail Carnes on behalf of Matthew Carnes, Hyde Park, Massachusetts, Court of Federal Claims Number 04–0312V.

185. Elizabeth and Bruce Collins on behalf of Ruby Collins, Quincy, Massachusetts, Court of Federal Claims Number 04–0313V.

186. Elizabeth and Matthew Corbeil on behalf of Bradley Corbeil, Salem, Massachusetts, Court of Federal Claims Number 04–0314V.

187. Gerald Dorsainvil on behalf of Nicholas Dorsainvil, Cambridge, Massachusetts, Court of Federal Claims Number 04–0315V.

188. John Doherty on behalf of Erica Rose Doherty, Torrance, California, Court of Federal Claims Number 04–0316V.

189. Paula and Lawrence Haite on behalf of Ryan Haite, Boston, Massachusetts, Court of Federal Claims Number 04–0317V.

190. Rita and Albert Gingras on behalf of Nicholas Gingras, Medford, Massachusetts, Court of Federal Claims Number 04–0318V.

191. Alison Bushnell on behalf of Joshua Bushnell, Boulder, Colorado, Court of Federal Claims Number 04–0319V.

192. Moulay and Shadiya Patton-Bey on behalf of Ilyas Patton-Bey, Memphis, Tennessee, Court of Federal Claims Number 04–0320V.

193. Linda and Michael Ball on behalf of Cameron Ball, Hartford, Connecticut, Court of Federal Claims Number 04–0321V.

194. Judith Baron on behalf of Julianne Baron, Boston, Massachusetts, Court of Federal Claims Number 04–0322V.

195. Marc Baron on behalf of Matthew Baron, Northhampton, Massachusetts, Court of Federal Claims Number 04–0323V.

196. Debra and Brian Richardson on behalf of Zachary Richardson, Newburyport, Massachusetts, Court of Federal Claims Number 04–0324V.

197. Jose Recinos on behalf of David Recinos, Boston, Massachusetts, Court of Federal Claims Number 04–0325V.

198. Andrea and Michael Phelan on behalf of Michael Phelan, Reading, Massachusetts, Court of Federal Claims Number 04–0326V.

199. Kathleen and William Paquette on behalf of William Paquette, Jr., Cambridge, Massachusetts, Court of Federal Claims Number 04–0327V.

200. Debora and Paul Smith on behalf of Paul Smith, Boston, Massachusetts, Court of Federal Claims Number 04–0328V.

201. Cynthia Bergeron on behalf of Joshua Bergeron, North Adams, Massachusetts, Court of Federal Claims Number 04–0329V.

202. Sandra and Gregory Strickland on behalf of Adrian Delisha Strickland, Houston, Texas, Court of Federal Claims Number 04–0330V.

203. Kelly Carver on behalf of Andrea Dawn Carver, Sedalia, Missouri, Court of Federal Claims Number 04–0331V.

204. Ethel Clark on behalf of Tameria Le'Na Clark, Houston, Texas, Court of Federal Claims Number 04–0332V.

205. Nicole White on behalf of Kenneth White, New Orleans, Louisiana, Court of Federal Claims Number 04–0337V.

206. Cheryl Smith on behalf of Darrell Lamont Whickum, New Orleans, Louisiana, Court of Federal Claims Number 04–0338V.

207. Mia Merrell on behalf of Anthony Merrell, New Orleans, Louisiana, Court of Federal Claims Number 04–0339V.

208. Melinda Horsley on behalf of Joseph Neal Horsley, New Orleans, Louisiana, Court of Federal Claims Number 04–0340V.

209. Jowanda Gross on behalf of Jo'Vohn Gross, New Orleans, Louisiana, Court of Federal Claims Number 04–0341V.

210. Kimberly Duhe on behalf of Andrew Duhe, New Orleans, Louisiana, Court of Federal Claims Number 04–0342V.

211. Lakeisha Catchings on behalf of Juan Catchings, New Orleans, Louisiana, Court of Federal Claims Number 04–0343V.

212. Kimberly and Lloyd Matherne on behalf of Shyler Thompson, New Orleans, Louisiana, Court of Federal Claims Number 04–0344V.

213. Edna Thomas on behalf of Yvad Marcel Diaz, New Orleans, Louisiana, Court of Federal Claims Number 04–0345V.

214. Sharon Roublau on behalf of Justin Michael Castanedo, New Orleans, Louisiana, Court of Federal Claims Number 04–0346V.

215. Kimberly Montgomery on behalf of Dewayne Reed, New Orleans, Louisiana, Court of Federal Claims Number 04–0347V.

216. Tina Malonson on behalf of Zachery Malonson, New Orleans, Louisiana, Court of Federal Claims Number 04–0348V.

217. Leslie Landry on behalf of Deont'a Landry, New Orleans, Louisiana, Court of Federal Claims Number 04–0349V.

218. Rose Lanasa on behalf of Henry Matthew Lanasa, New Orleans, Louisiana, Court of Federal Claims Number 04–0350V.

219. Angela Green on behalf of Angel Green, New Orleans, Louisiana, Court of Federal Claims Number 04–0351V.

220. Ashante Isaac on behalf of Tyran Gordon, New Orleans, Louisiana, Court of Federal Claims Number 04–0352V.

221. Randolph Doubleday on behalf of Randolph Doubleday, Jr., New Orleans, Louisiana, Court of Federal Claims Number 04–0353V.

222. Maria Chriss on behalf of Jared Anthony Chriss, New Orleans, Louisiana, Court of Federal Claims Number 04–0354V.

223. Tiffany Chopin on behalf of Giovanni Chopin, New Orleans, Louisiana, Court of Federal Claims Number 04–0355V.

224. Candida Breaux on behalf of Ty Jakob Breaux, New Orleans, Louisiana, Court of Federal Claims Number 04–0356V.

225. Blanche Boss on behalf of Cory Boss, New Orleans, Louisiana, Court of Federal Claims Number 04–0357V.

226. Julie and Eric Hand on behalf of James Hand, Chicago, Illinois, Court of Federal Claims Number 04–0358V.

227. Richard Rosypal on behalf of Jacob Frank Rosypal, Melbourne, Florida, Court of Federal Claims Number 04–0359V.

228. Daughn and William Sage on behalf of Joshua Sage, College Park, Georgia, Court of Federal Claims Number 04–0360V.

229. Christina and James Vanderford on behalf of Dustin Andrew Vanderford, Oxford, Mississippi, Court of Federal Claims Number 04–0361V.

230. Cheryl and William Tourville on behalf of Cole Benjamin Tourville, Maplewood, Minnesota, Court of Federal Claims Number 04–0362V.

231. Valerie and John Travis on behalf of Jacob Russell Travis, Houston, Texas, Court of Federal Claims Number 04–0363V.

232. Candy and Steven Varney on behalf of Steven J. Varney, Shelbiana, Kentucky, Court of Federal Claims Number 04–0364V.

233. Maryalyce and Ronald Turner on behalf of Kelly Amber Turner, Wading River, New York, Court of Federal Claims Number 04–0365V.

234. Tracey Captan on behalf of Jade Captan, Lindenwold, New Jersey, Court of Federal Claims Number 04–0369V.

235. Tammee and Brian Trawick on behalf of Jack Nelson Trawick, Fort Polk, Louisiana, Court of Federal Claims Number 04–0371V.

236. Talora Simpson on behalf of Khalil Da Juan Cowan, Toledo, Ohio, Court of Federal Claims Number 04–0372V.

237. Rhoda and Albert Sancho on behalf of Albert Burgess Sancho, Jr., Chicago, Illinois, Court of Federal Claims Number 04–0373V.

238. Leslie and Kelly Scott on behalf of Kelly Lee Scott, II, Wheeling, West Virginia, Court of Federal Claims Number 04–0374V.

239. Pamela and Joseph Sarli on behalf of Brian Joseph Sarli, Mentor, Ohio, Court of Federal Claims Number 04–0375V.

240. Kelly Anne Svedine on behalf of Nicholas Ryan Svedine, Plymouth, Massachusetts, Court of Federal Claims Number 04–0376V.

241. Vatanya and Nathaniel Smith on behalf of Zachary Nathan Smith, Plano, Texas, Court of Federal Claims Number 04–0377V.

242. Danielle Temple on behalf of Shane Nicholas Temple, Cincinnati, Ohio, Court of Federal Claims Number 04–0378V.

243. Lola and Michael Smith on behalf of Jeremiah James Smith, Richardson, Texas, Court of Federal Claims Number 04–0379V.

244. Maureen and Steve Awuzie on behalf of Brandon Chime Awuzie, San Jose, California, Court of Federal Claims Number 04–0380V.

245. Maureen and Steve Awuzie on behalf of Bradley Chima Awuzie, San Jose, California, Court of Federal Claims Number 04–0381V.

246. Jacqueline Hendrickson on behalf of Shane Hendrickson, Boston, Massachusetts, Court of Federal Claims Number 04–0386V.

247. Jacqueline Hendrickson on behalf of Liam Hendrickson, Boston, Massachusetts, Court of Federal Claims Number 04–0387V.

248. Jennifer and Christian White on behalf of Madison White, Ann Arbor, Michigan, Court of Federal Claims Number 04–0389V.

249. Melanie and Scott Davis on behalf of Jonathan Perrin Davis, Temecula, California, Court of Federal Claims Number 04–0390V.

250. Marylou and William Gifford on behalf of Samuel Gifford, Temecula, California, Court of Federal Claims Number 04–0391V.

251. Felicia and Tyrone Gaston on behalf of Tylicia La'Bria Gaston, Atlanta, Georgia, Court of Federal Claims Number 04–0392V.

252. Claire and Brian Dempsey on behalf of Zachary William Dempsey, Atlanta, Georgia, Court of Federal Claims Number 04–0393V.

253. Claire and Brian Dempsey on behalf of Kyle Joseph Dempsey, Atlanta, Georgia, Court of Federal Claims Number 04–0394V.

254. Jayne Duncan Cozic on behalf of Benjamin Cozic, Atlanta, Georgia, Court of Federal Claims Number 04–0395V.

255. Sheila and James Cassity on behalf of Ethan Pierce Cassity, Atlanta, Georgia, Court of Federal Claims Number 04–0396V.

256. Jo Ann and David Byrne on behalf of Andrew Byrne, Atlanta, Georgia, Court of Federal Claims Number 04–0397V.

257. Jo Ann and David Byrne on behalf of Nicholas David Byrne, Atlanta, Georgia, Court of Federal Claims Number 04–0398V.

258. Rebecca and Hubert Andrew Way on behalf of Blake Allen Way, Atlanta, Georgia, Court of Federal Claims Number 04–0399V.

259. Christy Craft and Edward Judson on behalf of Alexander Clinton Judson, Atlanta, Georgia, Court of Federal Claims Number 04–0400V.

260. Rebecca and Hubert Andrew Way on behalf of Grant Baird Way, Atlanta, Georgia, Court of Federal Claims Number 04–0401V.

261. Lyndelle and William Thomas Redwood on behalf of Will Redwood, Atlanta, Georgia, Court of Federal Claims Number 04–0402V.

262. Jeanette and L. Howard O'Dell on behalf of Trent Joshua O'Dell, Atlanta, Georgia, Court of Federal Claims Number 04–0403V.

263. Marcie and Nathan Brook on behalf of Alan Brook, Vienna, Virginia, Court of Federal Claims Number 04–0405V.

264. Mita Floria on behalf of Callie Floria, Boston, Massachusetts, Court of Federal Claims Number 04–0407V.

265. Mita Floria on behalf of Caitlin Floria, Boston, Massachusetts, Court of Federal Claims Number 04–0408V.

266. Robert Malone on behalf of Unity Malone, Boston, Massachusetts, Court of Federal Claims Number 04–0409V.

267. Robert Malone on behalf of Emmanuel Malone, Boston, Massachusetts, Court of Federal Claims Number 04–0410V.

268. Eddie and Monica Hughes on behalf of Eddie Hughes, IV, New Orleans, Louisiana, Court of Federal Claims Number 04–0412V.

269. Angel and Russell Fontenot on behalf of Russell Fontenot, Jr., New Orleans, Louisiana, Court of Federal Claims Number 04–0413V.

270. Linda and Dennis Stewart on behalf of Alexander Stewart, Miami, Florida, Court of Federal Claims Number 04–0414V.

271. Lisa and Donald Geisler on behalf of David Jacob Geisler, Houston, Texas, Court of Federal Claims Number 04–0416V.

272. Allison Kennedy on behalf of Jacob Kennedy, Houston, Texas, Court of Federal Claims Number 04–0417V.

273. Deidra and Jeffrey Ransom on behalf of Benjamin Ransom, Houston, Texas, Court of Federal Claims Number 04–0418V.

274. Sydnee and Jon Jorgl on behalf of Ian Jorgl, Houston, Texas, Court of Federal Claims Number 04–0419V.

275. Lisa Ferrell on behalf of Donovan Wyckoff, Houston, Texas, Court of Federal Claims Number 04–0420V.

276. Jennifer and Joseph Nolan on behalf of Joseph Nolan, Lake Grove, New York, Court of Federal Claims Number 04–0422V.

277. Juliane Baldasaro, Boston, Massachusetts, Court of Federal Claims Number 04–0426V.

278. Karen Douglas on behalf of Keston Douglas, Boston, Massachusetts, Court of Federal Claims Number 04–0427V.

279. Lorraine White on behalf of Colton Falcone, Boston, Massachusetts, Court of Federal Claims Number 04–0428V.

280. Marisol Otero-Morales on behalf of Gabriel Morales, Boston, Massachusetts, Court of Federal Claims Number 04–0429V.

281. Rakesh Radhakrishnan on behalf of Arjun Radhakrishnan, Boston, Massachusetts, Court of Federal Claims Number 04–0430V.

282. Regina and Ken Bradley on behalf of Jazz Hunter Goff, Houston, Texas, Court of Federal Claims Number 04–0431V.

283. Lucrecia Baldwin behalf of Christopher Arnold, Troy, Alabama, Court of Federal Claims Number 04–0432V.

284. Kathy Atkins on behalf of Kimberly Nicole Atkins, Kettering, Ohio, Court of Federal Claims Number 04–0433V.

285. Tony Lavette Allen on behalf of Xavier Enrique Allen, Arkadelphia, Arkansas, Court of Federal Claims Number 04–0434V.

286. Sherri Beaver on behalf of Brandon Lee Taylor, Columbus, Ohio, Court of Federal Claims Number 04–0435V.

287. Donna and Timothy Barber on behalf of Alyssa Lauren Barber, Edina, Minnesota, Court of Federal Claims Number 04–0436V.

288. Linda Armstrong on behalf of Joshua Earl Armstrong, Washington, District of Columbia, Court of Federal Claims Number 04–0437V.

289. Laura and Douglas Turner on behalf of Matthew Douglas Turner, La Honda, California, Court of Federal Claims Number 04–0438V.

290. Sue and Randy Becker on behalf of Cheyanne Rose Becker, Pittsburgh, Pennsylvania, Court of Federal Claims Number 04–0439V.

291. Amanda and Bruce Manuel on behalf of Magan Faith Manuel, Eunice, Louisiana, Court of Federal Claims Number 04–0441V.

292. Teresa and Francis Wickersham on behalf of Francis Wickersham, Houston, Texas, Court of Federal Claims Number 04–0442V.

293. Holli and Matthew Filewood on behalf of Colin Filewood, Houston, Texas, Court of Federal Claims Number 04–0443V.

294. Teresa and Francis Wickersham on behalf of Alexander Wickersham, Houston, Texas, Court of Federal Claims Number 04–0444V.

295. Eleonor Tester on behalf of Austin Tester, Houston, Texas, Court of Federal Claims Number 04–0445V.

296. Lisa Ferrell on behalf of Donovan Wyckoff, Houston, Texas, Court of Federal Claims Number 04–0446V.

297. Tara and Carroll Bohannon on behalf of Nicklas Bohannon, Houston, Texas, Court of Federal Claims Number 04–0447V.

298. Michele Sicillano on behalf of Vincent Sicillano, Ligonier, Pennsylvania, Court of Federal Claims Number 04–0449V.

299. Penny and Joseph Catalano on behalf of Joseph Dominic Catalano, Vienna, Virginia, Court of Federal Claims Number 04–0450V.

300. Kristine Davis on behalf of Joseph Davis, Vienna, Virginia, Court of Federal Claims Number 04–0451V.

301. Jeff Trelka on behalf of Lillian Trelka, Vienna, Virginia, Court of Federal Claims Number 04–0452V.

302. Jeff Trelka on behalf of Helena Trelka, Vienna, Virginia, Court of Federal Claims Number 04–0453V.

303. Cynthia Sauer on behalf of Michael Sauer, Vienna, Virginia, Court of Federal Claims Number 04–0454V.

304. Debra Gilbert on behalf of Adam Gilbert, Cleveland, Ohio, Court of Federal Claims Number 04–0455V.

305. Maria and Roberto Ochoa on behalf of Roberto Ochoa, Dallas, Texas, Court of Federal Claims Number 04–0456V.

306. Maria and Roberto Ochoa on behalf of Ricardo Ochoa, Dallas, Texas, Court of Federal Claims Number 04–0457V.

307. Daniel Betancourt, Houston, Texas, Court of Federal Claims Number 04–0458V.

308. Elizabeth Lewis and Quentin Yeats Woodhead on behalf of Henry Lewis Woodhead, Richmond, Virginia, Court of Federal Claims Number 04–0462V.

309. Joan and Todd Shepherd on behalf of Tate Shepherd, Dallas, Texas, Court of Federal Claims Number 04–0464V.

310. Janet and Adam Callens on behalf of Liam Callens, Alexandria, Virginia, Court of Federal Claims Number 04–0465V.

311. Janet and Adam Callens on behalf of Dharma Callens, Alexandria, Virginia, Court of Federal Claims Number 04–0466V.

312. Dorothy and Ricky Loupe on behalf of Blaine Loupe, Baton Rouge, Louisiana, Court of Federal Claims Number 04–0467V.

313. Dorothy and Ricky Loupe on behalf of Blair Loupe, Baton Rouge, Louisiana, Court of Federal Claims Number 04–0468V.

314. Priscilla Vogel on behalf of Brandon Quesada, Somers Point, New Jersey, Court of Federal Claims Number 04–0469V.

315. Marcy Townsend on behalf of Aaron Biehle, Boston, Massachusetts, Court of Federal Claims Number 04–0474V.

316. Julia Jones on behalf of Alex Jones, Boston, Massachusetts, Court of Federal Claims Number 04–0475V.

317. Karen Raposa on behalf of Thomas Raposa, Boston, Massachusetts, Court of Federal Claims Number 04–0476V.

318. Patricia Lewis on behalf of Ian Lewis, Boston, Massachusetts, Court of Federal Claims Number 04–0477V.

319. Patricia Lewis on behalf of Hannah Lewis, Boston, Massachusetts, Court of Federal Claims Number 04–0478V.

320. Hilary and Brian Rodriguez on behalf of Pierce Rodriguez, Dallas, Texas, Court of Federal Claims Number 04–0479V.

321. Joseph Giusti, Oak Park, Illinois, Court of Federal Claims Number 04–0486V.

322. Cathleen and Alan Flynt on behalf of Christian Joey Flynt, Houston, Texas, Court of Federal Claims Number 04–0488V.

323. E'Lise Anne Fogle on behalf of Christopher Allen Fogle, Fairfax, Virginia, Court of Federal Claims Number 04–0489V.

324. Dianna and Christopher Davis on behalf of Michael Josiah Davis, El Camino, California, Court of Federal Claims Number 04–0490V.

325. Connie and James Bell on behalf of Nathan Daniel Bell, Hamilton, Ohio, Court of Federal Claims Number 04–0491V.

326. Lori and Daniel McCoy on behalf of Austin Paul McCoy, Yardley, Pennsylvania, Court of Federal Claims Number 04–0492V.

327. Wanda and Quentin Evans on behalf of Joshua Mackenzie Evans, Albany, Georgia, Court of Federal Claims Number 04–0493V.

328. Michelle and Daren Forney on behalf of Jessica Breanne Forney, Fort Collins, Colorado, Court of Federal Claims Number 04–0494V.

329. Angela and Steve Forster on behalf of Marshall Nathaniel Forster, Houston, Texas, Court of Federal Claims Number 04–0495V.

330. Cynthia and William McIntyre on behalf of Kevin Donald McIntyre, Mokena, Illinois, Court of Federal Claims Number 04–0496V.

331. Kai Ellen and Darreck Bucher on behalf of Hadleigh Kai Bucher, Kalispell, Montana, Court of Federal Claims Number 04–0499V.

332. Mary Morriss on behalf of Grace Morriss, Bronxville, New York, Court of Federal Claims Number 04–0502V.

333. Yvonne Walton, Austin, Texas, Court of Federal Claims Number 04–0503V.

334. Deborah Arrington on behalf of Devonte Anthony Jones, New Orleans, Louisiana, Court of Federal Claims Number 04–0506V.

335. Carey Augustin on behalf of James Tevin Augustin, New Orleans, Louisiana, Court of Federal Claims Number 04–0507V.

336. Cassandra Berry on behalf of Qu'Ave Berry, New Orleans, Louisiana, Court of Federal Claims Number 04–0508V.

337. Shantell Bishop on behalf of Ro'Shone Bishop, New Orleans, Louisiana, Court of Federal Claims Number 04–0509V.

338. Acquanette Bornes on behalf of Jared Cy-Anthony Bornes, New Orleans, Louisiana, Court of Federal Claims Number 04–0510V.

339. Jacqueline Brown on behalf of Matthew Sloan Brown, New Orleans, Louisiana, Court of Federal Claims Number 04–0511V.

340. Lorraine Clark on behalf of Tia Ware, New Orleans, Louisiana, Court of Federal Claims Number 04–0512V.

341. Lisa Cox on behalf of Candace Mary Cox, New Orleans, Louisiana, Court of Federal Claims Number 04–0513V.

342. Victoria Echeverry on behalf of Michael Echeverry, New Orleans, Louisiana, Court of Federal Claims Number 04–0514V.

343. Dawn Harvey on behalf of Candice Maria Harvey, New Orleans, Louisiana, Court of Federal Claims Number 04–0515V.

344. Catrece Hawkins on behalf of Nathaniel Hawkins, New Orleans, Louisiana, Court of Federal Claims Number 04–0516V.

345. Dianell Jenkins on behalf of Devante Darius Jenkins, New Orleans, Louisiana, Court of Federal Claims Number 04–0517V.

346. Kim Labit on behalf of Richard Labit, New Orleans, Louisiana, Court of Federal Claims Number 04–0518V.

347. Dottie Loupe on behalf of Blaine Loupe, New Orleans, Louisiana, Court of Federal Claims Number 04–0519V.

348. Delilah Pabst on behalf of Forrest Mince, New Orleans, Louisiana, Court of Federal Claims Number 04–0520V.

349. Karen Singleton on behalf of Kenton Singleton, New Orleans, Louisiana, Court of Federal Claims Number 04–0521V.

350. Cameron and William Wells on behalf of Gina Wells, Bala Cynwyd, Pennsylvania, Court of Federal Claims Number 04–0524V.

351. Susan and Christopher Govatsos on behalf of Adam Charles Govatsos, Cohasset, Massachusetts, Court of Federal Claims Number 04–0525V.

352. Judith and Ewanshia Graham on behalf of Zaramoji Jay Graham, Houston, Texas, Court of Federal Claims Number 04–0526V.

353. Tammi and Don Hudson on behalf of Trevor Don Hudson, Fort Worth, Texas, Court of Federal Claims Number 04–0527V.

354. Patricia Noeggerath and Gerardo Garces on behalf of Sebastian Noeggerath Garces, Dallas, Texas, Court of Federal Claims Number 04–0528V.

355. Julia Howard on behalf of Julian Lee Howard, Chicago, Illinois, Court of Federal Claims Number 04–0529V.

356. Terri and Jimmy Milton on behalf of Brandon Tyrell Milton, Mobile, Alabama, Court of Federal Claims Number 04–0530V.

357. Elizabeth Mills on behalf of Phillip Taylor Mills, Baltimore, Maryland, Court of Federal Claims Number 04–0531V.

358. Amelia and Daniel Hummel on behalf of Jeremy Cole Hummel, Philipsburg, Pennsylvania, Court of Federal Claims Number 04–0532V.

359. Adriana and Jesus Gonzalez on behalf of Jesus Eduardo Gonzalez, Los Angeles, California, Court of Federal Claims Number 04–0533V.

360. Mary Ann Chestnut, Philadelphia, Pennsylvania, Court of Federal Claims Number 04–0534V.

361. Renetta Denise Ritter on behalf of Hunter Todd Glick, Dallas, Texas, Court of Federal Claims Number 04–0535V.

362. Brandy and Robert Decourcey on behalf of Robert Nelson Decourcey, Jr., Boyd, Kentucky, Court of Federal Claims Number 04–0536V.

363. Victoria and Percy Williams on behalf of Deon Edward Davis, Houston, Texas, Court of Federal Claims Number 04–0537V.

364. Bella Lapidus and Dimitry Gerzon on behalf of Roshel Sheina Gerzon, Woodland Hills, California, Court of Federal Claims Number 04–0538V.

365. Heidi and Tom Gallant on behalf of Lucas Walker Gallant, Mesa, Arizona, Court of Federal Claims Number 04–0539V.

366. Connie Garcia on behalf of Nicky Gabriel Garcia, San Bernardino, California, Court of Federal Claims Number 04–0540V.

Dated: September 14, 2004.

Elizabeth M. Duke,

Administrator.

[FR Doc. 04–21223 Filed 9–21–04; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HOMELAND SECURITY

Privacy Office; Privacy Act of 1974; System of Records

AGENCY: Privacy Office, DHS.

ACTION: Notice of Privacy Act system of records.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, the Privacy Office of the Department of Homeland Security (DHS) is giving notice that it proposes to implement a new system of records entitled "Oral History Program: The History of the Department of Homeland Security." This system will consist of information that is created and used by the DHS Office of Public Affairs (OPA) in creating and maintaining the history of DHS. The system will allow OPA to store and retrieve information pertaining to DHS employees and former employees, including political appointees, civilian and military personnel assigned or detailed to DHS, and other individuals who volunteer to be interviewed for the purpose of providing information for this history. No exemptions are claimed for this system.

DATES: Comments must be received on or before November 22, 2004 to be assured of consideration. This notice will be effective September 22, 2004.

ADDRESSES: You may submit comments, identified by [docket number DHS–2004–0004], by any of the following methods:

- Federal e-Docket Portal: *http://docket.epa.gov/edkfed/index.jsp.* Follow the instructions for submitting comments.
- Mail: Nuala O'Connor Kelly, Chief Privacy Officer, Department of Homeland Security, Washington, DC 20528.

All submissions received must include the agency name and docket number. All comments received will be posted without change to *http://docket.epa.gov/edkfed/index.jsp,* including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Elizabeth Withnell, (202) 772–5015.

SUPPLEMENTARY INFORMATION:

Statutory Basis

5 U.S.C. 301; 5 U.S.C. 552a; 44 U.S.C. 3101.

Background

The Department of Homeland Security's Office of Public Affairs (OPA) is responsible for DHS public outreach and media relations. In that capacity, it frequently receives inquiries from the public, the media, and other organizations regarding the history of DHS. In order to facilitate this exchange and promote an accurate and complete portrayal of DHS history, the OPA has engaged the services of a Departmental Historian who is developing a complete history of the department by conducting interviews with the individuals who participated in its creation and development.

This system of records contains personal information about individuals (*i.e.*, names, addresses, etc.) that is retrieved by a personal identifier. Therefore, the Privacy Act of 1974, as amended, requires publication of a notice in the **Federal Register** announcing the existence and character of the system of records and its routine uses. A "Report on a New System," required by 5 U.S.C. 552a(r), as implemented by Office of Management and Budget (OMB) Circular A–130, was sent to: the Chair, Senate Committee on Governmental Affairs; the Chair, House Committee on Government Reform; and the Administrator, Office of Information and Regulatory Affairs, OMB on or before September 22, 2004.

Nuala O'Connor Kelly,

Chief Privacy Officer.

DEPARTMENT OF HOMELAND SECURITY

SYSTEM NAME:

Oral History Program: The History of the Department of Homeland Security (DHS).

SYSTEM LOCATION:

U.S. Department of Homeland Security, Office of Public Affairs, Washington, DC 20528.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

DHS employees and former employees, including political appointees, civilian, and military personnel assigned or detailed to the DHS, and other individuals who volunteer to be interviewed for the purpose of providing information for a history of DHS.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records consist of oral history interviews that are stored on magnetic tape. Records may also include transcriptions of some or all of the interviews and photographs of some or all of the interviewees.

Interviews may include: a brief summary of the interviewee's biographical information; the interviewee's occupational background and position(s) at DHS; the interviewee's personal account and recollection of the events of September 11, 2001; the interviewee's account of the establishment and history of the Department; and the interviewee's comments on the major issues dealt with during DHS employment.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

44 U.S.C. 3101.

PURPOSE(S)

Interviews are conducted to support the DHS policy to inform its current and future leadership and employees, and the U.S. public, about the history of the Department. Interviews may be used as resource documents in preparing news releases or other public information material and may be used to respond to queries from government officials or members of the public.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSE OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, all or a portion of these records or information contained therein may specifically be disclosed outside DHS as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

(1) To the Government Printing Office or other publishing offices for production of a final document;

(2) To the news media and the public, unless it is determined that release of the specific information would constitute an unwarranted invasion of personal privacy;

(3) To the Department of Justice for the purpose of representing the DHS or any officer, employee, or member of the Department in pending or potential

litigation to which the record is relevant and necessary to the litigation;

(4) To a Congressional office from the record of an individual in response to an inquiry from the Congressional office made at the request of that individual;

(5) To the National Archives and Records Administration for records management inspections conducted under the authority of 44 U.S.C. 2904 and 2906;

(6) To contractors, grantees, experts, consultants, students, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for the Federal Government, when necessary to accomplish an agency function related to this system of records;

(7) To the National Archives and/or other government libraries in order to respond to inquiries about DHS.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

These records are maintained on magnetic tape. Transcripts of interviews may also be maintained in paper or electronic format.

RETRIEVABILITY:

Information may be retrieved by subject, by the interviewee's surname, or by the interviewee's DHS employment position title.

SAFEGUARDS:

The records are stored in a secure, guarded, gated facility, at which a badge must be shown to enter. The records may be accessed and used by employees only if there is a need to know the information to perform official duties or with permission of the DHS Historian.

RETENTION AND DISPOSAL:

DHS has sought an appropriate retention schedule from the National Archives and Records Administration. Until that schedule is approved, neither the recorded tapes nor any transcriptions may be destroyed.

SYSTEM MANAGER AND ADDRESS:

Historian, U.S. Department of Homeland Security, Office of Public Affairs, Washington, DC 20528.

NOTIFICATION PROCEDURE:

Address inquiries to the System Manager named above.

RECORD ACCESS PROCEDURE:

A request for access to records in this system may be made by writing to the System Manager, identified above, in conformance with 6 CFR Part 5, Subpart B, which provides the rules for requesting access to Privacy Act records maintained by DHS.

CONTESTING RECORD PROCEDURES:

Same as "Records access procedure."

RECORD SOURCE CATEGORIES:

Information in this system of records is obtained from interviews granted on a voluntary basis to the Historian and the Historian's staff.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

Dated: September 13, 2004.

Nuala O'Connor Kelly,

Chief Privacy Officer.

[FR Doc. 04–21279 Filed 9–21–04; 8:45 am]

BILLING CODE 4410–10–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2004–19085]

Collection of Information Under Review by Office of Management and Budget (OMB): OMB Control Numbers: 1625–0036, 1625–0058, and 1625–0061

AGENCY: Coast Guard, DHS.

ACTION: Request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Coast Guard intends to seek the approval of OMB for the renewal of three Information Collection Requests (ICRs). The ICRs comprise (1) 1625–0036, Plan Approval and Records for U.S. and Foreign Tank Vessels Carrying Oil in Bulk; (2) 1625–0058, Application for Permit to Transport Municipal and Commercial Waste; (3) 1625–0061, Commercial Fishing Industry Vessel Safety Regulations. Before submitting the ICRs to OMB, the Coast Guard is inviting comments on them as described below.

DATES: Comments must reach the Coast Guard on or before November 22, 2004.

ADDRESSES: To make sure that your comments and related material do not enter the docket (USCG–2004–19085) more than once, please submit them by only one of the following means:

(1) By mail to the Docket Management Facility, U.S. Department of Transportation (DOT), room PL–401, 400 Seventh Street, SW., Washington, DC 20590–0001.

(2) By delivery to 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. The telephone number is 202–366–9329.

(3) By fax to the Docket Management Facility at 202–493–2251.

(4) Electronically through the Web site for the Docket Management System at *http://dms.dot.gov.*

The Docket Management Facility maintains the public docket for this notice. Comments and material received from the public, as well as documents mentioned in this notice as being available in the docket, will become part of this docket and will be available for inspection or copying at 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. You may also find this docket on the Internet at *http://dms.dot.gov.*

Copies of the complete ICRs are available through this docket on the Internet at *http://dms.dot.gov*, and also from Commandant (CG–611), U.S. Coast Guard Headquarters, room 6106 (Attn: Mr. Arthur Requina), 2100 Second Street, SW., Washington, DC 20593–0001. The telephone number is 202–267–2326.

FOR FURTHER INFORMATION CONTACT: Mr. Arthur Requina, Office of Information Management, 202–267–2326, for questions on these documents; or Ms. Andrea M. Jenkins, Program Manager, Docket Operations, 202–366–0271, for questions on the docket.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

We encourage you to participate in this request for comment by submitting comments and related materials. We will post all comments received, without change, to *http://dms.dot.gov*, and they will include any personal information you have provided. We have an agreement with DOT to use the Docket Management Facility. Please see the paragraph on DOT's "Privacy Act Policy" below.

Submitting comments: If you submit a comment, please include your name and address, identify the docket number for this request for comment (USCG–2004–19085), indicate the specific section of this document to which each comment applies, and give the reason for each comment. You may submit your comments and material by electronic means, mail, fax, or delivery to the Docket Management Facility at the address under **ADDRESSES**; but please submit them by only one means. If you submit them by mail or delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for

copying and electronic filing. If you submit them by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period. We may change the documents supporting this collection of information or even the underlying requirements in view of them.

Viewing comments and documents: To view comments, as well as documents mentioned in this notice as being available in the docket, go to *http://dms.dot.gov* at any time and conduct a simple search using the docket number. You may also visit the Docket Management Facility in 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.

Privacy Act: Anyone can search the electronic form of all comments received in dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review the Privacy Act Statement of DOT in the **Federal Register** published on April 11, 2000 (65 FR 19477), or you may visit *http://dms.dot.gov.*

Information Collection Requests

1. *Title:* Plan Approval and Records for U.S. and Foreign Tank Vessels Carrying Oil in Bulk.

OMB Control Number: 1625–0036.

Summary: This information collection aids the Coast Guard in determining if a vessel complies with certain safety and environmental protection standards. Plans/records for construction or modification of U.S. or foreign vessels submitted and/or maintained on board are needed for compliance with these standards.

Need: Section 3703 of 46 U.S.C. provides the Coast Guard with the authority to regulate design, construction, alteration, repair, maintenance, operation, equipping, personnel qualification, and manning of vessels carrying oil in bulk.

Respondents: Owners and operators of vessels.

Frequency: On occasion.

Burden Estimate: The estimated burden is 582 hours a year.

2. *Title:* Application for Permit to Transport Municipal and Commercial Waste.

OMB Control Number: 1625–0058.

Summary: This information collection provides the basis for issuing or denying a permit for the transportation of municipal or commercial waste in the coastal waters of the United States.

Need: In accordance with 33 U.S.C. 2602, the U.S. Coast Guard issued regulations, 33 CFR 151.1009, requiring an owner or operator of a vessel to apply for a permit to transport municipal or commercial waste in the United States and to display an identification number or other marking on their vessel.

Respondents: Owners and operators of vessels.

Frequency: Every 18 months.

Burden Estimate: The estimated burden is 69 hours a year.

3. *Title:* Commercial Fishing Industry Vessel Safety Regulations.

OMB Control Number: 1625–0061.

Summary: This information collection is intended to improve safety on board vessels in the commercial fishing industry. The requirements apply to those vessels and to seamen on them.

Need: Under the authority of 46 U.S.C. 6104, the U.S. Coast Guard has promulgated regulations in 46 CFR part 28 to reduce the unacceptably high level of fatalities and accidents in the commercial fishing industry. The rules allowing the collection also provide means of verifying compliance and enhancing safe operation of fishing vessels.

Respondents: Owners, agents, individuals-in-charge of commercial fishing vessels, and insurance underwriters.

Frequency: On occasion.

Burden Estimate: The estimated burden is 7,720 hours a year.

Dated: September 13, 2004.

David McLeish,

Acting Assistant Commandant for Command, Control, Communications, Computers and Information Technology.

[FR Doc. 04–21246 Filed 9–21–04; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Information Collection Renewal Submitted to the Office of Management and Budget (OMB) for Approval Under the Paperwork Reduction Act; OMB Control Number 1018–0070; Incidental Take of Marine Mammals During Specified Activities Applications; 50 CFR 18, Subpart J

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice; request for comments.

SUMMARY: We, the Fish and Wildlife Service, have submitted the collection of information described below to OMB for approval under the provisions of the Paperwork Reduction Act of 1995. If you wish to obtain the proposed information collection or explanatory materials, contact the Information Collection Clearance Officer at the address or phone number listed below.

DATES: You must submit comments on or before October 22, 2004.

ADDRESSES: Send your comments on this information collection renewal to the Desk Officer for the Department of the Interior at OMB–OIRA at (202) 395–6566 (fax) or *OIRA_DOCKET@OMB.eop.gov* (e-mail). Please provide a copy of your comments to Hope Grey, Information Collection Clearance Officer, Fish and Wildlife Service, MS 222–ARLSQ, 4401 N. Fairfax Drive, Arlington, VA 22203; (703) 358–2269 (fax); or at *hope_grey@fws.gov* (e-mail).

FOR FURTHER INFORMATION CONTACT: To request a copy of the information collection request or explanatory information, contact Hope Grey by phone at (703) 358–2482 or by e-mail at *hope_grey@fws.gov.*

SUPPLEMENTARY INFORMATION: We have submitted a request to OMB to renew approval of the information collection clearance requirements for Incidental Take of Marine Mammals During Specified Activities Applications; 50 CFR 18, subpart J. Currently, we have approval from OMB to collect information under OMB control number 1018–0070. This approval expires on September 30, 2004. We may not conduct or sponsor, and a person is not required to respond to, a collection of information unless we display a currently valid OMB control number. OMB regulations at 5 CFR 1320, which implement provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), require that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities (*see* 5 CFR 1320.8(d)). OMB has up to 60 days to approve or disapprove our information collection request, but their response may be given as early as 30 days after our submittal. Therefore, to ensure consideration, send your comments to OMB by the date listed in the **DATES** section near the beginning of this notice.

On April 30, 2004, we published in the **Federal Register** (69 FR 23803) a 60-day notice of our intent to request renewal of this information collection authority from OMB. In that notice, we solicited public comments for 60 days ending on June 29, 2004. We received two comments, both from the same individual, regarding this **Federal**

Register notice. The commenter expressed opposition to use of the term "incidental" and further encouraged the Service to protect all animals. We note the concerns raised by this individual; however, we are required under section 101(a)(5)(A) of the Marine Mammal Protection Act (MMPA) of 1972, as amended (16 U.S.C. 1361 *et seq.*) to take certain actions with regard to the "incidental taking" of marine mammals. The regulations at 50 CFR 18.27(c) define incidental, but not intentional, taking as, "takings which are infrequent, unavoidable, or accidental. It does not mean that the taking must be unexpected." We have not made any changes to our information collection as a result of the comments received.

Section 101(a)(5)(A) of the MMPA authorizes the Service to allow the incidental, unintentional take of small numbers of marine mammals during a specified activity (other than commercial fishing) in a specified geographic region. Prior to allowing these takes, we must find that the total of such taking will have a negligible impact on the species or stocks and will not have an unmitigable adverse impact on the availability of the species or stocks for subsistence uses by Alaskan Natives.

The information that we propose to collect will be used to evaluate applications for specific incidental take regulations to determine whether or not such regulations and subsequent Letters of Authorization (LOAs) are consistent with the MMPA and should be issued. The information is needed to help establish the scope of specific incidental take regulations. The information is also required to evaluate the impacts of the activities on the species or stocks of the marine mammals and on the availability of the species or stocks for subsistence uses by Alaskan Natives. The information will enable us to ensure that all available means for minimizing the incidental take associated with a specific activity are considered by applicants.

We estimate that the total annual burden associated with the request will be 2,027 hours. This represents an average annual estimated burden taken over a 3-year period, which includes the 200 hours required to complete the request for specific procedural regulations (68 FR 66744). For each LOA expected to be requested and issued subsequent to issuance of specific procedural regulations, we estimate that 28 hours per project will be invested: 8 hours will be required to complete each request for an LOA, 12 hours will be required for onsite monitoring activities, and 8 hours will be required to complete each final monitoring report. We estimate that 10 companies will be requesting LOAs and submitting monitoring reports annually for each of 7 sites in the region covered by the specific regulations.

Title: Incidental Take of Marine Mammals During Specified Activities applications; 50 CFR 18, subpart J.

OMB Clearance Number: 1018–0070.

Form Number: None.

Frequency of Collection: Semiannual.

Description of Respondents: Oil and gas industry companies.

Total Annual Responses: 141.

Total Annual Burden Hours: 2,027.

We again invite comments on this information collection renewal on: (1) Whether or not this collection of information is necessary for us to properly perform our functions, including whether or not this information will have practical utility; (2) the accuracy of our estimate of burden, including the validity of the methodology and assumptions we use; (3) ways to enhance the quality, utility, and clarity of the information we are proposing to collect; and (4) ways for us to minimize the burden of the collection of information on respondents, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

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 allowable by law. There may also be limited circumstances in which we would withhold a respondent's identity from the rulemaking record, as allowable by law. If you wish us to withhold your name and/or address, you must state this clearly at the beginning of your comment. We will not consider anonymous comments. We generally make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public inspection in their entirety.

Dated: September 3, 2004.

Hope Grey,

Information Collection Clearance Officer, Fish and Wildlife Service.

[FR Doc. 04–21278 Filed 9–21–04; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Intent To Prepare a Comprehensive Conservation Plan and Environmental Assessment and Announcement of a Public Scoping Meeting for Marin Islands National Wildlife Refuge, Marin County, CA

AGENCY: Fish and Wildlife Service, Department of the Interior.

ACTION: Notice of intent and announcement of a public scoping meeting.

SUMMARY: The Fish and Wildlife Service (Service) is preparing a Comprehensive Conservation Plan (CCP) and Environmental Assessment (EA) for Marin Islands National Wildlife Refuge (Refuge). This notice advises the public that the Service intends to gather information necessary to prepare a CCP and EA pursuant to the National Wildlife Refuge System Administration Act of 1966, as amended, and the National Environmental Policy Act (NEPA). The public and other agencies are encouraged to participate in the planning process by sending written comments on courses of action that the Service should consider and potential impacts that could result from CCP implementation on the Marin Islands National Wildlife Refuge. In addition, the public and other agencies are encouraged to attend the public scoping meeting. The Service is also furnishing this notice in compliance with the Service CCP policy to obtain suggestions and information on the scope of issues to include in the EA.

DATES: To ensure that the Service has adequate time to evaluate and incorporate suggestions and other input into the planning process, comments should be received on or before November 8, 2004. A public scoping meeting to solicit comments on the contents of the CCP and the vision of the Refuge for the next 15 years will be held on October 19, 2004 from 6:30 p.m. to 8:30 p.m. at the Marin Center in San Rafael, California (address follows).

ADDRESSES: Send written comments or requests to be added to the mailing list to the following address: Winnie Chan, Refuge Planner, Marin Islands NWR, San Francisco Bay National Wildlife Refuge Complex, P.O. Box 524, Newark, California 94560. Written comments may also be faxed to (510) 792–5828.

FOR FURTHER INFORMATION CONTACT: Christy Smith, Refuge Manager, (707) 562–3000, or Winnie Chan, Refuge Planner, (510) 792–0222.

SUPPLEMENTARY INFORMATION: The National Wildlife Refuge System Administration Act of 1966, as amended by the National Wildlife Refuge System Improvement Act of 1997, mandates that all lands within the National Wildlife Refuge System are to be managed in accordance with an approved CCP. The CCP will guide management decisions for the next 15 years and identify refuge goals, long-range objectives, and management strategies for achieving these objectives. The planning process will consider many elements, including habitat and wildlife management, habitat protection, recreational use, and environmental effects. Public input into this planning process is very important. The CCP will provide other agencies and the public with a clear understanding of the desired conditions for the Refuge and how the Service will implement management strategies.

Comments received will be used to develop goals, key issues evaluated in the NEPA document, and habitat management strategies. All comments received, including names and addresses will become part of the administrative record and may be made available to the public. Opportunities for public participation will occur throughout the process. The address for the scoping meeting is the Marin Center at 10 Avenue of the Flags, San Rafael, California, 94903. Persons needing reasonable accommodations in order to attend and participate in the public scoping meeting should contact the Refuge Planner at (510) 792–0222 sufficiently in advance of the meeting to allow time to process the request.

The Service will send Planning Updates to people who are interested in the CCP process. These mailings will provide information on how to participate in the CCP process. The CCP is expected to be completed in early 2006. Interested federal, state, and local agencies, Tribes, organizations, and individuals will be contacted for input.

Background

The Marin Islands National Wildlife Refuge is located off the shoreline of the City of San Rafael, Marin County, in San Pablo Bay. The 339-acre Refuge of tidelands and two islands was established in 1992 "* * * for the development, advancement, management, conservation, and protection of fish and wildlife resources * * *" The Marin Islands are jointly owned by the California Department of Fish and Game, California State Lands Commission, and the Fish and Wildlife Service. The Fish-and-Game-owned lands are designated as a State Ecological Reserve and the Service-owned lands are designated as a National Wildlife Refuge. The Service provides day-to-day management of the entire Marin Islands NWR and State Ecological Reserve under the National Wildlife Refuge System Administration Act, as amended.

The Refuge supports one of the largest heron and egret colonies in northern California. The primary purpose of the Refuge is "to protect an important existing egret and heron rookery on West Marin Island and to increase colonial nesting bird use on East Marin Islands," as described in the 1992 Environmental Assessment.

A draft CCP and NEPA document is expected to be available for public review and comment in mid-2005.

Ken McDermond,

Acting Manager, CA/NV Operations, Sacramento, California.

[FR Doc. 04–21268 Filed 9–21–04; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CA 670 1232 FH]

Final Supplementary Rules on Public Land in California

AGENCY: Bureau of Land Management, Interior.

ACTION: Final supplementary rules for payment of special recreation permit fees immediately upon arrival at the Imperial Sand Dunes Recreation Area.

SUMMARY: This notice contains final supplementary rules which will apply to the public lands within the El Centro Resource Field Office, California Desert District, Imperial County, California. The Bureau of Land Management's (BLM) El Centro Field Office will be enforcing the new supplementary rules. The supplementary rules require the payment of special recreation permit fees immediately upon arrival at the Imperial Sand Dunes Recreation Area. Any primary vehicle while on public lands within the Planning Area Boundary or the recreation area must display a weekly or seasonal permit for the areas identified above. The definition of a primary vehicle is described in the **Federal Register**, Vol. 63, No. 242 on Thursday, December 17, 1998, page 69,647, paragraph 3. It stated "A primary transportation vehicle is a street legal vehicle used for transportation to the site." The rules are to enhance the Imperial Sand Dunes Recreation Fee Program and provide revenue for resource protection, and for public health and safety.

EFFECTIVE DATE: The final rules are effective on September 22, 2004.

ADDRESSES: *Mail:* Bureau of Land Management, El Centro Field Office, 1661 S. 4th St., El Centro, CA 92243.

Personal or messenger delivery: Bureau of Land Management, El Centro Field Office, 1661 S. 4th St., El Centro, CA 92243.

Internet e-mail: Neil_Hamada@ca.blm.gov.

FOR FURTHER INFORMATION CONTACT: Neil Hamada, Dunes Manager, Imperial Sand Dunes Recreation Area, Bureau of Land Management, El Centro Field Office, 1661 S. 4th St., El Centro, CA 92243, (760) 337–4451.

SUPPLEMENTARY INFORMATION:

I. Comments

The proposed supplementary rule was published on November 20, 2003 [68 FR 65471] informing the public that comments on the rule were due on December 22, 2003. The BLM received nine letters. Some of these letters contained comments on several issues. The following is a summary of the comments:

• Six comments were beyond the scope of this proposed rule.

• Four comments stated that purchasing the passes was inconvenient.

—BLM Response—BLM has established off site sale for visitor convenience.

• One comment stated that first time visitors will not know where to purchase passes.

—BLM Response—Signs are located along all the major entry points.

• Three comments opposed the rule.

—BLM Response—Comment noted.

• One comment stated that the rule will cause traffic congestion.

—BLM Response—The rule's implementation will not change current traffic patterns or add additional congestion. The BLM will continue to enfore permit compliance in the same manner, through check points and campsite visits. The BLM does not plan to changes any activities to alter traffic patterns.

• One comment wanted to keep the current rule.

—BLM Response—The rule is needed to enhance fee compliance to provide revenue for resource protection, and for public health and safety. The current rule allows visitors a 30 minute grace period before purchasing a permit. Due to the high levels of visitation (over one million

per year), it is inefficient for law enforcement wait 30 minutes for each visitor to comply with the permit regulations. The new rule will allow law enforcement to efficiently enforce permit compliance as visitors arrive at fee checkpoints.

II. Background

These supplementary rules are consistent with the preferred alternative in the Imperial Sand Dunes Recreation Area Management Plan (RAMP). Special Recreation Permit fees were initially implemented in January 1999. Supplementary rules were published on December 17, 1998 [63 FR 69646] establishing those fees. These additional proposed supplementary rules were published in the **Federal Register** on November 20, 2003 [68 FR 65471] to clarify the existing rules, and are to be appended to the 1998 supplementary rules.

III. Discussion of Supplementary Rules

The BLM has regularly recorded over one million visits to the Dunes on an annual basis. Implementing these supplementary rules would require the payment of special recreation permit fees immediately upon arrival at the Imperial Sand Dunes Recreation Area. Any primary vehicle while on public lands within the Planning Area Boundary or the recreation area will be required to display a weekly or seasonal permit for these areas. The supplementary rules are consistent with the preferred alternative in the Imperial Sand Dunes RAMP, and only clarify when the public needs to pay their special recreation permit fee. The RAMP's objectives are to provide the public a safe and enjoyable experience while visiting the dunes and to protect the BLM employees and volunteers maintaining the natural resources. The goals are to reduce or eliminate assaults, drug use, driving under the influence of drugs or alcohol, theft, and any unruly behavior that may lead to any of these, and to encourage users to obey all safety rules and regulations, so as to prevent accidents. The implementation of special recreation permit fees in the dunes will provide the resources necessary to meet these goals and objectives.

These supplementary rules will apply to the public lands within the area identified in the Imperial Sand Dunes Recreation Area Management Plan as the Planning Area Boundary, Mammoth Wash Management Area, North Algodones Dunes Wilderness Management Area, Gecko Management Area, Glamis Management Area, Adaptive Management Area, Ogilby Management Area, Dune Buggy Flats Management Area, and the Buttercup Management Area. BLM has determined these supplementary rules are necessary to enhance the Imperial Sand Dunes Recreation Fee Program and to provide revenue for resource protection and for public health and safety.

IV. Procedural Matters

Executive Order 12866, Regulatory Planning and Review

These supplementary rules are not a significant regulatory action and are not subject to review by Office of Management and Budget under Executive Order 12866. These supplementary rules will not have an effect of $100 million or more on the economy. They are not intended to affect commercial activity, but merely clarify when a fee that is already charged must be paid.

The supplementary rules will not adversely affect, in a material way, the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities. The proposed supplementary rules will not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency. The supplementary rules will not alter the budgetary effects of entitlements, grants, user fees, or loan programs or the right or obligations of their recipients; nor will they raise novel legal or policy issues.

National Environmental Policy Act

BLM has determined that these final supplementary rules requiring the payment of special recreation permit fees immediately upon arrival at Imperial Sand Dunes Recreation Area and certain other locations are purely administrative in nature. Therefore, they are categorically excluded from environmental review under section 102(2)(C) of the National Environmental Policy Act, pursuant to 516 Departmental Manual (DM), Chapter 2, Appendix 1. In addition, the proposed rules do not meet any of the 10 criteria for exceptions to categorical exclusions listed in 516 DM, Chapter 2, Appendix 2. Pursuant to Council on Environmental Quality regulations (40 CFR 1508.4) and the environmental policies and procedures of the Department of the Interior, the term "categorical exclusions" means a category of actions that do not individually or cumulatively have a significant effect on the human environment, that have been found to have no such effect in procedures adopted by a Federal agency, and for which neither an environmental assessment nor an environmental impact statement is required.

Regulatory Flexibility Act

Congress enacted the Regulatory Flexibility Act (RFA) of 1980, as amended, 5 U.S.C. 601–612, to ensure that Government regulations do not unnecessarily or disproportionately burden small entities. The RFA requires a regulatory flexibility analysis if a rule would have a significant economic impact, either detrimental or beneficial, on a substantial number of small entities. The supplementary rule does not pertain specifically to commercial or governmental entities of any size, but to public recreational use of specific public lands. It merely makes clear when a fee that is already charged must be paid. Therefore, BLM has determined under the RFA that the final supplementary rule would not have a significant economic impact on a substantial number of small entities.

Small Business Regulatory Enforcement Fairness Act (SBREFA)

The supplementary rules do not constitute a "major rule" as defined at 5 U.S.C. 804(2). Again, the supplementary rules merely clarify when a fee that is already charged must be paid. The supplementary rules have no effect on business—commercial or industrial—use of the public lands.

Executive Order 12630, Governmental Actions and Interference With Constitutionally Protected Property Rights (Takings)

The final supplementary rules do not represent a government action capable of interfering with constitutionally protected property rights. They merely clarify when a fee that is already charged must be paid. Therefore, the Department of the Interior has determined that the final rules would not cause a taking of private property or require further discussion of takings implications under this Executive Order.

Executive Order 13132, Federalism

The final rules 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. They merely clarify when a fee that is already charged must be paid. Therefore, in accordance with Executive Order 13132, BLM has determined that these final rules do not have sufficient Federalism

implications to warrant preparation of a Federalism Assessment.

Executive Order 12988, Civil Justice Reform

Under Executive Order 12988, the Office of the Solicitor has determined that these final rules would not unduly burden the judicial system and that it meets the requirements of sections 3(a) and 3(b)(2) of the Order.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments [Replaces Executive Order 13084]

In accordance with Executive Order 13175, we have found that the final supplementary rules do no include policies that have tribal implications. They merely clarify when a fee that is already charged must be paid.

Paperwork Reduction Act

These final rules do not contain information collection requirements that the Office of Management and Budget must approve under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*

Author

The principal author of the final rules is Chief Area Ranger Robert Zimmer, Bureau of Land Management, El Centro Field Office, California. Final Rules for Payment of Special Recreation Permit Fees Immediately Upon Arrival at the Imperial Sand Dunes Recreation Area Under 43 CFR 8365.1–8365.6, the Bureau of Land Management will enforce the following final rules on the public lands within the area identified as defined in the Imperial Sand Dunes Recreation Area Management Plan as the Planning Area Boundary, Mammoth Wash Management Area, North Algodones Dunes Wilderness Management Area, Gecko Management Area, Glamis Management Area, Adaptive Management Area, Ogilby Management Area, Dune Buggy Flats Management Area, and the Buttercup Management Area. These lands are within the Imperial Sand Dunes Special Recreation Management Area within the lands managed by the El Centro Field Office of the California Desert District, California. You must follow these rules:

Sec. 1 When must visitors pay the special recreation permit fees?

You must pay the special recreation permit fees immediately upon arrival.

Sec. 2 How must permits be displayed?

Any primary vehicle while on public lands within the Planning Area Boundary or the recreation area must display a weekly or seasonal permit for the areas described above.

Sec. 3 What are the penalties for violations of these rules?

Under section 303(a) of the Federal Land Policy and Management Act of 1976 (43 U.S.C. 1733(a)) and 43 CFR 8360.0–7 if you violate any of these final rules on public lands within the boundaries established in the rules, you may be tried before a United States Magistrate and fined no more than $1000 or imprisoned for no more than 12 months, or both. Such violations may also be subject to the enhanced fines provided for by 18 U.S.C. 3571.

Dated: June 7, 2004.

Mike Pool,

California State Director.

[FR Doc. 04–21261 Filed 9–21–04; 8:45 am]

BILLING CODE 4310–40–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–55,371]

Ace Products, Inc., Lineville, AL; Notice of Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, as amended, an investigation was initiated on August 4, 2004, in response to a worker petition filed by a company official on behalf of workers at Ace Products, Inc., Lineville, Alabama.

The petitioner has requested that the petition be withdrawn. Consequently, further investigation would serve no purpose and the investigation has been terminated.

Signed at Washington, DC, this 30th day of August, 2004.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E4–2308 Filed 9–21–04; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–55,308 and TA–W–55,308A]

Candor Hosiery Mills, Inc., Troy, NC, and Candor Hosiery Mills, Inc., Biscoe, NC; Notice of Revised Determination on Reconsideration

By letter dated August 25, 2004, a petitioner requested administrative reconsideration regarding Alternative Trade Adjustment Assistance (ATAA). The negative determination was signed on July 29, 2004, and published in the **Federal Register** on August 20, 2004 (69 FR 51716).

The workers of Candor Hosiery Mills, Inc., Troy, North Carolina and Biscoe, North Carolina were certified for Trade Adjustment Assistance (TAA) on July 29, 2004.

The initial ATAA investigation determined that the skills of the subject worker group are easily transferable to other positions in the local area.

The petitioner alleges in the request for reconsideration that the skills of the workers at the subject firm are not easily transferable.

Additional investigation has determined that the workers possess skills that are not easily transferable. A significant number or proportion of the worker group are age fifty years or over. Competitive conditions within the industry are adverse.

Conclusion

After careful review of the additional facts obtained on reconsideration, I conclude that the requirements of section 246 of the Trade Act of 1974, as amended, have been met for workers at the subject firm.

In accordance with the provisions of the Act, I make the following certification:

All workers of Candor Hosiery Mills, Inc., Troy, North Carolina (TA–W–55,308) and Candor Hosiery Mills, Inc., Biscoe, North Carolina (TA–W–55,308A), who became totally or partially separated from employment on or after July 22, 2003, through July 29, 2006, are eligible to apply for adjustment assistance under section 223 of the Trade Act of 1974, and are also eligible to apply for alternative trade adjustment assistance under section 246 of the Trade Act of 1974.

Signed in Washington, DC this 10th day of September, 2004.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E4–2307 Filed 9–21–04; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–54,768]

Crystal Springs Apparel, LLC, Crystal Springs, Mississippi; Notice of Revised Determination on Reconsideration

On July 27, 2004, the Department issued an Affirmative Determination Regarding Application on

Reconsideration applicable to workers and former workers of the subject firm. The Notice was published in the **Federal Register** on August 10, 2004 (69 FR 48526).

On June 21, 2004, the Department initially denied TAA to workers of Crystal Springs Apparel, LLC, Crystal Springs, Mississippi because the workers performed administrative and warehousing activities and did not produce an article as defined by the Trade Act of 1974, as amended.

In the request for reconsideration, the company official stated that the subject worker are not service workers. Rather, the subject worker group produces knit shirts and woven shirts (men's and ladies') and are not separately identifiable by product line.

During the reconsideration investigation, the Department determined that the subject worker group are production workers and conducted an investigation to determine whether the workers are eligible to apply for trade adjustment assistance.

The reconsideration investigation revealed that subject company sales, production, imports and employment levels declined in 2003 from 2002 levels and declined during January–April 2004 from the corresponding time period in 2003.

The Department also surveyed the subject company's major declining customers regarding their purchases of knit and woven shirts (men's and ladies') for time periods 2002, 2003, January–April 2003 and January–April 2004. The survey revealed that major declining customers increased their imports of knit and woven shirts like and directly competitive with those produced at the subject company while decreasing their purchases from the subject company during the relevant period.

Conclusion

After careful review of the additional facts obtained on reconsideration, I conclude that increased imports of articles like or directly competitive with knit and woven shirts produced at the subject firm contributed importantly to the declines in sales or production and to the total or partial separation of workers of Crystal Springs Apparel, LLC, Crystal Springs, Mississippi. In accordance with the provisions of the Act, I make the following certification:

"All workers of Crystal Springs Apparel, LLC, Crystal Springs, Mississippi who became totally or partially separated from employment on or after April 21, 2003 through two years of this certification, are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974."

Signed in Washington, DC, this 10th day of September, 2004.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E4–2305 Filed 9–21–04; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–55,432]

Down River LLC, White City, OR; Notice of Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, an investigation was initiated on August 12, 2004 in response to a petition filed by a company official on behalf of workers at Down River LLC, White City, Oregon.

The petitioner has requested that the petition be withdrawn. Consequently, the investigation has been terminated.

Signed in Washington, DC, this 1st day of September, 2004.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E4–2310 Filed 9–21–04; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–55,490]

Federal Mogul Corporation, Lagrange, GA; Notice of Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, an investigation was initiated on August 20, 2004 in response to a petition filed by a company official on behalf of workers at Federal Mogul Corporation, LaGrange, Georgia.

The petitioner has requested that the petition be withdrawn. Consequently, the investigation has been terminated.

Signed in Washington, DC, this 26th day of August 2004.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E4–2312 Filed 9–21–04; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–55,404]

Johnson Controls, Inc., Glasgow, KY; Notice of Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, as amended, an investigation was initiated on August 9, 2004 in response to a worker petition filed by the company on behalf of workers at Johnson Controls, Inc., Automotive Group, Glasgow, Kentucky.

The petitioner has requested that the petition be withdrawn. Consequently, the investigation has been terminated.

Signed at Washington, DC this 31st day of August, 2004.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E4–2309 Filed 9–21–04; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment And Training Administration

[TA–W–54,674]

Major League, Inc., Mt. Airy, NC; Notice of Affirmative Determination Regarding Application for Reconsideration

By application of August 3, 2004, a petitioner requested administrative reconsideration of the Department of Labor's Notice of Negative Determination Regarding Eligibility to Apply for Worker Adjustment Assistance, applicable to workers of the subject firm. The denial notice was signed on May 14, 2004, and published in the **Federal Register** on June 2, 2004 (69 FR 31135).

A previous request for administrative reconsideration was dismissed on July 21, 2004. The Department's Notice of Dismissal of Application for Reconsideration was published in the **Federal Register** on August 4, 2004 (69 FR 47182).

The Department carefully reviewed the August 3, 2004 request for reconsideration and has determined that the Department will conduct further investigation based on new information provided by the petitioner and the company official.

Conclusion

After careful review of the application, I conclude that the claim is of sufficient weight to justify reconsideration of the Department of

Labor's prior decision. The application is, therefore, granted.

Signed at Washington, DC, this 9th day of September, 2004.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E4–2304 Filed 9–21–04; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–55,499]

Marshall Erdman, Waunakee, WI; Notice of Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, as amended, an investigation was initiated on August 23, 2004 in response to a petition filed by the United Brotherhood of Carpenters and Joiners Local 2190 on behalf of workers at Marshall Erdman, Waunakee, Wisconsin.

The petitioning group of workers is covered by an active certification (TA–W–50,208) that remains in effect through March 10, 2005. Consequently, further investigation in this case would serve no purpose, and the investigation has been terminated.

Signed at Washington, DC, this 27th day of August 2004.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E4–2313 Filed 9–21–04; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–55,021]

Parametric Technology Corporation Solutions and Marketing Group WC Publication and Documentation Department, Needham, MA; Notice of Negative Determination Regarding Application for Reconsideration

By application of July 22, 2004, a petitioner requested administrative reconsideration of the Department's negative determination regarding eligibility to apply for Trade Adjustment Assistance (TAA), applicable to workers and former workers of the subject firm. The denial notice was signed on July 1, 2004, and published in the **Federal Register** on August 3, 2004 (69 FR 46574).

Pursuant to 29 CFR 90.18(c) reconsideration may be granted under the following circumstances:

(1) If it appears on the basis of facts not previously considered that the determination complained of was erroneous;

(2) If it appears that the determination complained of was based on a mistake in the determination of facts not previously considered; or

(3) If in the opinion of the Certifying Officer, a misinterpretation of facts or of the law justified reconsideration of the decision.

The petition for the workers of Parametric Technology Corporation, Solutions and Marketing Group, WC Publication and Documentation Departments, Needham, Massachusetts engaged in developing, writing and maintaining technical documentation integrated into the software code was denied because the petitioning workers did not produce an article within the meaning of section 222 of the Act.

The petitioner contends that the Department erred in its interpretation of work performed at the subject facility as a service and further conveys that workers of the subject company produced manuals and help systems which were components of compact disks—a physical product sold to customers. He further states that because these components were essential parts of complete products, the workers writing manuals should be considered workers engaged in production.

A company official was contacted for clarification in regard to the nature of the work performed at the subject facility. The official stated that petitioning group of workers at the subject firm develops, writes, and maintains technical documentation, which indeed includes online help files and manuals. The official further clarified that the documentation created is merged with the software code which is further compiled onto the gold CDs. However, the physical gold CDs are not sold to customers, but rather represent a master copy of the software, which in its turn is sent to an independent non-affiliated party vendor for further duplication and distribution. The official supported the information previously provided by the subject firm that codes and software created at the subject facility are not recorded on any media device by the subject firm for further duplication and distribution to customers and that there are no products manufactured within Parametric Technology Corporation, Needham, Massachusetts.

The sophistication of the work involved is not an issue in ascertaining whether the petitioning workers are eligible for trade adjustment assistance, but rather only whether they produced an article within the meaning of section 222 of the Trade Act of 1974.

Developing, writing, editing, and maintaining on-line technical documentation are not considered production of an article within the meaning of section 222 of the Trade Act. Petitioning workers do not produce an "article" within the meaning of the Trade Act of 1974. Information electronic databases, technical documentation and codes, which are not printed or recorded on media devices (such as CD-ROMs) for further mass production and distribution, are not tangible commodities, and they are not listed on the Harmonized Tariff Schedule of the United States (HTS), as classified by the United States International Trade Commission (USITC), Office of Tariff Affairs and Trade Agreements, which describes articles imported to the United States.

To be listed in the HTS, an article would be subject to a duty on the tariff schedule and have a value that makes it marketable, fungible and interchangeable for commercial purposes. Although a wide variety of tangible products are described as articles and characterized as dutiable in the HTS, informational products that could historically be sent in letter form and that can currently be electronically transmitted are not listed in the HTS. Such products are not the type of products that customs officials inspect and that the TAA program was generally designed to address.

The investigation on reconsideration supported the findings of the primary investigation that the petitioning group of workers does not produce an article.

The petitioner further alleges that because workers lost their jobs due to a transfer of job functions to India, petitioning workers should be considered import impacted.

The company official stated that some technical writing positions were shifted to India. The official further stated that the results of the work assignments completed in India is transmitted back to the US group who create the gold CD via Parametric's Technology Corporation's electronic internal systems.

Informational material that is electronically transmitted is not considered production within the context of TAA eligibility requirements, so there are no imports of products in this instance. Further, as the technical material does not become a product

until it is recorded on media device, there was no shift in production of an "article" within the meaning of the Trade Act of 1974.

In your request for reconsideration, you doubt the accuracy of the information provided by Parametric Technology Corporation and request copies of all the submissions made by the subject firm during the investigation process.

The Department has no evidence that would suggest that the officials of the Parametric Technology Corporation had any reason to mislead the investigation or that they had any interest in the outcome of this determination that might have been adverse to the former employees of the subject firm.

The Department is unable to provide you with the requested copies of documents as all commercial and financial data submitted by the subject firm is entitled to confidential treatment, in accordance with 29 CFR 90.33, and will not be disclosed except to the extent required by applicable law or court order.

Conclusion

After review of the application and investigative findings, I conclude that there has been no error or misinterpretation of the law or of the facts which would justify reconsideration of the Department of Labor's prior decision. Accordingly, the application is denied.

Signed in Washington, DC, this 10th day of September, 2004.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E4–2306 Filed 9–21–04; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–55,482]

TI Automotive, Cass City, MI; Notice of Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, an investigation was initiated on August 20, 2004 in response to petition filed by a company official on behalf of workers at TI Automotive, Cass City, Michigan.

The petitioner has requested that the petition be withdrawn. Consequently, further investigation in this case would serve no purpose, and the investigation has been terminated.

Signed in Washington, DC, this 27th day of August, 2004.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E4–2311 Filed 9–21–04; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

Summary of Decisions Granting in Whole or in Part Petitions for Modification

AGENCY: Mine Safety and Health Administration (MSHA), Labor.

ACTION: Notice of affirmative decisions issued by the Administrators for Coal Mine Safety and Health and Metal and Nonmetal Mine Safety and Health on petitions for modification of the application of mandatory safety standards.

SUMMARY: Under section 101 of the Federal Mine Safety and Health Act of 1977, the Secretary of Labor (Secretary) may allow the modification of the application of a mandatory safety standard to a mine if the Secretary determines either that an alternate method exists at a specific mine that will guarantee no less protection for the miners affected than that provided by the standard, or that the application of the standard at a specific mine will result in a diminution of safety to the affected miners.

Final decisions on these petitions are based on the petitioner's statements, comments and information submitted by interested persons, and a field investigation of the conditions at the mine. MSHA, as designee of the Secretary, has granted or partially granted the requests for modification listed below. In some instances, the decisions are conditioned upon compliance with stipulations stated in the decision. The term FR Notice appears in the list of affirmative decisions below. The term refers to the **Federal Register** volume and page where MSHA published a notice of the filing of the petition for modification.

FOR FURTHER INFORMATION CONTACT: Petitions and copies of the final decisions are available for examination by the public in the Office of Standards, Regulations, and Variances, MSHA, 1100 Wilson Boulevard, Room 2350, Arlington, Virginia 22209. For further information contact Barbara Barron at 202–693–9447.

Dated at Arlington, Virginia this 15th day of September 2004.

Marvin W. Nichols, Jr.,

Director, Office of Standards, Regulations, and Variances.

Affirmative Decisions on Petitions for Modification

Docket No.: M–2002–028–C.
FR Notice: 67 FR 19284.
Petitioner: Consolidation Coal Company.
Regulation Affected: 30 CFR 75.364(b)(2).
Summary of Findings: Petitioner's proposal is to amend the Proposed Decision and Order (PDO) for its previously granted petition for modification, docket number M–1993–275–C, as it relates to air courses ventilating the No. 3 North seals and the No. 2½ North seals at the Loveridge No. 22 Mine. The petitioner's request is to amend paragraph 4 of the previous PDO to permit a certified person to conduct weekly examinations of each of the eight (8) monitoring stations to evaluate the quality of methane and oxygen content (measured by a hand-held instrument) and quantity of air entering and exiting the monitoring station, and to determine air course leakage. This is considered an acceptable alternative method for the Loveridge No. 22 Mine. MSHA grants the petition for modification for continuous monitoring using intrinsically safe sensors installed as part of the mine's Atmospheric Monitoring System (AMS) and weekly evaluation of air entering and leaving the intake air courses ventilating No. 3 North seals and No. 2½ North seals for the Loveridge No. 22 Mine with conditions.

Docket No.: M–2002–043–C.
FR Notice: 67 FR 37443.
Petitioner: Lone Mountain Processing, Incorporated.
Regulation Affected: 30 CFR 75.901(a).
Summary of Findings: Petitioner's proposal is to use a 480-volt, three-phase, 300KW/375VA diesel powered generator (DPG) set to supply power to a three-phase wye connected 300 KVA auto transformer and three-phase 480-volt and 995-volt power circuits. This is considered an acceptable alternative method for the Darby Fork No. 1 Mine. MSHA grants the petition for modification for the LIMA MAC, 480-volt, Model No. 68MDL10094, 300KW diesel powered generator (DPG) set, supplying power to a 300 KVA autotransformer to develop 995-volt power circuits for the Darby Fork No. 1 Mine with conditions.

Docket No.: M–2002–044–C.

FR Notice: 67 FR 37443.

Petitioner: Lone Mountain Processing, Incorporated.

Regulation Affected: 30 CFR 75.901(a).

Summary of Findings: Petitioner's proposal is to use a 480-volt, three-phase, 300KW/375VA diesel powered generator (DPG) set to supply power to a three-phase wye connected 300 KVA auto transformer and three-phase 480-volt and 995-volt power circuits. This is considered an acceptable alternative method for the Huff Creek Mine No. 1. MSHA grants the petition for modification for the LIMA MAC, 480-volt, Model No. 68MDL10094, 300KW diesel powered generator (DPG) set, supplying power to a 300 KVA autotransformer to develop 995-volt power circuits for the Huff Creek Mine No. 1 with conditions.

Docket No.: M–2002–073–C.

FR Notice: 67 FR 59318.

Petitioner: Mountain Coal Company, L.L.C.

Regulation Affected: 30 CFR 75.352.

Summary of Findings: Petitioner's proposal is to temporarily use a portion of the #4 Belt Entry as a return air course and use specific stipulations listed in the petition for modification to achieve an equivalent level of safety when implementing its proposed alternative method. These stipulations will remain in effect only until a return air course can be established between the E-seam and the shaft that connects the B-seam to the F-seam. This is considered an acceptable alternative method for the West Elk Mine. MSHA grants the petition for modification for use of belt haulage in a return air course, only between the F and B coal seams along the No. 4 belt in the No. 1 Rock Slope entry, during initial development of the E-seam, between the rock slopes and the inner-seam return air shaft, conditioned upon compliance with the terms and conditions listed in the Proposed Decision and Order for the West Elk Mine.

Docket No.: M–2003–027–C.

FR Notice: 68 FR 23501.

Petitioner: Baylor Mining, Inc.

Regulation Affected: 30 CFR 75.364(b)(2).

Summary of Findings: Petitioner's proposal is to have a certified person check the quantity and quality of air at four monitoring stations (identified as EP No. 3, EP No. 4, EP No. 5, and EP No. 6) intake and return air courses on a weekly basis in the area approximately 700 feet of the return air course in the 1st Left section of the Beckley Crystal Mine due to extremely hazardous roof conditions and several roof falls. The petitioner asserts that traveling the affected areas would be unsafe. The petitioner filed this petition for modification seeking to modify the application of 30 CFR 75.364(a)(1). MSHA determined that the petitioned area is not a worked out area and is best classified as a designated return air course. Therefore, the petition is being treated as a request to modify the application of 30 CFR 75.364(b)(2). This is considered an acceptable alternative method for the Beckley Crystal Mine. MSHA grants the petition for modification for the examination of approximately 700 feet of unsafe-to-travel return air course in the 1st Left Section from Spad No. 1839 to one block inby Spad No. 1792 for the Beckley Crystal Mine with conditions.

Docket No.: M–2003–038–C.

FR Notice: 68 FR 37176.

Petitioner: Anker West Virginia Mining Company, Inc.

Regulation Affected: 30 CFR 75.364(b)(1).

Summary of Findings: Petitioner's proposal is to establish evaluation points to monitor the quality, quantity, and direction of air flow through the A Mains intake air course starting at Spad 428 and ending at Spad 388, a distance of 3,100 feet. The evaluation points will be established at the inby end of the intake air course near Spad 388 to test for methane accumulation oxygen deficiency, quantity of air and for the proper direction of air flow; the evaluation points will be examined on a weekly basis; test results will be recorded in a book provided on the surface; and preshift examination of the belt side of the intake stopping line separating the belt from the intake air course will be made every 8 hours and any hazardous conditions found will be recorded in a book provided on the surface. This is considered an acceptable alternative method for the Spruce Fork Mine No. 1. MSHA grants the petition for modification for evaluation of the unsafe-for-examination intake air course segment (approximately 3,100 feet) known as the A Mains Air Course Area for the Spruce Fork Mine No. 1 with conditions.

Docket No.: M–2003–041–C.

FR Notice: 68 FR 37177.

Petitioner: R & D Coal Company, Inc.

Regulation Affected: 30 CFR 75.311(b)(2) and (b)(3).

Summary of Findings: Petitioner's request is that electrical circuits entering the underground mine remain energized to the mine's de-watering pumps while the mine ventilation fan is intentionally stopped during idle shifts while no miners are underground. This is considered an acceptable alternative method for the Buck Mountain Slope Mine. MSHA grants the petition for modification to permit the electrical circuits entering the underground mine to remain energized to the mine's de-watering pumps while the mine ventilation fan is intentionally stopped during idle shifts while no miners are underground for the Buck Mountain Slope Mine with conditions.

Docket No.: M–2003–042–C.

FR Notice: 68 FR 37177.

Petitioner: Orchard Coal Company, Inc.

Regulation Affected: 30 CFR 75.311(b)(2) and (b)(3).

Summary of Findings: Petitioner's request is that electrical circuits entering the underground mine remain energized to the mine's de-watering pumps while the mine ventilation fan is intentionally stopped during idle shifts while no miners are underground. This is considered an acceptable alternative method for the Orchard Slope Mine. MSHA grants the petition for modification to permit the electrical circuits entering the underground mine to remain energized to the mine's de-watering pumps while the mine ventilation fan is intentionally stopped during idle shifts while no miners are underground for the Orchard Slope Mine with conditions.

Docket No.: M–2003–053–C.

FR Notice: 68 FR 47367.

Petitioner: Jim Walter Resources, Inc.

Regulation Affected: 30 CFR 75.507.

Summary of Findings: Petitioner's proposal is to use deep well submersible pumps driven by sealed areas in the underground mines. This is considered an acceptable alternative method for the No. 4, No. 5, and No. 7 Mines. MSHA grants the petition for modification for the use of 4,160-volt, three-phase, and alternating-current submersible pump(s) installed in boreholes in the No. 4, No. 5, and No. 7 Mines with conditions.

Docket No.: M–2003–066–C.

FR Notice: 68 FR 57933.

Petitioner: Little Eagle Coal Company, LLC.

Regulation Affected: 30 CFR 75.900.

Summary of Findings: Petitioner's proposal is to use a vacuum contactor in series with the circuit breaker to perform tripping tasks normally associated with the circuit breaker using specific procedures listed in the petition for modification. This is considered an acceptable alternative method for the Little Eagle Mine. MSHA grants the petition for modification to allow the use of contactors to provide under-voltage, grounded phase, and monitor the grounding conductors for low- and

medium-voltage power circuits serving three-phase alternating current equipment located in the Little Eagle Mine with conditions.

Docket No.: M–2003–068–C.
FR Notice: 68 FR 61701.
Petitioner: Black Beauty Coal Company.
Regulation Affected: 30 CFR 75.1700.
Summary of Findings: Petitioner's proposal is to mine through oil and gas wells in lieu of plugging the wells and to establish and maintain a barrier around various abandoned wells. This is considered an acceptable alternative method for the Francisco Mine, Underground Pit. MSHA grants the petition for modification for mining through or near (whenever the safety barrier diameter is reduced to a distance less than the District Manager would approve pursuant to Section 75.1700) plugged oil or gas wells penetrating the Indiana V coal seam and other mineable coal seams for the Francisco Mine, Underground Pit with conditions.

Docket No.: M–2004–070–C.
FR Notice: 68 FR 61701.
Petitioner: Consolidation Coal Company.
Regulation Affected: 30 CFR 75.364(b)(2).
Summary of Findings: Petitioner's proposal is to establish check points to monitor the area of the return air course from Main North 104 block to 3 West 12 block due to deteriorating roof conditions which has caused the affected area to be unsafe for travel in its entirety to conduct weekly examinations. The petitioner proposes to establish check points 3W–1 and 3W–2 to measure air quality and quantity at the inlet to the affected air course, and check point 3W–3 to measure air quality and quantity at the outlet from the affected air course; maintain the check points in safe condition at all times; and have a certified person test for methane and the quantity of air on a weekly basis and record the results of the test in book with their initials, date, and time and kept on the surface for inspection by interested person(s). This is considered an acceptable alternative method for the Robinson Run Mine. MSHA grants the petition for modification for the examination of approximately 2,200 feet of unsafe-to-travel return air course from Main North 104 Block to 3 West 12 Block for the Robinson Run Mine with conditions.

Docket No.: M–2003–072–C.
FR Notice: 68 FR 61701.
Petitioner: Bowie Resources, Limited.
Regulation Affected: 30 CFR 75.901(a).
Summary of Findings: Petitioner's proposal is to use an alternate method of compliance for the grounding of a diesel generator. The petitioner proposes to use a 460KW diesel powered generator to move electrically powered mining equipment in, out, and around the mine only, and to perform work in areas outby section loading points where permissible equipment is not required. This is considered an acceptable alternative method for the Bowie No. 3 Mine. MSHA grants the petition for modification for the Bowie No. 3 Mine with conditions.

Docket No.: M–2003–075–C.
FR Notice: 68 FR 61702.
Petitioner: Bowie Resources Limited.
Regulation Affected: 30 CFR 75.1726(a).
Summary of Findings: Petitioner's proposal is to use modified diesel powered L.H.D.'s or "scoops" as elevated mobile work platforms at the Bowie No. 3 Mine using specific procedures listed in the petition for modification. This is considered an acceptable alternative method for the Bowie No. 3 Mine. MSHA grants the petition for modification for the Bowie No. 3 Mine with conditions.

Docket No.: M–2003–078–C.
FR Notice: 68 FR 64129.
Petitioner: Consol Pennsylvania Coal Company.
Regulation Affected: 30 CFR 75.507.
Summary of Findings: Petitioner's proposal is to install non-permissible submersible pumps to be installed in bleeder and return entries and sealed areas of the Enlow Fork Mine. On December 2, 2003, the petitioner filed an amended petition for modification requesting that the Bailey Mine also apply to this petition (69 FR 42070, July 13, 2004). This is considered an acceptable alternative method for the Enlow Fork and Bailey Mines. MSHA grants the petition for modification for the use of low- and medium-volt, three phase, alternating current, non-permissible submersible pump(s) installed in bleeder and return entries and sealed areas for the Enlow Fork and Bailey Mines with conditions.

Docket No.: M–2003–080–C.
FR Notice: 68 FR 64129.
Petitioner: KenAmerican Resources, Inc.
Regulation Affected: 30 CFR 75.364(b)(2).
Summary of Findings: Petitioner's proposal is to establish a Measuring Point Location in the Main East return at x-cut #10 (MPL 1B) and the ventilation entries at x-cut #7 (MPL C & D), and in the Main North return at x-cut #1, due to deteriorating roof conditions which causes unsafe conditions for traveling the entire affected area to conduct weekly examinations. This is considered an acceptable alternative method for the Paradise #9 Mine. MSHA grants the petition for modification for the unsafe-to-travel segment (approximately 1,300 feet) of the Main North and Main East return air course for the Paradise #9 Mine with conditions.

Docket No.: M–2003–081–C.
FR Notice: 68 FR 64129.
Petitioner: Bowie Resources Limited.
Regulation Affected: 30 CFR 75.1002.
Summary of Findings: Petitioner's proposal is to use high-voltage continuous miners inby the last crosscut and within 150 feet of the pillar workings. This is considered an acceptable alternative method for the Bowie No. 3 Mine. MSHA grants the petition for modification for the use of the 2,400-volt high-voltage continuous miner(s) at the Bowie No. 3 Mine with conditions, Proposed Decision and Order (PDO) dated May 3, 2004. On April 26, 2004, the petitioner requested application of relief to give effect to the PDO, because to delay the effective date of the PDO for the normal 30-day period would cause an unnecessary disruption of mining activities and significant economic loss. On May 3, 2004, MSHA grants application for relief to give effect to May 3, 2004, to allow the high-voltage continuous miner, previously granted modification under Docket Number M–2003–023–C, to be used at the Bowie No. 3 Mine under identical granting terms and conditions.

Docket No.: M–2003–083–C.
FR Notice: 68 FR 67217.
Petitioner: Genwal Resources, Inc.
Regulation Affected: 30 CFR 75.500(b).
Summary of Findings: Petitioner's proposal is to use the following non-permissible low-voltage or battery-powered electronic testing and diagnostic equipment inby the last open crosscut: Lap top computers, oscilloscopes, vibration analysis machines, cable fault detectors, point temperature probes, infrared temperature devices and recorders, pressure and flow measurement devices, signal analyzer devices, ultrasonic thickness gauges, electronic component testers, and electronic tachometers, and battery operated drills. The petitioner states that all other test and diagnostic equipment may be used if approved in advance by MSHA's District Office. This is considered an acceptable alternative method for the South Crandall Canyon Mine. MSHA grants the petition for modification for the use of low-voltage or battery-powered non-permissible electronic testing and diagnostic

equipment in or inby the last open crosscut or within 150 feet of pillar workings or longwall face, under controlled conditions, for testing and diagnosing the mining equipment at the South Crandall Canyon Mine with conditions.

Docket No.: M–2003–085–C.
FR Notice: 68 FR 67218.
Petitioner: Genwal Resources, Inc.
Regulation Affected: 30 CFR 75.1002–1(a) now 75.1002(a).
Summary of Findings: Petitioner's proposal is to use the following non-permissible low-voltage or battery-powered electronic testing and diagnostic equipment inby the last open crosscut: Lap top computers, oscilloscopes, vibration analysis machines, cable fault detectors, point temperature probes, infrared temperature devices and recorders, pressure and flow measurement devices, signal analyzer devices, ultrasonic thickness gauges, electronic component testers, and electronic tachometers, and battery operated drills. The petitioner states that all other test and diagnostic equipment may be used if approved in advance by MSHA's District Office. This is considered an acceptable alternative method for the South Crandall Canyon Mine. MSHA grants the petition for modification for the use of low-voltage or battery-powered non-permissible electronic testing and diagnostic equipment in or inby the last open crosscut or within 150 feet of pillar workings or longwall face, under controlled conditions, for testing and diagnosing the mining equipment at the South Crandall Canyon Mine with conditions.

Docket No.: M–2003–087–C.
FR Notice: 68 FR 67218.
Petitioner: White County Coal, LLC.
Regulation Affected: 30 CFR 75.1700.
Summary of Findings: Petitioner's proposal is to plug oil and gas wells using the proven techniques described in this petition for modification and then mine in close proximity or through such plugged wells using the specific procedures listed in the petition. This is considered an acceptable alternative method for the Pattiki II Mine. MSHA grants the petition for modification for mining through or near (whenever the safety barrier diameter is reduced to a distance less than the District manager would approve pursuant to Section 75.1700) plugged or gas wells penetrating the Illinois No. 6 coal seam and other mineable coal seams using continuous miners, conventional mining, or longwall mining methods for the Pattiki II Mine with conditions.

Docket No.: M–2003–089–C.
FR Notice: 68 FR 67218.
Petitioner: Warrior Coal, LLC.
Regulation Affected: 30 CFR 75.1700.
Summary of Findings: Petitioner's proposal is to mine through oil and gas wells in all mineable coal beds using the specific terms and conditions listed in this petition for modification. This is considered an acceptable alternative method for the Cardinal Mine. MSHA grants the petition for modification for mining through or near (whenever the safety barrier diameter is reduced to a distance less than the District Manager would approve pursuant to Section 75.1700) plugged oil or gas wells penetrating the Kentucky Numbers 9 and 11 coal seams and other mineable coal seams using continuous miners, conventional mining, or longwall mining methods for the Cardinal Mine with conditions.

Docket No.: M–2003–098–C.
FR Notice: 69 FR 3948.
Petitioner: Little Buck Coal Company.
Regulation Affected: 30 CFR 49.2(b).
Summary of Findings: Petitioner's proposal is to reduce the two mine rescue teams with five members and one alternate each, to two mine rescue teams with three members and one alternate for either team. This is considered an acceptable alternative method for the No. 2 Slope Mine. MSHA grants the petition for modification for the No. 2 Slope Mine with conditions.

Docket No.: M–2004–002–C.
FR Notice: 69 FR 7796.
Petitioner: CONSOL of Kentucky, Inc.
Regulation Affected: 30 CFR 75.1101–8.
Summary of Findings: Petitioner's proposal is to use a single line of automatic sprinklers for its fire protection system on main and secondary belt conveyors in the Jones Fork E–3 Mine. The petitioner proposes to: (i) Use a single overhead pipe system with ½-inch orifice automatic sprinklers located on 10-foot centers, to cover 50 feet of fire-resistant belt or 150 feet of non-fire resistant belt, with actuation temperatures between 200 and 230 degrees Fahrenheit and the water pressure equal to or greater than 10 psi; (ii) locate automatic sprinklers not more than 10 feet apart so that the discharge of water will extend over the belt drive, belt take-up, electrical control, and gear reducing unit; (iii) conduct a test during installation of each new system and during any subsequent repair or replacement of any critical part thereof; (iv) conduct a functional test to insure proper operation during subsequent repair or replacement of any critical part thereof; and (v) conduct an annual functional test of each sprinkler system. This is considered an acceptable alternative method for the Jones Fork E–3 Mine. MSHA grants the petition for modification for a single overhead pipe sprinkler system in the Jones Fork E–3 Mine with conditions.

Docket No.: M–2004–003–C.
FR Notice: 69 FR 7796.
Petitioner: Paramount Coal Company Virginia, LLC.
Regulation Affected: 30 CFR 77.214(a).
Summary of Findings: Petitioner's proposal is to place scalp rock in an area containing abandoned mine openings. The petitioner proposes to use the existing abandoned VICC #3 mine pit, located on Russell Creek off State Route 655 in Virginia City, Wise County, Virginia, for disposing scalp rock from the VICC #3 and VICC #10 Mines, and reclaim the highwall above the abandoned VICC #8 Portals. Disposal of the scalp rock will necessitate the sealing of the three mine openings. This is considered an acceptable alternative method for the VICC No. 3 and VICC No. 10 Mines. MSHA grants the petition for modification for the VICC No. 3 and No. 10 Mines with conditions.

Docket No.: M–2004–007–C.
FR Notice: 69 FR 11894.
Petitioner: Mingo Logan Coal Company.
Regulation Affected: 30 CFR 77.214(a).
Summary of Findings: Petitioner's proposal is to use coarse coal mine refuse material from the Black Bear Preparation Plant to seal and reclaim four mine openings of the abandoned Select Mining, Inc., Mine No. 5. This is considered an acceptable alternative method for the Black Bear Preparation Plant. MSHA grants the petition for modification for the Black Bear Preparation Plant with conditions.

Docket No.: M–2004–008–C.
FR Notice: 69 FR 11894.
Petitioner: Remington, LLC.
Regulation Affected: 30 CFR 75.1002.
Summary of Findings: Petitioner's proposal is to use a high-voltage 2,400-volt Joy 14CM27 continuous miner at the Stockburg No. 2 Mine. This is considered an acceptable alternative method for the Stockburg No. 2 Mine. MSHA grants the petition for modification for the Stockburg No. 2 Mine with conditions, Proposed Decision and Order (PDO) dated May 11, 2004. On May 7, 2004, the petitioner requested application of relief to give effect to the PDO, because to delay the effective date of the PDO for the normal 30-day period would cause an unnecessary disruption of mining activities and significant economic loss.

On May 11, 2004, MSHA grants application for relief to give effect to May 11, 2004, to allow the high-voltage continuous miner, previously granted modification under Docket Number M–1998–001–C, to be used at the Stockburg No. 2 Mine under current and nearly identical granting terms and conditions.

Docket No.: M–2004–009–C.
FR Notice: 69 FR 13593.
Petitioner: Coteau Properties Company.
Regulation Affected: 30 CFR 77.803.
Summary of Findings: Petitioner's proposal is to use an alternative method of compliance when raising or lowering the boom/mast during construction/maintenance, most likely during disassembly or major maintenance. The petitioner proposes to use this procedure only to raise or lower the boom/mast on draglines using the on-board motor generator sets. This is considered an acceptable alternative method for the Freedom Mine. MSHA grants the petition for modification for dragline boom or mast raising, lowering, assembling, disassembling or during major repairs which require raising or lowering the dragline boom or mast by the on-board generators for the Freedom Mine with conditions.

Docket No.: M–2004–010–C.
FR Notice: 69 FR 13593.
Petitioner: TXU Mining Company LP.
Regulation Affected: 30 CFR 77.803.
Summary of Findings: Petitioner's proposal is to use an alternative method of compliance when raising or lowering the boom/mast during construction/maintenance, most likely during disassembly or major maintenance. The petitioner proposes to use this procedure only to raise or lower the boom/mast on draglines using the on-board motor generator sets. This is considered an acceptable alternative method for the Big Brown Strip Mine, Winfield North Strip Mine, Winfield South Strip Mine, Beckville Strip Mine, Tatum Strip Mine, and Oak Hill Strip Mine. MSHA grants the petition for modification for dragline boom or mast raising, lowering, assembling, disassembling or during major repairs which require raising or lowering the dragline boom or mast by the on-board generators for the Big Brown Strip Mine, Winfield North Strip Mine, Winfield South Strip Mine, Beckville Strip Mine, Tatum Strip Mine, and Oak Hill Strip Mine with conditions.

Docket No.: M–2004–012–C.
FR Notice: 69 FR 18986.
Petitioner: The Sabiné Mining Company.
Regulation Affected: 30 CFR 77.803.
Summary of Findings: Petitioner's proposal is to use an alternative method of compliance when raising or lowering the boom/mast during necessary repairs. The machine will not be in operation during the procedure for raising and lowering the boom for construction/maintenance. This modification will not replace any other mechanical precautions or the requirements of 30 CFR 77.405(b) that are necessary to safely secure booms/masts during construction or maintenance procedures. This is considered an acceptable alternative method for the South Hallsville No. 1 Mine. MSHA grants the petition for modification for dragline boom or mast raising, lowering, assembling, disassembling or during major repairs which require raising or lowering the dragline boom or mast by the on-board generators for the South Hallsville No. 1 Mine.

Docket No.: M–2004–013–C.
FR Notice: 69 FR 18986.
Petitioner: CONSOL of Kentucky, Inc.
Regulation Affected: 30 CFR 75.1101–8.
Summary of Findings: Petitioner's proposal is to use a single line of automatic sprinklers for its fire protection system on main and secondary belt conveyors in the Raccoon E–1 Mine. The petitioner proposes to use a single overhead pipe system with ½-inch orifice automatic sprinklers located on 10-foot centers, located to cover 50 feet of fire-resistant belt or 150 feet of non-fire resistant belt, with actuation temperatures between 200 and 230 degrees Fahrenheit, and with water pressure equal to or greater than 10 psi. The petitioner also proposes to have the automatic sprinklers located not more than 10 feet apart so that the discharge of water will extend over the belt drive, belt take-up, electrical control, and gear reducing unit; conduct a test to insure proper operation during the installation of each new system and during any subsequent repair or replacement of any critical part of the sprinkler system; conduct a functional test to insure proper operation during subsequent repair or replacement of any critical part of the sprinkler system; and conduct a functional test on an annual basis. This is considered an acceptable alternative method for the Raccoon E–1 Mine. MSHA grants the petition for modification for a single overhead pipe sprinkler system for the Raccoon E–1 Mine with conditions.

Docket No.: M–2003–002–M.
FR Notice: 68 FR 55293.
Petitioner: Phelps Dodge Morenci Incorporated.
Regulation Affected: 30 CFR 56.6309.
Summary of Findings: Petitioner's proposal is to use recycled waste oil to prepare ammonium nitrate-fuel oil at the Morenci Mine using the specific procedures listed in the petition for modification. This is considered an acceptable alternative method for the Morenci Mine. MSHA grants the petition for modification for the Morenci Mine with conditions.

[FR Doc. 04–21231 Filed 9–21–04; 8:45 am]
BILLING CODE 4510–43–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

Petitions for Modification

The following parties have filed petitions to modify the application of existing safety standards under section 101(c) of the Federal Mine Safety and Health Act of 1977.

1. Brooks Run Mining Company, LLC

[Docket No. M–2004–040–C]

Brooks Run Mining Company, LLC, has filed a petition to modify the application of 30 CFR 75.1711 (Sealing of mines) to its Mine No. 3 (MSHA I.D. No. 46–06043) located in Webster County, West Virginia. The petitioner proposes to barricade or fence-off mine openings to prevent entrance to the Mine No. 3, instead of sealing mine openings. The petitioner states that the Mine No. 3 has remaining coal reserves that may be economically recoverable in the future; currently no miners are employed at the mine site; and the mine has been idle and the portals barricaded since October 5, 1999. The petitioner asserts that the proposed alternative method would provide at least the same measure of protection as the existing standard.

2. Relgis, Inc.

[Docket No. M–2004–041–C]

Relgis, Inc., 800 Main Street, Summersville, West Virginia 26651 has filed a petition to modify the application of 30 CFR 75.1103–4(a) (Automatic fire sensor and warning device systems; installation; minimum requirements) to its Lick Branch No. 2 Mine (MSHA I.D. No. 46–08676) located in Fayette County, West Virginia. The petitioner proposes to install a carbon monoxide monitoring system as an early warning fire detection system near the center and in the upper third of the belt entry in a location that would not expose personnel working on the system to unsafe situations. The petitioner states that sensors will not be located in intersections, abnormally high areas, or in other areas where airflow patterns do not permit products of combustion to be

carried to the sensors. The petitioner asserts that the proposed alternative method would provide at least the same measure of protection as the existing standard.

Request for Comments

Persons interested in these petitions are encouraged to submit comments via e-mail to *comments@msha.gov*, by fax at (202) 693–9441, or by regular mail to the Office of Standards, Regulations, and Variances, Mine Safety and Health Administration, 1100 Wilson Boulevard, Room 2350, Arlington, Virginia 22209. All comments must be postmarked or received in that office on or before October 22, 2004. Copies of these petitions are available for inspection at that address.

Dated at Arlington, Virginia this 16th day of September 2004.

Marvin W. Nichols, Jr.,

Director, Office of Standards, Regulations, and Variances.

[FR Doc. 04–21230 Filed 9–21–04; 8:45 am]

BILLING CODE 4510–43–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. ICR 1218–0206 (2004)]

Grain Handling Facilities Standard; Extension of the Office of Management and Budget's (OMB) Approval of Information Collection (Paperwork) Requirements

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Request for public comment.

SUMMARY: OSHA solicits comments concerning its request for an extension of the Information Collection Requirements contained in the Grain Handling Facilities Standard (29 CFR 1910.272). The purpose of these requirements is to establish safety practices, means, methods and operations for employees working in grain handling facilities.

DATES: Comments must be submitted by the following dates:

Hard copy: Your comments must be submitted (postmarked or received) by November 22, 2004.

Facsimile and electronic transmission: Your comments must be received by November 22, 2004.

ADDRESSES: You may submit comments, identified by OSHA Docket No. ICR–1218–0206(2004), by any of the following methods:

Regular mail, express delivery, hand delivery, and messenger service: Submit your comments and attachments to the OSHA Docket Office, Room N–2625, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone (202) 693–2350 (OSHA's TTY number is (877) 889–5627). OSHA Docket Office and Department of Labor hours are 8:15 a.m. to 4:45 p.m., ET.

Facsimile: If your comments are 10 pages or fewer in length, including attachments, you may fax them to the OSHA Docket Office at (202) 693–1648.

Electronic: You may submit comments through the Internet at *http://ecomments.osha.gov*. Follow instructions on the OSHA Web page for submitting comments.

Docket: For access to the docket to read or download comments or background materials, such as the complete Information Collection Request (ICR) (containing the Supporting Statement, OMB–83–I Form, and attachments), go to OSHA's Web page at *http://OSHA.gov*. In addition, comments, submissions and the ICR are available for inspection and copying at the OSHA Docket Office at the address above. You may also contact Todd Owen or Theda Kenney at the address below to obtain a copy of the ICR.

(For additional information on submitting comments, please see the "Public Participation" heading in the **SUPPLEMENTARY INFORMATION** section of this document.)

FOR FURTHER INFORMATION CONTACT: Theda Kenney or Todd Owen, Directorate of Standards and Guidance OSHA, Room N–3609, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone (202) 693–2222.

SUPPLEMENTARY INFORMATION:

I. Submission of Comments on This Notice and Internet Access to Comments and Submissions

You may submit comments and supporting materials in response to this notice by (1) hard copy, (2) FAX transmission (facsimile), or (3) electronically through the OSHA Web page. Because of security related problems there may be significant delay in the receipt of comments by regular mail. Please contact the OSHA Docket Office at (202) 693–2350 (TTY (877) 889–5627) for information about security procedures concerning the delivery of submissions by express delivery, hand delivery and courier service.

All comments, submissions and background documents are available for inspection and copying at the OSHA Docket Office at the above address. Comments and submissions posted on OSHA's Web page are available at *http://www/OSHA.gov*. Contact the OSHA Docket Office for information about materials not available through the OSHA Web page and for assistance using the Web page to locate docket submissions.

Electronic copies of this **Federal Register** notice as well as other relevant documents are available on OSHA's Web page.

II. Background

The Department of Labor, as part of it continuing effort to reduce paperwork and respondent (i.e., employer) burden, conducts a preclearance consultation program to provide the public with an opportunity to comment on proposed and continuing information collection requirements in accordance with the Paperwork Reduction Act of 1995 (PRA–95) (44 U.S.C. 3506(c)(2)(A)).

This program ensures that information is in the desired format, reporting burden (time and costs) is minimal, collection instruments are clearly understood, and OSHA's estimate of the information collection burden is accurate. The Occupational Safety and Health Act of 1970 (the Act) (29 U.S.C. 651 *et seq.*) authorizes information collection by employers as necessary or appropriate for enforcement of the Act or for developing information regarding the causes and prevention of occupational injuries, illnesses, and accidents (29 U.S.C. 657).

The Grain Handling Facilities Standard (the Standard) (29 CFR 1910.272) specifies several paperwork requirements. The following sections describe what information is collected under each requirement, who uses the information, and how they use it.

Paragraph (d) of the standard requires the employer to develop and implement an emergency action plan so that employees will be aware of the appropriate actions to take in the event of an emergency.

Paragraph (e)(1) requires that employers provide training to employees at least annually and when changes in job assignment will expose them to new hazards.

Paragraph (f)(1) requires the employer to issue a permit for all hot work. Under paragraph (f)(2) the permit shall certify that the requirements contained in 1910.272(a) have been implemented prior to beginning the hot work operations and shall be kept on file until completion of the hot work operation.

Paragraph (g)(1)(i) requires the employer to issue a permit for entering bins, silos, or tanks unless the employer or the employer's representative is

present during the entire operation. The permit shall certify that the precautions contained in paragraph (g) have been implemented prior to employees entering bins, silos or tanks and shall be kept on file until completion of the entry operations.

Paragraph (g)(4) requires the employer to implement procedures for the use of tags and locks which will prevent the inadvertent application of energy or motion to equipment being repaired, serviced, or adjusted.

Paragraphs (i)(1) and (i)(2) require the employer to inform contractors performing work at the grain handling facility of known potential fire and explosion hazards related to the contractor's work area and to explain to the contractor the applicable provisions of the emergency action plan.

Paragraph (j)(1) requires the employer to develop and implement a written housekeeping program that establishes the frequency and method(s) determined best to reduce accumulations of fugitive grain dust on ledges, floors, equipment, and other exposed surfaces.

The purpose of the housekeeping program is to require employers to have a planned course of action for the control and reduction of dust in grain handling facilities reducing the fuel available in a grain facility. The housekeeping program must specify in writing the frequency that housekeeping will be performed and the dust control methods that the employer believes will best reduce dust accumulations in the facility.

Under paragraph (m)(1), the employer is required to implement preventive maintenance procedures consisting of regularly scheduled inspections of at least the mechanical and safety control equipment associated with dryers, grain stream processing equipment, dust collection equipment including filer collectors, and bucket elevators. Paragraph (m)(3) requires a certification be maintained of each inspection.

III. Special Issues for Comment

OSHA has a particular interest in comments on the following issues:

- Whether the proposed information collection requirements are necessary for the proper performance of the Agency's functions, including whether the information is useful;
- The accuracy of OSHA's estimate of the burden (time and costs) of the information-collection requirements, including the validity of the methodology and assumptions used;
- The quality, utility, and clarity of the information collected; and
- Ways to minimize the burden on employers who must comply; for example, by using automated or other technological information collection and transmission techniques.

IV. Proposed Actions

OSHA is proposing to extend the information collection requirements contained in the Grain Handling Facilities Standard (29 CFR 1910.272). The Agency will summarize the comments submitted in response to this notice, and will include this summary in its request to OMB to extend the approval of the information collection requirements contained in the Standard.

Type of Review: Extension of current approved information collection requirements.

Title: Grain Handling Facilities (29 CFR 1910.272).

OMB Number: 1218–0206.

Affected Public: Business or other for-profit; not-for-profit institutions; Federal government; State, local, or Tribal governments.

Number of Respondents: 19,791.

Frequency of Response: On occasion; monthly; annually.

Average Time per Response: Varies from 1 minute (2.0 hour) to maintain certification records to 3 hours to develop procedures for tags and locks.

Estimated Total Burden Hours: 69,336.

Estimated Cost (Operation and Maintenance): $0.

V. Authority and Signature

John L. Henshaw, Assistant Secretary of Labor for Occupational Safety and Health, directed the preparation of this notice. The authority for this notice is the Paperwork Reduction Act of 1995 (44 U.S.C. 3506 *et seq.*), and Secretary of Labor's Order No. 5–2002 (67 FR 65008).

Signed at Washington, DC, on September 16, 2004.

John L. Henshaw,

Assistant Secretary of Labor.

[FR Doc. 04–21297 Filed 9–21–04; 8:45 am]

BILLING CODE 4510–26–M

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

Meetings of Humanities Panel

AGENCY: The National Endowment for the Humanities.

ACTION: Notice of meetings.

SUMMARY: Pursuant to the provisions of the Federal Advisory Committee Act (Public Law 92–463, as amended), notice is hereby given that the following meetings of the Humanities Panel will be held at the Old Post Office, 1100 Pennsylvania Avenue, NW., Washington, DC 20506.

FOR FURTHER INFORMATION CONTACT: Daniel Schneider, Advisory Committee Management Officer, National Endowment for the Humanities, Washington, DC 20506; telephone (202) 606–8322. Hearing-impaired individuals are advised that information on this matter may be obtained by contacting the Endowment's TDD terminal on (202) 606–8282.

SUPPLEMENTARY INFORMATION: The proposed meetings are for the purpose of panel review, discussion, evaluation and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including discussion of information given in confidence to the agency by the grant applicants. Because the proposed meetings will consider information that is likely to disclose trade secrets and commercial or financial information obtained from a person and privileged or confidential and/or information of a personal nature the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, pursuant to authority granted me by the Chairman's Delegation of Authority to Close Advisory Committee meetings, dated July 19, 1993, I have determined that these meetings will be closed to the public pursuant to subsections (c)/(4), and (6) of section 552b of Title 5, United States Code.

1. *Date:* October 1, 2004.
Time: 9 a.m. to 5 p.m.
Room: 415.
Program: This meeting will review applications for World Studies I, submitted to the Division of Preservation and Access at the July 15, 2004, deadline.

2. *Date:* October 5, 2004.
Time: 9 a.m. to 5 p.m.
Room: 415.
Program: This meeting will review applications for History of Science, Technology, and Philosophy, submitted to the Division of Preservation and Access at the July 15, 2004, deadline.

3. *Date:* October 8, 2004.
Time: 9 a.m. to 5 p.m.
Room: 415.
Program: This meeting will review applications for American History and Culture I, submitted to the Division of Preservation and Access at the July 15, 2004, deadline.

4. *Date:* October 13, 2004.
Time: 9 a.m. to 5 p.m.
Room: 415.
Program: This meeting will review applications for Anthropology/Archaeology, submitted to the Division of Preservation and Access at the July 15, 2004, deadline.

5. *Date:* October 15, 2004.
Time: 9 a.m. to 5 p.m.
Room: 415.
Program: This meeting will review applications for World Studies II, submitted to the Division of Preservation and Access at the July 15, 2004, deadline.

6. *Date:* October 19, 2004.
Time: 9 a.m. to 5 p.m.
Room: 415.
Program: This meeting will review applications for Music, submitted to the Division of Preservation and Access at the July 15, 2004, deadline.

7. *Date:* October 22, 2004.
Time: 9 a.m. to 5 p.m.
Room: 415.
Program: This meeting will review applications for American History and Culture II, submitted to the Division of Preservation and Access at the July 15, 2004, deadline.

8. *Date:* October 26, 2004.
Time: 9 a.m. to 5 p.m.
Room: 415.
Program: This meeting will review applications for American History and Culture III, submitted to the Division of Preservation and Access at the July 15, 2004, deadline.

9. *Date:* October 29, 2004.
Time: 9 a.m. to 5 p.m.
Room: 415.
Program: This meeting will review applications for American History and Culture IV, submitted to the Division of Preservation and Access at the July 15, 2004, deadline.

Daniel Schneider,
Advisory Committee Management Officer.
[FR Doc. 04–21232 Filed 9–21–04; 8:45 am]
BILLING CODE 7536–01–P

NATIONAL SCIENCE FOUNDATION

National Science Board ad hoc Committee on NSB Nominees for Class of 2006–2012; Sunshine Act Meeting

DATE AND TIME: October 4, 2004 3 p.m.–4 p.m.

PLACE: National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230.

STATUS: This meeting will be closed to the public.

MATTERS TO BE CONSIDERED: Nominees for appointment as NSB members.

FOR FURTHER INFORMATION CONTACT: Dr. Michael P. Crosby,Executive Officer and NSB Office Director, (703) 292–7000, *http://www.nsf.gov/nsb.*

Michael P. Crosby,
Executive Officer and NSB Office Director.
[FR Doc. 04–21330 Filed 9–17–04; 4:26 pm]
BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

Documents Containing Reporting or Recordkeeping Requirements: Office of Management and Budget (OMB) Review

AGENCY: U. S. Nuclear Regulatory Commission (NRC).

ACTION: Notice of the OMB review of information collection and solicitation of public comment.

SUMMARY: The NRC has recently submitted to OMB for review the following proposal for the collection of information under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

1. *Type of submission, new, revision, or extension:* Revision.

2. *The title of the information collection:* Proposed Rule—10 CFR part 110, Export and Import of High-Risk Radioactive Materials: Security Policies.

3. *The form number if applicable:* NRC Form 7.

4. *How often the collection is required:* On occasion.

5. *Who will be required or asked to report:* Any licensee who wishes to export or import high-risk radioactive material subject to the requirements of a specific license.

6. *An estimate of the number of annual responses:* 1,005.

7. *The estimated number of annual respondents:* 30.

8. *An estimate of the total number of hours needed annually to complete the requirement or request:* 617 hours (2.4 hours per application, 15 minutes per notification and 15 minutes per recipient's certification to licensee).

9. *An indication of whether section 3507(d), Pub. L. 104–13 applies:* Applicable.

10. *Abstract:* The Nuclear Regulatory Commission (NRC is proposing to amend its regulations pertaining to the export and import of nuclear equipment and radioactive materials. This proposed rule reflects recent changes to the nuclear and radioactive material security policies of the Commission and the Executive Branch, for the import and export of radioactive material. A specific license will be required for the import and export of high-risk radioactive material.

Submit, by November 22, 2004, 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 submittal 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. The proposed rule indicated in "The title of the information collection" is or has been published in the **Federal Register** within several days of the publication date of this **Federal Register** notice. The OMB clearance package and rule are available at the NRC World Wide Web site: *http://www.nrc.gov/public-involve/doc-comment/omb/index.html* for 60 days after the signature date of this notice and are also available at the rule forum site, *http://ruleforum.llnl.gov.*

Comments and questions should be directed to the OMB reviewer by October 22, 2004: OMB Desk Officer, Office of Information and Regulatory Affairs (3150–0036 and 3150–0027), NEOB–10202, Office of Management and Budget, Washington DC 20503.

Comments can also be submitted by telephone at (202) 395–3087.

The NRC Clearance Officer is Brenda Jo. Shelton, 301–415–7233.

Dated in Rockville, Maryland, this 15th day of September, 2004.

For the Nuclear Regulatory Commission.

Brenda J. Shelton,
NRC Clearance Officer, Office of the Chief Information Officer.
[FR Doc. 04–21254 Filed 9–21–04; 8:45 am]
BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–271; ASLBP No. 04–832–02–OLA]

Entergy Nuclear Vermont Yankee, LLC, and Entergy Operations, Inc.; Establishment of Atomic Safety and Licensing Board

Pursuant to delegation by the Commission dated December 29, 1972, published in the **Federal Register**, 37 Fed. Reg. 28,710 (1972), and the Commission's regulations, see 10 CFR 2.104, 2.300, 2.303, 2.309, 2.311, 2.318, and 2.321, notice is hereby given that an Atomic Safety and Licensing Board is being established to preside over the following proceeding: Entergy Nuclear Vermont Yankee, LLC, and Entergy Operations, Inc. Vermont Yankee

Nuclear Power Station (Operating License Amendment).

This proceeding concerns hearing requests submitted on August 30, 2004, by the Vermont Department of Public Service and the New England Coalition of Brattleboro, Vermont. Those requests, which were filed in response to a June 15, 2004 notice of consideration of issuance of facility operating license amendment and opportunity for hearing published in the **Federal Register** on July 1, 2004 (69 FR 39976), challenge the request of Entergy Nuclear Vermont Yankee, LLC, and Entergy Operations, Inc., to change the operating license for the Vermont Yankee Nuclear Power Station to increase the maximum authorized power level from 1593 megawatts thermal (MWt) to 1912 MWt, an increase of approximately twenty percent above the current maximum authorized power level.

The Board is comprised of the following administrative judges:

Alex S. Karlin, Chair, Atomic Safety and Licensing Board Panel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

Dr. Anthony J. Baratta, Atomic Safety and Licensing Board Panel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

Lester S. Rubenstein, Atomic Safety and Licensing Board Panel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

All correspondence, documents, and other materials shall be filed with the administrative judges in accordance with 10 CFR 2.302.

Issued at Rockville, Maryland, this 14th day of September 2004.

G. Paul Bollwerk, III,

Chief Administrative Judge, Atomic Safety and Licensing Board Panel.

[FR Doc. 04–21256 Filed 9–21–04; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–266 and 50–301]

Nuclear Management Company, LLC; Notice of Withdrawal of Application for Amendment to Facility Operating License

The U.S. Nuclear Regulatory Commission (NRC) has granted the request of Nuclear Management Company, LLC (the licensee), to withdraw its September 26, 2003, application for a proposed amendment to Facility Operating License Nos. DPR–24 and DPR–27 for the Point Beach Nuclear Plant, Unit Nos. 1 and 2 , located in Manitowoc County, WI.

The proposed amendment would have revised Technical Specification 5.6.5, "Reactor Coolant System (RCS) Pressure and Temperature Limits Report (PTLR)," Paragraph b. to reference an NRC approval of a revised pressurized thermal shock screening evaluation methodology for Unit 2. This methodology, described in Babcock & Wilcox Report BAW–2308, Revision 1, "Initial RT_{NDT} [reference nil-ductility temperature] of Linde 80 Weld Materials" (August 2003), was submitted by Framatome ANP on behalf of the Babcock & Wilcox Owners Group Reactor Vessel Working Group for NRC review on August 19, 2003.

The Commission had previously issued a Notice of Consideration of Issuance of Amendment published in the **Federal Register** on November 25, 2003 (68 FR 66138). As discussed, the amendment request was based on an evaluation methodology that was being reviewed, but had not yet been approved for use, by the NRC when the request was submitted. The NRC conveyed to the licensee that the additional time required to complete its review of the BAW–2308, Revision 1 methodology, which remains under review, had the potential to impact the NRC's review activities associated with Point Beach license renewal. By letter dated August 3, 2004, the licensee withdrew the proposed change.

For further details with respect to this action, see the application for amendment dated September 26, 2003, and the licensee's letter dated August 3, 2004, which withdrew the application for license amendment. Documents may be examined, and/or copied for a fee, at the NRC's Public Document Room (PDR), located at One White Flint North, Public File Area O1 F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible electronically from the Agencywide Documents Access and Management Systems (ADAMS) Public Electronic Reading Room on the Internet at the NRC Web site, *http://www.nrc.gov/reading-rm/adams/html.* Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS, should contact the NRC PDR Reference staff by telephone at 1–800–397–4209, or 301–415–4737 or by e-mail to *pdr@nrc.gov.*

Dated in Rockville, Maryland, this 16th day of September, 2004.

For the Nuclear Regulatory Commission.

Harold K. Chernoff,

Project Manager, Section 1, Project Directorate III, Division of Licensing Project Management, Office of Nuclear Reactor Regulation.

[FR Doc. 04–21253 Filed 9–21–04; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–390–CivP, 50–327–CivP, 50–328–CivP, 50–259–CivP, 50–260–CivP, 50–296–CivP (EA 99–234); ASLBP No. 04–830–01–R]

Tennessee Valley Authority, Watts Bar Nuclear Plant, Unit 1, Sequoyah Nuclear Plant, Units 1 and 2, Browns Ferry Nuclear Plant, Units 1, 2 and 3; Establishment of Atomic Safety and Licensing Board

Pursuant to delegation by the Commission dated December 29, 1972, published in the **Federal Register**, 37 FR 28710 (1972), and §§ 2.205, 2.700, 2.702, 2.714, 2.714a, 2.717, 2.721, and 2.772(j) of the Commission's Regulations (as they were in effect prior to February 13, 2004), an Atomic Safety and Licensing Board is being established to preside over the following proceeding: Tennessee Valley Authority Watts Bar Nuclear Plant, Unit 1 Sequoyah Nuclear Plant, Units 1 & 2 Browns Ferry Nuclear Plant, Units 1, 2 & 3 Order Imposing Civil Monetary Penalty.

This Board is being established pursuant to the August 18, 2004 Commission memorandum and order (CLI–04–24, 60 NRC _ (Aug. 18, 2004)) remanding for further proceedings this matter regarding the request of the Tennessee Valley Authority (TVA), the licensee for the Watts Bar (Unit 1), Sequoyah (Units 1 and 2), and Browns Ferry (Units 1, 2 and 3) Nuclear Plants, for a hearing challenging an Order issued by the Director, Office of Enforcement, dated May 4, 2001, entitled "Order Imposing Civil Monetary Penalty" (65 FR 27166 (May 4, 2001)).

The Board is comprised of the following administrative judges:

Charles Bechhoefer, Chairman, Atomic Safety and Licensing Board Panel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

Dr. Richard F. Cole, Atomic Safety and Licensing Board Panel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

Ann Marshall Young, Atomic Safety and Licensing Board Panel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

All correspondence, documents and other materials shall be filed with the Panel Judges in accordance with 10 CFR 2.701.

Issued at Rockville, Maryland, this 14th day of September 2004.

G. Paul Bollwerk, III,

Chief Administrative Judge, Atomic Safety and Licensing Board Panel.

[FR Doc. 04–21255 Filed 9–21–04; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Number 030–18228]

Notice of Availability of Environmental Assessment and Finding of No Significant Impact for License Amendment for Surmodics, Inc., Eden Prairie, MN

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of availability of Environmental Assessment and Finding of No Significant Impact.

FOR FURTHER INFORMATION CONTACT: Dr. Peter J. Lee, Division of Nuclear Materials Safety, U.S. Nuclear Regulatory Commission, Region III, 2443 Warrenville Road, Lisle, Illinois 60532–4352; telephone (630) 829–9870; or by e-mail at *pjl2@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

The U.S. Nuclear Regulatory Commission (NRC) is considering the issuance of a license amendment of Material License No. 22–20307–01 issued to SurModics, Inc. (the licensee), to a terminate its license and authorize release of its Eden Prairie, Minnesota facility for unrestricted use.

The NRC staff has prepared an Environmental Assessment (EA) in support of this licensing action in accordance with the requirements of 10 CFR part 51. Based on the EA, the NRC has concluded that a Finding of No Significant Impact (FONSI) is appropriate. The amendment will be issued following the publication of this Notice.

II. EA Summary

The purpose of the proposed action is to terminate SurModics, Inc.'s license and release its Eden Prairie, Minnesota facility for unrestricted use. On September 27, 1982, the NRC authorized SurModics, Inc. to use labeled compounds of phosphorus-32 (P–32), iodine-125 (I–125), tritium (H–3), carbon-14 (C–14), etc. for research and development. On June 15, 2004, SurModics, Inc. submitted a license amendment request to terminate its license and release its Eden Prairie facility for unrestricted use. SurModics, Inc. has conducted surveys of the facility and provided information to the NRC to demonstrate that the site meets the license termination criteria in Subpart E of 10 CFR Part 20 for unrestricted release. The staff has examined SurModics, Inc.'s request and the information that the licensee has provided in support of its request, including the surveys performed by SurModics, Inc. to demonstrate compliance with 10 CFR 20.1402, "'Radiological Criteria for Unrestricted Use,'" to ensure that the NRC's decision is protective of the public health and safety and the environment.

III. Finding of No Significant Impact

The staff has prepared the EA (summarized above) in support of SurModics, Inc.'s proposed license amendment to terminate its license and release the Eden Prairie facility for unrestricted use. Based on its review, the staff has determined that the affected environment and the environmental impacts associated with the decommissioning of SurModics, Inc.'s facility are bounded by the impacts evaluated by the "Generic Environmental Impact Statement in Support of Rulemaking on Radiological Criteria for License Termination of NRC-Licensed Nuclear Facilities" (NUREG–1496). No outdoor areas were affected by the use of licensed materials. Additionally, no non-radiological impacts or other activities that could result in cumulative impacts were identified. The staff also finds that the proposed release for unrestricted use of the SurModics, Inc.'s facility is in compliance with the 10 CFR 20.1402. On the basis of the EA, the staff has concluded that the environmental impacts from the proposed action would not be significant. Accordingly, the staff has determined that a FONSI is appropriate, and has determined that the preparation of an environmental impact statement is not warranted.

IV. Further Information

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," SurModics, Inc.'s request, the EA summarized above, and the documents related to this proposed action are available electronically for public inspection and copying from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). The NRC's document system is accessible from the NRC Web site at *http://www.nrc.gov/reading-rm/adams.html.* These documents include SurModics, Inc.'s letter dated June 15, 2004, with enclosures (Accession No. ML042530661); and the EA summarized above (Accession No. ML042540419). These documents may also be viewed electronically on the public computers located at the NRC's Public Document Room (PDR), O 1 F21, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852. The PDR reproduction contractor will copy documents for a fee. Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS, should contact the NRC PDR Reference staff by telephone at 1–800–397–4209 or (301) 415–4737, or by e-mail to *pdr@nrc.gov.*

Dated at Lisle, Illinois, this 10th day of September 2004.

Kenneth G. O'Brien,

Chief, Decommissioning Branch, Division of Nuclear Materials Safety, RIII.

[FR Doc. 04–21252 Filed 9–21–04; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards; Subcommittee Meeting on Planning and Procedures; Notice of Meeting

The ACRS Subcommittee on Planning and Procedures will hold a meeting on October 6, 2004, Room T–2B1, 11545 Rockville Pike, Rockville, Maryland.

The entire meeting will be open to public attendance, with the exception of a portion that may be closed pursuant to 5 U.S.C. 552b(c)(2) and (6) to discuss organizational and personnel matters that relate solely to the internal personnel rules and practices of the ACRS, and information the release of which would constitute a clearly unwarranted invasion of personal privacy.

The agenda for the subject meeting shall be as follows:

Wednesday, October 6, 2004—1:30 p.m.–3:30 p.m.

The Subcommittee will discuss proposed ACRS activities and related matters. The Subcommittee will gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the full Committee.

Members of the public desiring to provide oral statements and/or written comments should notify the Designated Federal Official, Mr. Sam Duraiswamy (telephone: 301–415–7364) between

7:30 a.m. and 4:15 p.m. (e.t.) five days prior to the meeting, if possible, so that appropriate arrangements can be made. Electronic recordings will be permitted only during those portions of the meeting that are open to the public.

Further information regarding this meeting can be obtained by contacting the Designated Federal Official between 7:30 a.m. and 4:15 p.m. (e.t.). Persons planning to attend this meeting are urged to contact the above named individual at least two working days prior to the meeting to be advised of any potential changes in the agenda.

Dated: September 16, 2004.

Michael R. Snodderly,

Acting Associate Director for Technical Support, ACRS/ACNW.

[FR Doc. 04–21257 Filed 9–21–04; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards; Meeting Notice

In accordance with the purposes of Sections 29 and 182b of the Atomic Energy Act (42 U.S.C. 2039, 2232b), the Advisory Committee on Reactor Safeguards (ACRS) will hold a meeting on October 7–9, 2004, 11545 Rockville Pike, Rockville, Maryland. The date of this meeting was previously published in the **Federal Register** on Monday, November 21, 2003 (68 FR 65743).

Thursday, October 7, 2004, Conference Room T–2B3, Two White Flint North, Rockville, Maryland

8:30 a.m.–8:35 a.m.: Opening Remarks by the ACRS Chairman (Open)—The ACRS Chairman will make opening remarks regarding the conduct of the meeting.

8:35 a.m.–10:45 a.m.: Safety Evaluation of the Industry Guidelines Related to Pressurized Water Reactor (PWR) Sump Performance (Open)—The Committee will hear presentations by and hold discussions with representatives of the NRC staff and the Nuclear Energy Institute regarding the staff's evaluation of the industry guidelines associated with the resolution of Generic Safety Issue (GSI)–191, "Potential Impact of Debris Blockage on Emergency Recirculation During Design-Basis Accidents at PWRs" and related matters.

11 a.m.–12:30 p.m.: Pre-Application Safety Assessment Report for the Advanced CANDU 700 (ACR–700) Design (Open)—The Committee will hear presentations by and hold discussions with representatives of the NRC staff regarding the staff's Safety Assessment Report related to the pre-application review of the ACR–700 design and related matters.

1:30 p.m.–3 p.m.: Proposed Recommendations for Resolving GSI–185, "Control of Recriticality Following Small-Break LOCAs in PWRs" (Open)—The Committee will hear presentations by and hold discussions with representatives of the NRC staff and its contractors regarding the proposed recommendations for resolving GSI–185.

3:15 p.m.–4:45 p.m.: Mitigating System Performance Index Program (Open)—The Committee will hear presentations by and hold discussions with representatives of the NRC staff regarding the Mitigating System Performance Index Program.

5 p.m.–7 p.m.: Preparation of ACRS Reports (Open)—The Committee will discuss proposed ACRS reports on matters considered during this meeting. In addition, the Committee will discuss a proposed report responding to the August 25, 2004 EDO response to the May 21, 2004 ACRS letter on resolution of certain items identified by the ACRS in NUREG–1740, "Voltage-Based Alternative Repair Criteria."

Friday, October 8, 2004, Conference Room T–2B3, Two White Flint North, Rockville, Maryland

8:30 a.m.–8:35 a.m.: Opening Remarks by the ACRS Chairman (Open)—The ACRS Chairman will make opening remarks regarding the conduct of the meeting.

8:35 a.m.–10 a.m.: Technology Neutral Framework for Future Plant Licensing (Open)—The Committee will hear presentations by and hold discussions with representatives of the NRC staff regarding the technology neutral framework for licensing of future plant designs.

10:15 a.m.–11:30 a.m.: Assessment of the Quality of the NRC Research Projects (Open)—The Committee will discuss the preliminary results of the cognizant ACRS members' assessment of the research projects on Sump Blockage and on MACCS code.

11:30 a.m.–12:15 p.m.: Divergence in Regulatory Approaches and Requirements Between U.S. and Other Countries (Open)—The Committee will discuss the draft Final White Paper prepared by Dr. Nourbakhsh, ACRS Senior Staff Engineer, regarding divergence in regulatory approaches and requirements between U.S. and other Countries.

1:15 p.m.–2:15 p.m.: Future ACRS Activities/Report of the Planning and Procedures Subcommittee (Open)—The Committee will discuss the recommendations of the Planning and Procedures Subcommittee regarding items proposed for consideration by the full Committee during future meetings. Also, it will hear a report of the Planning and Procedures Subcommittee on matters related to the conduct of ACRS business, including anticipated workload and member assignments.

2:15 p.m.–2:30 p.m.: Reconciliation of ACRS Comments and Recommendations (Open)—The Committee will discuss the responses from the NRC Executive Director for Operations (EDO) to comments and recommendations included in recent ACRS reports and letters. The EDO responses are expected to be made available to the Committee prior to the meeting.

2:45 p.m.–7 p.m.: Preparation of ACRS Reports (Open)—The Committee will discuss proposed ACRS reports.

Saturday, October 10, 2004, Conference Room T–2B3, Two White Flint North, Rockville, Maryland

8:30 a.m.–2 p.m.: Preparation of ACRS Reports (Open)—The Committee will continue its discussion of proposed ACRS reports.

2 p.m.–2:30 p.m.: Miscellaneous (Open)—The Committee will discuss matters related to the conduct of Committee activities and matters and specific issues that were not completed during previous meetings, as time and availability of information permit.

Procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on October 16, 2003 (68 FR 59644). In accordance with those procedures, oral or written views may be presented by members of the public, including representatives of the nuclear industry. Electronic recordings will be permitted only during the open portions of the meeting. Persons desiring to make oral statements should notify the Cognizant ACRS staff named below five days before the meeting, if possible, so that appropriate arrangements can be made to allow necessary time during the meeting for such statements. Use of still, motion picture, and television cameras during the meeting may be limited to selected portions of the meeting as determined by the Chairman. Information regarding the time to be set aside for this purpose may be obtained by contacting the Cognizant ACRS staff prior to the meeting. In view of the

possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with the Cognizant ACRS staff if such rescheduling would result in major inconvenience.

Further information regarding topics to be discussed, whether the meeting has been canceled or rescheduled, as well as the Chairman's ruling on requests for the opportunity to present oral statements and the time allotted therefor can be obtained by contacting Mr. Sam Duraiswamy, Cognizant ACRS staff (301–415–7364), between 7:30 a.m. and 4:15 p.m., ET.

ACRS meeting agenda, meeting transcripts, and letter reports are available through the NRC Public Document Room at *pdr@nrc.gov*, or by calling the PDR at 1–800–397–4209, or from the Publicly Available Records System (PARS) component of NRC's document system (ADAMS) which is accessible from the NRC Web site at *http://www.nrc.gov/reading-rm/adams.html* or *http://www.nrc.gov/reading-rm/doc-collections/* (ACRS & ACNW Mtg schedules/agendas).

Videoteleconferencing service is available for observing open sessions of ACRS meetings. Those wishing to use this service for observing ACRS meetings should contact Mr. Theron Brown, ACRS Audio Visual Technician (301–415–8066), between 7:30 a.m. and 3:45 p.m., ET, at least 10 days before the meeting to ensure the availability of this service. Individuals or organizations requesting this service will be responsible for telephone line charges and for providing the equipment and facilities that they use to establish the videoteleconferencing link. The availability of videoteleconferencing services is not guaranteed.

Dated: September 16, 2004.

Annette Vietti-Cook,

Secretary of the Commission.

[FR Doc. 04–21258 Filed 9–21–04; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Nuclear Regulatory Commission.

DATE: Weeks of September 20, 27, October 4, 11, 18, 25, 2004.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and closed.

MATTERS TO BE CONSIDERED:

Week of September 20, 2004

There are no meetings scheduled for the week of September 20, 2004.

Week of September 27, 2004—Tentative

There are no meetings scheduled for the week of September 27, 2004.

Week of October 4, 2004—Tentative

Thursday, October 7, 2004

10:30 a.m. Discussion of Security Issues (Closed—Ex. 1).

1 p.m. Discussion of Security Issues (Closed—Ex. 1).

Week of October 11, 2004—Tentative

Wednesday, October 13, 2004

9:30 a.m. Briefing on Decommissioning Activities and Status (Public Meeting) (Contact: Claudia Craig, (301) 415–7276).

This meeting will be webcast live at the Web address—*http://www.nrc.gov.*

1:30 p.m. Discussion of Intragovernmental Issues (Closed—Ex. 1 & 9).

Week of October 18, 2004—Tentative

There are no meetings scheduled for the week of October 18, 2004.

Week of October 25, 2004—Tentative

There are no meetings scheduled for the week of October 25, 2004.

*The schedule for Commission meetings is subject to change on short notice. To verify the status of meetings call (recording)—(301) 415–1292. Contact person for more information: Dave Gamberoni, (301) 415–1651.

* * * * *

The NRC Commission Meeting Schedule can be found on the Internet at: *http://www.nrc.gov/what-we-do/policy-making/schedule.html.*

* * * * *

The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings, or need this meeting notice or the transcript or other information from the public meetings in another format (*e.g.* braille, large print), please notify the NRC's Disability Program Coordinator, August Spector, at (301) 415–7080, TDD: (301) 415–2100, or by e-mail at *aks@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

* * * * *

This notice is distributed by mail to several hundred subscribers; if you no longer wish to receive it, or would like to be added to the distribution, please contact the Office of the Secretary, Washington, DC 20555 (301) 415–1969). In addition, distribution of this meeting notice over the Internet system is available. If you are interested in receiving this Commission meeting schedule electronically, please send an electronic message to *dkw@nrc.gov.*

Dated: September 17, 2004.

Dave Gamberoni,

Office of the Secretary.

[FR Doc. 04–21336 Filed 9–20–04; 9:34 am]

BILLING CODE 7590–01–M

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon written request, copies available from: Securities and Exchange Commission Office of Filings and Information Services, Washington, DC 20549.

Extension: Form N–8F; SEC File No. 270–136; OMB Control No. 3235–0157.

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) the Securities and Exchange Commission ("Commission") is soliciting comments on the collections of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget ("OMB") for extension and approval.

Form N–8F (17 CFR 274.218) is the form prescribed for use by registered investment companies in certain circumstances to request orders of the Commission declaring that the registration of that investment company cease to be in effect. The form requests, from investment companies seeking a deregistration order, information about (i) the investment company's identity, (ii) the investment company's distributions, (iii) the investment company's assets and liabilities, (iv) the events leading to the request to deregister, and (v) the conclusion of business. The information is needed by the Commission to determine whether an order of deregistration is appropriate.

The Form takes approximately 3 hours on average to complete. It is estimated that approximately 261 investment companies file Form N–8F annually, so that the total annual burden for the form is estimated to be 783 hours. The estimate of average burden hours is made solely for the purposes of the Paperwork Reduction Act and is not derived from a

comprehensive or even a representative survey or study.

Written comments are requested on: (a) Whether the collections of information are necessary for the proper performance of the functions of the Commission, including whether the information has practical utility; (b) the accuracy of the Commission's estimate of the burdens of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information 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. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

Please direct your written comments to R. Corey Booth, Director/Chief Information Officer, Office of Information Technology, Securities and Exchange Commission, 450 5th Street, NW., Washington, DC 20549.

Dated: September 15, 2004.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. E4–2289 Filed 9–21–04; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 26599; 812–12996]

Atlas Assets, Inc. and Atlas Advisers, Inc.; Notice of Application

September 16, 2004.

AGENCY: Securities and Exchange Commission ("Commission").

ACTION: Notice of an application under section 6(c) of the Investment Company Act of 1940 ("Act") for an exemption from section 15(a) of the Act and rule 18f–2 under the Act, as well as certain disclosure requirements.

Summary of Application

Applicants request an order that would permit them to enter into and materially amend subadvisory agreements without shareholder approval and would grant relief from certain disclosure requirements.

Applicants: Atlas Assets, Inc. (the "Company") and Atlas Advisers, Inc. (the "Adviser").

Filing Dates: The application was filed on August 1, 2003 and amended on September 8, 2004. Applicants have agreed to file an amendment during the notice period, the substance of which is reflected in this notice.

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 applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on October 12, 2004, and should be accompanied by proof of service on the applicants, 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 may request notification of a hearing by writing to the Commission's Secretary.

ADDRESSES: Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Applicants, 794 Davis Street, San Leandro, CA 94577.

FOR FURTHER INFORMATION CONTACT: Christine Y. Greenlees, Senior Counsel, at (202) 942–0581, or Mary Kay Frech, Branch Chief, at (202) 942–0564 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee at the Commission's Public Reference Branch, 450 Fifth Street, NW., Washington, DC 20549–0102 (tel. (202) 942–8090).

Applicants' Representations

1. The Company, a Maryland corporation, is registered under the Act as an open-end management investment company. The Company currently is comprised of sixteen series (each a "Fund" and collectively, the "Funds"), each with a separate investment objective, policy and restrictions.[1] The Adviser is registered as an investment adviser under the Investment Advisers Act of 1940 ("Advisers Act") and serves as investment adviser to the Funds pursuant to an investment advisory agreement ("Advisory Agreement") with the Company. The Advisory Agreement has been approved by the Company's board of directors (the "Board"), including a majority of the directors who are not "interested persons," as defined in section 2(a)(19) of the Act, of the Company or the Adviser ("Independent Directors"), as well as by the shareholders of each Fund.

2. Under the terms of the Advisory Agreement, the Adviser provides investment advisory services to each Fund, supervises the investment program for each Fund, and has the authority, subject to Board approval, to enter into investment subadvisory agreements ("Subadvisory Agreements") with one or more subadvisers ("Subadvisers"). Each Subadviser is registered under the Advisers Act. The Adviser monitors and evaluates the Subadvisers and recommends to the Board their hiring, retention or termination. Subadvisers recommended to the Board by the Adviser are selected and approved by the Board, including a majority of the Independent Directors. Each Subadviser has discretionary authority to invest the assets or a portion of the assets of a particular Fund. The Adviser compensates each Subadviser out of the fees paid to the Adviser under the Advisory Agreement.

3. Applicants request an order to permit the Adviser, subject to Board approval, to enter into and materially amend Subadvisory Agreements without obtaining shareholder approval. The requested relief will not extend to any Subadviser that is an affiliated person, as defined in section 2(a)(3) of the Act, of the Company or of the Adviser, other than by reason of serving as a Subadviser to one or more of the Funds ("Affiliated Sub-Adviser").

4. Applicants also request an exemption from the various disclosure provisions described below that may require a Fund to disclose fees paid by the Adviser to each Subadviser. An exemption is requested to permit the Company to disclose for each Fund (as both a dollar amount and as a percentage of each Fund's net assets): (a) The aggregate fees paid to the Adviser and any Affiliated Subadvisers; and (b) the aggregate fees paid to Subadvisers other than Affiliated Subadvisers ("Aggregate Fee Disclosure"). For any Fund that employs an Affiliated Subadviser, the Fund will provide separate disclosure of any fees paid to the Affiliated Subadviser.

[1] Applicants also request relief with respect to future series of the Company and any other existing or future registered open-end management investment company or series thereof that: (a) Is advised by the Adviser or a person controlling, controlled by, or under common control with the Adviser; (b) uses the management structure described in the application; and (c) complies with the terms and conditions of the application (included in the term "Funds"). The only existing registered open-end management investment company that currently intends to rely on the requested order is named as an applicant. All references to the term "Adviser" herein include (a) the Adviser, and (b) an entity controlling, controlled by, or under common control with the Adviser. If the name of any Fund contains the name of a Subadviser (as defined below), the name of the Adviser or the name of the entity controlling, controlled by, or under common control with the Adviser that serves as the primary adviser to the Fund will precede the name of the Subadviser.

Applicants' Legal Analysis

1. Section 15(a) of the Act provides, in relevant part, that it is unlawful for any person to act as an investment adviser to a registered investment company except under a written contract that has been approved by the vote of a majority of the company's outstanding voting securities. Rule 18f–2 under the Act provides that each series or class of stock in a series company affected by a matter must approve such matter if the Act requires shareholder approval.

2. Form N–1A is the registration statement used by open-end investment companies. Item 15(a)(3) of Form N–1A requires disclosure of the method and amount of the investment adviser's compensation.

3. Rule 20a–1 under the Act requires proxies solicited with respect to an investment company to comply with Schedule 14A under the Securities Exchange Act of 1934 ("1934 Act"). Items 22(c)(1)(ii), 22(c)(1)(iii), 22(c)(8) and 22(c)(9) of Schedule 14A, taken together, require a proxy statement for a shareholder meeting at which the advisory contract will be voted upon to include the "rate of compensation of the investment adviser," the "aggregate amount of the investment adviser's fees," a description of the "terms of the contract to be acted upon," and, if a change in the advisory fee is proposed, the existing and proposed fees and the difference between the two fees.

4. Form N–SAR is the semi-annual report filed with the Commission by registered investment companies. Item 48 of Form N–SAR requires investment companies to disclose the rate schedule for fees paid to their investment advisers, including the Subadvisers.

5. Regulation S–X sets forth the requirements for financial statements required to be included as part of investment company registration statements and shareholder reports filed with the Commission. Sections 6–07(2)(a), (b), and (c) of Regulation S–X require that investment companies include in their financial statements information about investment advisory fees.

6. Section 6(c) of the Act provides that the Commission may exempt any person, security, or transaction or any class or classes of persons, securities, or transactions from any provisions of the Act, or from any rule thereunder, if such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Applicants state that their requested relief meets this standard for the reasons discussed below.

7. Applicants assert that the shareholders are relying on the Adviser's experience to select one or more Subadvisers best suited to achieve a Fund's investment objectives. Applicants assert that, from the perspective of the investor, the role of the Subadvisers is comparable to that of the individual portfolio managers employed by traditional investment company advisory firms. Applicants state that requiring shareholder approval of each Subadvisory Agreement would impose costs and unnecessary delays on the Funds, and may preclude the Adviser from acting promptly in a manner considered advisable by the Board. Applicants note that the Advisory Agreement and any Subadvisory Agreement with an Affiliated Subadviser will remain subject to section 15(a) of the Act and rule 18f–2 under the Act.

8. Applicants assert that some Subadvisers use a "posted" rate schedule to set their fees. Applicants state that while Subadvisers are willing to negotiate fees that are lower than those posted on the schedule, they are reluctant to do so where the fees are disclosed to other prospective and existing customers. Applicants submit that the requested relief will encourage potential Subadvisers to negotiate lower subadvisory fees with the Adviser, the benefits of which are passed on to Fund shareholders.

Applicants' Conditions

Applicants agree that any order granting the requested relief will be subject to the following conditions:

1. Before a Fund may rely on the order requested in the application, the operation of the Fund in the manner described in the application will be approved by a majority of the Fund's outstanding voting securities, as defined in the Act, or, in the case of a Fund whose public shareholders purchase shares on the basis of a prospectus containing the disclosure contemplated by condition 2 below, by the sole initial shareholder before offering the Fund's shares to the public.

2. The prospectus for each Fund will disclose the existence, substance, and effect of any order granted pursuant to the application. Each Fund will hold itself out to the public as employing the management structure described in the application. The prospectus will prominently disclose that the Adviser has ultimate responsibility (subject to oversight by the Board) to oversee the Subadvisers and recommend their hiring, termination, and replacement.

3. Within 90 days of the hiring of a new Subadviser, the affected Fund shareholders will be furnished all information about the new Subadviser that would be included in a proxy statement, except as modified to permit Aggregate Fee Disclosure. This information will include Aggregate Fee Disclosure and any change in such disclosure caused by the addition of the new Subadviser. To meet this obligation, the Fund will provide shareholders within 90 days of the hiring of a new Subadviser with an information statement meeting the requirements of Regulation 14C, Schedule 14C, and Item 22 of Schedule 14A under the 1934 Act, except as modified by the order to permit Aggregate Fee Disclosure.

4. The Adviser will not enter into a Subadvisory Agreement with any Affiliated Subadviser without that agreement, including the compensation to be paid thereunder, being approved by the shareholders of the applicable Fund.

5. Each Fund will comply with the fund governance standards that the Commission adopted in Investment Company Act Release No. 26520 (July 27, 2004) by the compliance date set forth in that Release ("Compliance Date"). Prior to the Compliance Date, a majority of the Board will be Independent Directors, and the nomination of new or additional Independent Directors will be at the discretion of the then existing Independent Directors.

6. When a Subadviser change is proposed for a Fund with an Affiliated Subadviser, the Board, including a majority of the Independent Directors, will make a separate finding, reflected in the applicable Board minutes, that such change is in the best interests of the Fund and its shareholders and does not involve a conflict of interest from which the Adviser or the Affiliated Subadviser derives an inappropriate advantage.

7. Independent counsel, as defined in rule 0–1(a)(6) under the Act, will be engaged to represent the Independent Directors. The selection of such counsel will be within the discretion of the then existing Independent Directors.

8. The Adviser will provide the Board, no less frequently than quarterly, with information about the profitability of the Adviser on a per-Fund basis. The information will reflect the impact on profitability of the hiring or termination of any Subadviser during the applicable quarter.

9. Whenever a Subadviser is hired or terminated, the Adviser will provide the Board with information showing the

expected impact on the profitability of the Adviser.

10. The Adviser will provide general management services to each Fund, including overall supervisory responsibility for the general management and investment of the Fund's assets, and, subject to review and approval of the Board, will: (a) Set each Fund's overall investment strategies, (b) evaluate, select and recommend Subadvisers to manage all or a part of a Fund's assets, (c) when appropriate, allocate and reallocate a Fund's assets among multiple Subadvisers; (d) monitor and evaluate the performance of Subadvisers, and (e) implement procedures reasonably designed to ensure that the Subadvisers comply with each Fund's investment objective, policies and restrictions.

11. No director or officer of the Company, or director or officer of the Adviser, will own directly or indirectly (other than through a pooled investment vehicle that is not controlled by such person), any interest in a Subadviser, except for: (a) Ownership of interests in the Adviser or any entity that controls, is controlled by, or is under common control with the Adviser, or (b) ownership of less than 1% of the outstanding securities of any class of equity or debt of a publicly traded company that is either a Subadviser or an entity that controls, is controlled by, or is under common control with a Subadviser.

12. Each Fund will disclose in its registration statement the Aggregate Fee Disclosure.

13. The requested order will expire on the effective date of rule 15a–5 under the Act, if adopted.

For the Commission, by the Division of Investment Management, under delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. E4–2288 Filed 9–21–04; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–50375; File No. S7–24–89]

Joint Industry Plan; Order Granting Approval of Amendment No. 13C to the Joint Self-Regulatory Organization Plan Governing the Collection, Consolidation and Dissemination of Quotation and Transaction Information for Nasdaq-Listed Securities Traded on Exchanges on an Unlisted Trading Privileges Basis; Submitted by the Pacific Exchange, Inc., the National Association of Securities Dealers, Inc., the American Stock Exchange LLC, the Boston Stock Exchange, Inc., the Chicago Stock Exchange, Inc., the Cincinnati Stock Exchange, Inc., and the Philadelphia Stock Exchange, Inc.

September 14, 2004.

I. Introduction

On April 22, 2004, the Pacific Exchange, Inc. ("PCX"), on behalf of itself and the National Association of Securities Dealers, Inc. ("NASD"), the American Stock Exchange LLC ("Amex"), the Boston Stock Exchange, Inc. ("BSE"), the Chicago Stock Exchange, Inc. ("CHX"), the Cincinnati Stock Exchange, Inc. ("CSE"),[1] and the Philadelphia Stock Exchange, Inc. ("PHLX") (hereinafter referred to as "Participants"),[2] as members of the Operating Committee[3] of the Plan submitted to the Securities and Exchange Commission ("Commission") a proposal to amend the Plan ("Amendment 13C") pursuant to Rule 11Aa3–2[4] and Rule 11Aa3–1[5] under the Securities Exchange Act of 1934 ("Act"). Amendment 13C[6] reflects several changes unanimously adopted by the Committee. On May 7, 2004, the Commission summarily put into effect Amendment 13C upon publication in the **Federal Register** on a temporary basis not to exceed 120 days.[7] Amendment 13C was published for comment in the **Federal Register** on May 18, 2004.[8] The Commission received no comment letters on Amendment 13C. This order approves the changes made in Amendment 13C on a permanent basis.

II. Plan Background

The Plan governs the collection, consolidation, and dissemination of quotation and transaction information for The Nasdaq Stock Market, Inc. ("Nasdaq") National Market ("NNM") and Nasdaq SmallCap securities listed on Nasdaq or traded on an exchange pursuant to unlisted trading privileges ("UTP").[9] The Plan provides for the collection from Plan Participants and the consolidation and dissemination to vendors, subscribers, and others of quotation and transaction information in "eligible securities."[10]

The Commission originally approved the Plan on a pilot basis on June 26, 1990.[11] The parties did not begin trading until July 12, 1993, accordingly, the pilot period commenced on July 12, 1993. The Plan has since been in operation on an extended pilot basis.[12]

---

[1] The Commission notes that the CSE changed its name to the National Stock Exchange, Inc. *See* Securities Exchange Act Release No. 48774 (November 12, 2003), 68 FR 65332 (November 19, 2003) (File No. SR–CSE–2003–12).

[2] PCX and its subsidiary the Archipelago Exchange were elected co-chairs of the operating committee ("Operating Committee" or "Committee") for the Joint Self-Regulatory Organization Plan Governing the Collection, Consolidation and Dissemination of Quotation and Transaction Information for Nasdaq-Listed Securities Traded on Exchanges on an Unlisted Trading Privilege Basis ("Nasdaq UTP Plan" or "Plan") by the Participants.

[3] The Operating Committee is made up of all the Participants.

[4] 17 CFR 240.11Aa3–2.

[5] 17 CFR 240.11Aa3–1.

[6] At the time Amendment 13C was approved by the Committee, Amendment 13A had been published in the **Federal Register**. *See* Securities Exchange Act Release No. 49137 (January 28, 2004), 69 FR 5217 (February 3, 2004). Amendment 13A has since been approved by the Commission. *See* Securities Exchange Act Release No. 49711 (May 14, 2004), 69 FR 29339 (May 21, 2004). The Operating Committee adopted Amendment 13B, but agreed to hold the amendment pending resolution of the current status of the SIP selection process. Amendment 13B has not been filed with the Commission. The Operating Committee had reserved Amendment 14 for significant future modifications to the Plan that would, among other things, reflect changes in preparation for implementation of the new SIP. Accordingly, this Amendment is numbered 13C.

[7] *See* Securities Exchange Act Release No. 49669 (May 7, 2004), 69 FR 28182 (May 18, 2004).

[8] *Id.*

[9] Section 12 of the Act generally requires an exchange to trade only those securities that the exchange lists, except that Section 12(f) of the Act permits UTP under certain circumstances. 15 U.S.C. 78*l*(f). For example, Section 12(f) of the Act, among other things, permits exchanges to trade certain securities that are traded over-the-counter pursuant to UTP, but only pursuant to a Commission order or rule. For a more complete discussion of the Section 12(f) requirement, *see* November 1995 Extension Order, *infra* note 11.

[10] Section III.B. of the Plan defines "Eligible Security" as any NNM or Nasdaq SmallCap security, as defined in NASD Rule 4200: (i) As to which UTP have been granted to a national securities exchange pursuant to Section 12(f) of the Act or which become eligible for such trading pursuant to order of the Commission; or (ii) which also is listed on a national securities exchange.

[11] *See* Securities Exchange Act Release No. 28146, 55 FR 27917 (July 6, 1990).

[12] *See* Securities Exchange Act Release Nos. 34371 (July 13, 1994), 59 FR 37103 (July 20, 1994); 35221 (January 11, 1995), 60 FR 3886 (January 19, 1995); 36102 (August 14, 1995), 60 FR 43626 (August 22, 1995); 36226 (September 13, 1995), 60 FR 49029 (September 21, 1995); 36368 (October 13, 1995), 60 FR 54091 (October 19, 1995); 36481

III. Description and Purpose of the Amendment

As a result of aberrant pricing in trading of shares on December 5, 2003, the Division of Market Regulation ("Division") requested the Participants to provide better coordination among the self-regulatory organization ("SRO") trading markets concerning SRO trading halts.[13] The NASD, acting through its subsidiary, Nasdaq, proposed Amendment 13C to address changes to the Plan related to the coordination of instituting and lifting SRO trading halts. Amendment 13C to the Plan reflects changes to the regulatory halt section that were unanimously approved by the Operating Committee. The following is a summary of the changes to the Plan made in Amendment 13C.

1. Section III.T. of the Plan provides for the definition of Regulatory Halt. Amendment 13C added to the definition of Regulatory Halt an "Extraordinary Market Regulatory Halt," which is a trading halt due to extraordinary market activity as a result of system misuse or malfunction as further described in a Section X.E.1. of the Plan.

2. Section X of the Plan previously provided that the Primary Market [14] declared Regulatory Halts. Amendment 13C replaced Primary Market with "Listing Market," which is defined as the Participant's Market on which a security is listed. In the case of dual listings, the Listing Market is the Participant's Market on which the Eligible Security is listed, which also has the highest number of the average of reported transactions and reported share volume for the preceding 12-month period as determined at the beginning of each calendar quarter.

3. Amendment 13C clarified that "Participant" for purposes of Section X includes Nasdaq despite the fact that Nasdaq is not currently a signatory to the Plan.

4. Amendment 13C added Section X.E., which established communication procedures to coordinate communication among Plan Participants in the instance of a trading halt. Specifically, Amendment 13C introduced the use of the "Hoot-n-Holler" for communicating real-time information among Participants. Furthermore, the Amendment requires continuous monitoring of the Hoot-n-Holler by all Participants during market hours. The procedures in the instance of a Participant(s) experiencing extraordinary market activity in an Eligible Security include:

a. Best efforts to provide immediate notification over the Hoot-n-Holler system;

b. Best efforts to determine the source of the extraordinary market activity;

c. Best efforts by the Participant(s) in determining whether to prevent, and actually preventing, quotes from a direct or indirect market participant from being transmitted to the Processor;

d. If the problem is not rectified, the Participant(s) will cease transmitting quotes to the Processor in the affected security; and

e. If within five minutes the problem is not rectified from the initial notification over the Hoot-n-Holler, or if decided earlier through unanimous approval from all Participants actively trading the affected security, the Listing Market based on facts and circumstances may declare over the Hoot-n-Holler an Extraordinary Market Regulatory Halt.

5. Amendment 13C amended the Plan to add Section X.F. to clarify procedures for the resumption of trading after a Regulatory Halt. This includes a requirement that all Participants will use best efforts to indicate their intentions with respect to canceling or modifying trades within fifteen minutes of the declaration of the halt. Furthermore, the Amendment clarified that Participants will disseminate information regarding canceled or modified trades as soon as possible before the resumption of trading. Lastly, the Listing Market will notify Participants over the Hoot-n-Holler when trading may resume.

IV. Discussion and Commission Findings

The Commission previously determined, pursuant to Rule 11Aa3–2(c)(4) under the Act,[15] to summarily put into effect the amendments detailed above in Amendment 13C on a temporary basis not to exceed 120 days beyond May 18, 2004. After careful consideration of Amendment 13C to the Plan, the Commission finds that approving Amendment 13C on a permanent basis is consistent with the requirements of the Act and the rules and regulations thereunder, and, in particular, Section 11A(a)(1) [16] of the Act and Rules 11Aa3–1 and 11Aa3–2(c)(2) thereunder.[17] Section 11A of the Act directs the Commission to facilitate the development of a national market system for securities, "having due regard for the public interest, the protection of investors, and the maintenance of fair and orderly markets," and cites as an objective of that system the "fair competition * * * between exchange markets and markets other than exchange markets." [18] Rule 11Aa3–2(c)(2) requires the Commission to approve a plan or amendment "if it finds that such plan or amendment is necessary or appropriate in the public interest, for the protection of investors, and the maintenance of fair and orderly markets, to remove impediments to, and perfect the mechanisms of, a national market system, or otherwise in furtherance of the purposes of the Act." [19]

The Commission finds that approving Amendment 13C is appropriate in the public interest and otherwise in furtherance of the purposes of the Act. The Commission believes that the changes made in Amendment 13C enhance investor protection, further the maintenance of fair and orderly markets, and remove impediments to, and perfect the mechanisms of, a national market system by: (1) Improving the coordination among SROs when instituting and lifting trading halts; (2) making necessary changes to the terms and definitions contained within the Plan related to trading halts; (3)

(November 13, 1995), 60 FR 58119 (November 24, 1995) ("November 1995 Extension Order"); 36589 (December 13, 1995), 60 FR 65696 (December 20, 1995); 36650 (December 28, 1995), 61 FR 358 (January 4, 1996); 36934 (March 6, 1996), 61 FR 10408 (March 13, 1996); 36985 (March 18, 1996), 61 FR 12122 (March 25, 1996); 37689 (September 16, 1996), 61 FR 50058 (September 24, 1996); 37772 (October 1, 1996), 61 FR 52980 (October 9, 1996); 38457 (March 31, 1997), 62 FR 16880 (April 8, 1997); 38794 (June 30, 1997) 62 FR 36586 (July 8, 1997); 39505 (December 31, 1997) 63 FR 1515 (January 9, 1998); 40151 (July 1, 1998) 63 FR 36979 (July 8, 1998); 40896 (December 31, 1998), 64 FR 1834 (January 12, 1999); 41392 (May 12, 1999), 64 FR 27839 (May 21, 1999); 42268 (December 23, 1999), 65 FR 1202 (January 6, 2000); 43005 (June 30, 2000), 65 FR 42411 (July 10, 2000); 44099 (March 23, 2001), 66 FR 17457 (March 30, 2001); 44348 (May 24, 2001), 66 FR 29610 (May 31, 2001); 44552 (July 13, 2001), 66 FR 37712 (July 19, 2001); 44694 (August 14, 2001), 66 FR 43598 (August 20, 2001); 44804 (September 17, 2001), 66 FR 48299 (September 19, 2001); 45081 (November 19, 2001), 66 FR 59273 (November 27, 2001); 44937 (October 15, 2001), 66 FR 53271 (October 19, 2001); 46139 (June 28, 2001), 67 FR 44888 (July 5, 2002); 46381 (August 19, 2002), 67 FR 54687 (August 23, 2002); 46729 (October 25, 2002), 67 FR 66685 (November 1, 2002); 48318 (August 12, 2003), 68 FR 49534 (August 18, 2003); 48882 (December 4, 2003), 68 FR 69731 (December 15, 2003); 49669 (May 7, 2004), 69 FR 28182 (May 18, 2004); and 49711 (May 14, 2004), 69 FR 29339 (May 21, 2004).

[13] *See* letter from Annette L. Nazareth, Director, Division, Commission, to Bridget Farrell and Michael Roundtree, Co-Chairpersons, Nasdaq UTP Operating Committee, dated December 9, 2003.

[14] The Plan defined "Primary Market" as Nasdaq, provided that if for any 12-month period the number of reported transactions and amount of reported share volume in any other Participant's market exceeded 50% of the aggregated reported transactions and share volume, then that Participant's market would have been the Primary Market for such Eligible Security.

[15] 17 CFR 240.11Aa3–2(c)(4).

[16] 15 U.S.C. 78k–1(a)(1).

[17] 17 CFR 240.11Aa3–1 and 17 CFR 240.11Aa3–2(c)(2).

[18] 15 U.S.C. 78k–1(a).

[19] 17 CFR 240.11Aa3–2(c)(2).

establishing clear procedures to coordinate communication among Plan Participants before and during the instance of a trading halt; and (4) clarifying procedures for the resumption of trading after a trading halt.

V. Conclusion

It is therefore ordered, pursuant to Section 11A of the Act [20] and paragraph (c)(2) of Rule 11Aa3–2 [21] thereunder, that Amendment 13C to the Plan be, and hereby is, approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[22]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. E4–2314 Filed 9–21–04; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–50376]

Order Granting Exemption to National Association of Securities Dealers, Inc. From Certain Reporting Requirements Under Section 31 of the Exchange Act

September 14, 2004.

I. Introduction

Section 36 of the Securities Exchange Act of 1934 ("Exchange Act") [1] authorizes the Securities and Exchange Commission ("Commission")—by rule, regulation, or order—to conditionally or unconditionally exempt any person, security, transaction (or any class or classes of persons, securities, or transactions) from any provision or provisions of the Exchange Act or any rule or regulation thereunder, to the extent such exemption is necessary or appropriate in the public interest and is consistent with the protection of investors. By this Order, the Commission is exempting the National Association of Securities Dealers, Inc. ("NASD") from certain reporting requirements, described below, that are imposed by Rules 31 and 31T and Form R31,[2] which implement Section 31 of the Exchange Act.[3]

[20] 15 U.S.C. 78k–1.

[21] 17 CFR 240.11Aa3–2(c)(2).

[22] 17 CFR 200.30–3(a)(27).

[1] 15 U.S.C. 78mm.

[2] 17 CFR 240.31, 240.31T, and 249.11. The Commission established Rules 31 and 31T and Form R31 in June 2004. *See* Securities Exchange Act Release No. 49928 (June 28; 2004), 69 FR 41060 (July 7, 2004) ("Rule 31 Adopting Release").

[3] 15 U.S.C. 78ee.

II. Background

Section 31, among other things, requires NASD to pay the Commission fees based on the aggregate dollar amount of certain sales of securities. Rules 31 and 31T and Form R31 established a procedure for the calculation and collection of Section 31 fees on the "covered sales" of NASD and the national securities exchanges.[4] Paragraph (b)(1) of Rule 31 requires NASD to submit a completed Form R31 for each month by the tenth business day of the following month. NASD must provide on Form R31 the aggregate dollar amount of its covered sales having a "charge date" [5] in the month of the report. The first Form R31 required by Rule 31 covers the month of July 2004 and was due on August 13, 2004. Paragraph (b) of temporary Rule 31T requires NASD to submit a completed Form R31 for each of the months September 2003 to June 2004, inclusive; these forms also were due on August 13, 2004. Based on the data provided by NASD, the Commission will calculate the amount of Section 31 fees owed and send a bill to NASD.

For NASD, the charge date for most covered sales is the trade date (rather than the settlement date).[6] NASD has requested, however, that it be permitted to use a charge date other than the trade date for certain covered sales that are reported on an "as-of" basis.[7] NASD rules generally require its members, during normal market hours, to report securities transactions within 90 seconds after execution. There are situations in which a member fails to report a transaction on the trade date during normal market hours, although NASD trade reporting systems were open, and the member was obligated to do so within 90 seconds. These trades are reported as "as-of" trades.[8] NASD considers such "as-of" trades to be late and in violation of NASD rules.[9] An "as-of" report also could result when a trade is executed when NASD trade reporting systems are not open. The trade, therefore, must be reported on the next business day when NASD systems re-open. NASD trade reporting rules allow for the next-day reporting of these transactions; NASD does not consider these trades to be reported late or in violation of NASD rules. NASD reviewed the "as-of" trades reported by its members over a selected period and found that, during the review period, the percentage of trades reported "as-of" was relatively consistent on a month-to-month basis, and the vast majority of "as-of" trades were reported to NASD in the same month that the trades occurred.[10]

NASD has stated that it considered making adjustments to its internal systems to track "as-of" covered sales by trade date but determined that it could not do so prior to August 13, 2004. Even if NASD could make these changes, another problem would arise: a previously submitted Form R31 would be rendered inaccurate if an "as-of" trade were reported in a month different from the month in which the trade was actually effected.[11] Therefore, NASD has requested relief to be permitted to report "as-of" covered sales based on the report date rather than the trade date, as would otherwise be required.

NASD also has requested relief from the requirement, for the months September 2003 to June 2004, to report on Form R31 covered sales with a price substantially unrelated to the current market price.[12] Rules 31 and 31T and Form R31 require NASD to include the aggregate dollar amount of such "away-from-the-market" covered sales in Part III of its Form R31. NASD's rules [13] currently do not require members to report such trades to the Automated Confirmation Transaction Service

[4] For NASD, a covered sale is the sale of a security (other than an exempt sale or a sale of a security future) that occurs by or through any NASD member otherwise than on a national securities exchange, if the security is registered on a national securities exchange or is subject to prompt last sale reporting pursuant to NASD rules. *See* 15 U.S.C. 78ee(c); 17 CFR 240.31(a)(6).

[5] The charge date is the date on which a covered sale occurs for purposes of determining the liability of a national securities exchange or national securities association pursuant to Section 31 of the Exchange Act. *See* 17 CFR 240.31(a)(3).

[6] The only covered sales for which NASD does not incur liability based on the trade date are those resulting from the exercise of options that are not listed or registered on a national securities exchange, in which case the charge date is the exercise date. *See* 17 CFR 240.31(a)(3)(ii).

[7] *See* letter from Marc Menchel, Executive Vice President and General Counsel, NASD, to Margaret McFarland, Deputy Secretary, Commission, dated August 11, 2004.

[8] An "as-of" trade is a trade that is reported to NASD after the date that the actual trade occurred.

[9] *See* NASD Rules 4632, 4642, 5430, 6420, 6550, 6620, and related interpretive material.

[10] *See* letter from Patrice M. Gliniecki, Senior Vice President and Deputy General Counsel, NASD, to Margaret McFarland, Deputy Secretary, Commission, dated August 18, 2004. NASD also found that, during the review period, the number of "as-of" trades represented a *de minimus* percentage of the total number of trades.

[11] For instance, assume that an "as-of" covered sale is effected in July 2004 but not reported to NASD until December 2004. In the absence of this Section 36 exemption, the July 2004 Form R31 would no longer contain an accurate tabulation of NASD's aggregate dollar amount of covered sales for that month.

[12] *See* letter from Marc Menchel, Executive Vice President and General Counsel, NASD, to Annette L. Nazareth, Director, Division of Market Regulation, Commission, dated August 5, 2004.

[13] *See* NASD Rules 4632(e)(5), 4642(e)(4), 6420(e)(5), and 6920(e)(2).

("ACT").[14] Because away-from-the-market covered sales are not captured in ACT, the only way that NASD could obtain data on them would be to require its members to report them manually.

Presently, NASD does not require its members to manually report data on away-from-the-market covered sales, and NASD members do not have practices and procedures in place for collecting such data. NASD argues that, in the absence of such practices and procedures and in light of an earlier Commission interpretation with respect to away-from-the-market covered sales,[15] requesting historical information from NASD member firms on away-from-the-market covered sales for the period from September 2003 to June 2004—which would enable NASD to carry out its reporting obligations under temporary Rule 31T—would be unduly burdensome. NASD believes that the number of away-from-the-market covered sales is *de minimis,* while the cost associated with requiring all member firms to search for such historical data would be high. Therefore, NASD has requested relief from the obligation imposed by Rule 31T to report the aggregate dollar amount of away-from-the-market covered sales on its Form R31 submissions for the months September 2003 to June 2004.

With respect to its ongoing obligations under Rule 31, NASD has represented that it will promptly amend its "self-reporting" form [16] to solicit information from NASD member firms on away-from-the-market covered sales prospectively. However, NASD has stated that its members would not be able to provide data on away-from-the-market covered sales for the July 2004 reporting period before August 13, 2004. NASD has represented, however, that it will report away-from-the-market covered sales occurring in July 2004 on its August 2004 Form R31.[17] Therefore, NASD also has requested relief from the obligation to report the aggregate dollar amount of its away-from-the-market covered sales occurring in July 2004 in its Form R31 for that month, and instead to report such covered sales along with its August 2004 Part III covered sales in its August 2004 Form R31.

III. Discussion

After careful consideration, the Commission believes that exercising its exemptive authority under Section 36 of the Exchange Act to grant NASD the relief it has requested is necessary or appropriate in the public interest and consistent with the protection of investors.

As discussed below, the Commission believes that, in view of the structure of the over-the-counter ("OTC") markets, using the report date rather than the trade date for "as-of" covered sales is a practical solution that should have no net impact on the Commission's ability to collect the appropriate amount of Section 31 fees from NASD. While some OTC trading occurs through NASD's facilities (such as the Nasdaq Stock Market), other trading activity results from direct negotiation between NASD members or their customers. NASD must rely on its members to report these trades in a timely fashion. While the Commission expects NASD to zealously enforce its trade reporting rules to minimize the instances of late reporting by members, sometimes late reporting will occur.

Based on the NASD representations noted above, the Commission believes that, in most instances, using the report date rather than the trade date as the charge date of these "as-of" covered sales will not affect the aggregate dollar amount of NASD's covered sales reported on Form R31 in a given month.[18] In the limited circumstances when the trade date and the report date are not in the same month, the aggregate dollar amounts of covered sales reported by NASD in the affected months will change, but the Commission will still collect the same amount of Section 31 fees unless there is a fee rate change in the intervening period.[19] Furthermore, the Commission believes that, in the very limited circumstances when a fee rate change occurs between the trade date and the report date, allowing NASD to report "as-of" trades using report date should not materially affect the amount of Section 31 fees that the Commission collects.[20] On this basis, the Commission believes that granting NASD's request for an exemption with respect to "as-of" covered sales is necessary or appropriate in the public interest and consistent with the protection of investors.

With respect to away-from-the-market covered sales, NASD previously has not obtained data on such trades, and NASD members do not have practices and procedures to provide NASD with such data. The Commission believes that, based on NASD's representations,[21] the minimal aggregate dollar amount of such covered sales—and the correspondingly limited Section 31 fees on such covered sales—does not justify the substantial cost of collecting the historical data from NASD (through its members). Therefore, the Commission believes that granting NASD's request for relief from the requirements of Rules 31 and 31T and Form R31 with respect to away-from-the-market covered sales occurring between September 2003 and June 2004 is necessary or appropriate in the public interest and consistent with the protection of investors. The Commission further believes that reporting July 2004 away-from-the-market covered sales along with NASD's August 2004 data is a practical solution. NASD will have additional time to obtain this information from its members, and the delayed reporting of one month's worth of this data will not

[14] ACT is the automated system owned and operated by the Nasdaq Stock Market which compares trade information entered by ACT participants and submits "locked-in" trades to National Securities Clearing Corporation for clearance and settlement; transmits reports of the transactions automatically to the National Trade Reporting System, if required, for dissemination to the public and the industry; and provides participants with monitoring and risk management capabilities to facilitate participation in a "locked-in" trading environment. *See* NASD Rule 6110(d). ACT is a "trade reporting system" as defined in Rule 31(a)(18), 17 CFR 240.31(a)(18).

[15] In a 1996 release wherein the Commission adopted amendments to prior Rule 31–1 under the Exchange Act, the Commission stated that "no transaction fee will arise from transactions where the buyer and the seller have agreed to trade at a price substantially unrelated to the current market price for the securities, *e.g.*, to enable the seller to make a gift." Securities Exchange Act Release No. 38073 (December 23, 1996), 61 FR 68590, 68592 n.27 (December 30, 1996).

[16] NASD currently uses this form to collect data from its members on covered sales that: (1) occur in odd lots (*i.e.*, for less than 100 shares), where the trade is not captured by ACT; or (2) result from the exercise of non-exchange-traded options that settle by physical delivery of the underlying securities.

Because these two types of covered sales are not captured in a trade reporting system, NASD must include the aggregate dollar amount of such trades in Part III of Form R31.

[17] The August 2004 Form R31 is due to the Commission by September 15, 2004, the tenth business day of September.

[18] For example, assume that an OTC covered sale is effected on May 3 but is reported "as-of" to NASD on May 13 and there is no fee rate change in the intervening period. The Commission will collect exactly the same amount of Section 31 fees from NASD because NASD's aggregate dollar amount of covered sales for the month of May is unchanged.

[19] For example, assume that the covered sale occurs on May 13 but is reported "as-of" to NASD on June 13 and that no fee rate change occurs in the intervening period. Although the dollar amount of this "as-of" covered sale will be included in the June rather than the May Form R31 figures, the fees due in the billing period will be unchanged because May and June are in the same billing period. *See* 17 CFR 240.31(a)(2).

[20] NASD has reported that, in a sample period, the number of "as-of" trades reported to ACT is relatively consistent on a month-to-month basis. Therefore, the "as-of" covered sales that are "lost" to a future period where a different fee rate applies (*i.e.*, the trade is effected in the current period but the "as-of" report to NASD is not made until the next period) should be roughly offset by the "as-of" trades "gained" from a previous period (*i.e.*, the trade was effected in a prior period but was reported to NASD "as-of" in the current period).

[21] *See supra* note 12.

affect the amount of Section 31 fees that NASD will owe the Commission.[22] Therefore, the Commission believes that granting NASD's request for relief from the requirements of Rules 31 and 31T and Form R31 with respect to away-from-the-market covered sales occurring in July 2004 is necessary or appropriate in the public interest and consistent with the protection of investors. After August 2004, NASD must report away-from-the-market covered sales occurring in a given month in the Form R31 due by the tenth business day of the following month, as required by Rule 31.

IV. Conclusion

It is hereby ordered, pursuant to section 36 of the Exchange Act, that NASD: (1) May use the report date rather than the trade date as the charge date of any covered sale reported to NASD "as-of"; (2) is not required to include in its Form R31 submissions for the months September 2003 to July 2004, inclusive, the aggregate dollar amount of any away-from-the-market covered sales; and (3) may report in its August 2004 Form R31 the aggregate dollar amount of away-from-the-market covered sales that occurred in July 2004 and August 2004.

By the Commission.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. E4–2290 Filed 9–21–04; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–50399; File No. SR–DTC–2004–09]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending the By-Laws of The Depository Trust Company

September 16, 2004.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] notice is hereby given that on September 7, 2004, the Depository Trust Company ("DTC") filed with the Securities and Exchange Commission ("Commission") the proposed rule change described in items I, II, and III below, which items have been prepared primarily by DTC. The Commission is publishing this notice to solicit comments on the proposed rule change from interested parties.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change consists of changes to the By-Laws of The Depository Trust Company ("DTC") to provide for indemnity for non-director members of DTC board committees.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, DTC 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. DTC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of these statements.[2]

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In order to help assure the fair representation of the users of DTC, the DTC board of directors has delegated significant responsibilities to the DTC Equity Operations and Planning Committee, the DTC Fixed Income Operations and Planning Committee, and the DTC Membership and Risk Management Committee and has appointed to these committees, in addition to directors, non-director DTC-user representatives.[3]

The purpose of the proposed rule change is to revise DTC's By-Laws to specify that non-director members of DTC board committees will be indemnified in the same manner as DTC directors and officers.

DTC believes that the proposed rule change is consistent with the requirements of section 17A of the Act[4] and the rules and regulations thereunder applicable to DTC because the proposed change strengthens DTC's board committee structure and thereby helps DTC provide its participants with fair representation in the administration of its affairs.

(B) Self-Regulatory Organization's Statement on Burden on Competition

DTC perceives no impact on competition by reason of the proposed rule change.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments from DTC participants or others have not been solicited or received on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective upon filing pursuant to section 19(b)(3)(A)(iii) of the Act[5] and Rule 19b–4(f)(3)[6] thereunder because the proposed rule is concerned solely with the administration of DTC. At any time within 60 days of the filing of such rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

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–DTC–2004–09 on the subject line.

Paper Comments

- Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609.

All submissions should refer to File Number SR–DTC–2004–09. 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

[22] July 2004 and August 2004 are in the same billing period and the same fee rate applies to covered sales occurring in these months.

[1] 15 U.S.C. 78s(b)(1).

[2] The Commission has modified the text of the summaries prepared by DTC.

[3] The changes to the DTC By-Laws are modeled on the current indemnification provisions contained in the By-Laws of both the Fixed Income Clearing Corporation and Emerging Markets Clearing Corporation. The National Securities Clearing Corporation has filed a proposed rule change similar to this proposed rule change. Securities Exchange Act Release No. 50398 (September 16, 2004) (File No. SR–NSCC–2004–05).

[4] 15 U.S.C. 78q–1.

[5] 15 U.S.C. 78s(b)(3)(A)(iii).

[6] 17 CFR 240.19b–4(f)(3).

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, 450 Fifth Street, NW., Washington, DC 20549. Copies of such filing also will be available for inspection and copying at the principal office of DTC and on DTC's Web site at *http://www.dtc.org*. 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–DTC–2004–09 and should be submitted on or before October 13, 2004.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[7]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. E4–2291 Filed 9–21–04; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–50392; File No. SR–FICC–2003–14]

Self-Regulatory Organizations; Fixed Income Clearing Corporation; Order Approving a Proposed Rule Change Relating to Amending Impractical or Inconsistent Rules and Adding Rules To Protect the Clearing Corporation and Its Members

September 15, 2004.

On November 17, 2003, the Fixed Income Clearing Corporation ("FICC") filed with the Securities and Exchange Commission ("Commission") a proposed rule change pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1] (File No. SR–FICC–2003–14) and on January 15, 2004, and March 3, 2004, amended the proposed rule change. Notice of the proposal was published in the **Federal Register** on March 23, 2004.[2] No comment letters were received. For the reasons discussed below, the Commission is approving the proposed rule change.

I. Description

The proposed rule change will eliminate and amend certain of FICC's Government Securities Division ("GSD") and Mortgage-Backed Securities Division ("MBSD") rules that are inconsistent with current practice.

1. Remove the term "Clearing Agent Bank Member" and corresponding references to it in GSD's rules.

This category of GSD membership no longer has any practical meaning and is not used. Entities that are clearing agent banks that wish to join the netting service would become bank netting members.[3]

2. Amend GSD's Rules to remove outdated eligibility qualifications for comparison-only members.

Prior to this rule change, GSD's rules provided for the following types of entities to be eligible to become a comparison-only member: (i) A registered government securities broker or dealer, (ii) a clearing agent bank, or (iii), if neither (i) nor (ii), an entity that has demonstrated to FICC that its business and capabilities are such that it could reasonably expect material benefit from direct access to FICC's services.[4]

FICC believes that GSD's comparison system provides a riskless service whose use should be advantageous to any entity regardless that is an active market participant regardless of the entity's legal or regulatory structure. Accordingly, FICC believes that a better approach to the eligibility criteria for comparison-only entities which would also be consistent with the way that FICC's management views the purpose of comparison-only membership, would be to replace (i) and (ii) with the requirement that a comparison-only applicant be a legal entity that is eligible to apply to be a GSD netting member. FICC would maintain the current (iii) renumbered as (ii).

3. Clarify GSD's rule on voluntary termination of membership.

The proposed change will modify the language in GSD Rule 2, Section 11, to provide that: (i) a member must provide 10 days written notice of terminating its membership but GSD can accept such notice of termination within a shorter period, (ii) the requested termination of membership would not be effective until accepted by GSD, and (iii) GSD's acceptance would be evidenced by a notice to all members announcing the termination date of such member. Paragraphs (ii) and (iii) are new.

4. Add a provision to GSD's Rules to permit it to have access to the books and records of members.

Prior to this rule change, GSD's rules permited GSD to access an applicant's books and records but not a member's books and records. Extending GSD's authority to review member's books and records is consistent with other clearing agencies' rules such as those of the National Securities Clearing Corporation.[5]

5. Add a provision to MBSD's Rules to provide for the confidential treatment of documents submitted by applicants as part of the application process.

This rule change will provide appropriate comfort to applicants and will make MBSD's rules consistent with GSD's rules.[6]

6. Add a new provision to MBSD's Rules that provides that at the request of FICC a non-domestic participant must provide an update of the legal opinion submitted by the foreign member or a written status report on FICC's rights under the relevant non-domestic law and add a similar new provision to GSD Rules.[7]

FICC believes that the old language of this MBSD rule is ambiguous and potentially burdensome for members. FICC believes that a better approach would be to provide that if FICC is alerted to a change in circumstances or to an issue of law that brings into question the reliability of the legal opinion previously submitted by a non-domestic participant, FICC will have the right to require the participant to revisit its legal opinion and to provide an update as to the status of FICC's rights under the relevant non-domestic law. FICC will add this provision to GSD's Rules as well.

II. Discussion

Section 17A(b)(3)(F) of the Act[8] requires that the rules of a clearing agency be designed to assure the safeguarding of securities and funds in its custody or control or for which it is responsible. The Commission finds that the proposed rule change is consistent with FICC's obligations under Section 17A(b)(3)(F) because clarifying FICC's

[7] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] Securities Exchange Act Release No. 49421 (Mar. 16, 2004), 69 FR 13604.

[3] GSD Rule 1.

[4] GSD Rule 2, Section 1.

[5] New Section 13 of GSD Rule 2.

[6] New Section 11 of MBSD Rules, Article III, Rule 1.

[7] New language to subsection (g) of GSD Rule 2, Section 3; proposed new subsection (iii) of MBSD Article III, Rule 1, Section 14.

[8] 15 U.S.C. 78q–1(b)(3)(F).

rules relating to membership, books and records, and legal opinions will provide greater certainty as to FICC's participants' rights and obligations and will enhance FICC's ability to mitigate legal risk posed by non-domestic participants.

III. Conclusion

On the basis of the foregoing, the Commission finds that the proposal is consistent with the requirements of the Act and in particular with the requirements of Section 17A of the Act[9] and the rules and regulations thereunder.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act, that the proposed rule change (File No. SR–FICC–2003–14) be, and hereby is, approved.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[10]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. E4–2287 Filed 9–21–04; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–50389; File No. SR–FICC–2003–06]

Self-Regulatory Organizations; Fixed Income Clearing Corporation; Order Granting Approval of a Proposed Rule Change Relating to the Assessment of Funds-Only Settlement Obligations

September 15, 2004.

I. Introduction

On July 11, 2003, Fixed Income Clearing Corporation ("FICC") filed with the Securities and Exchange Commission ("Commission") proposed rule change SR–FICC–2003–06 pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act").[1] Notice of the proposal was published in the **Federal Register** on February 23, 2004.[2] No comment letters were received. For the reasons discussed below, the Commission is granting approval of the proposed rule change.

II. Description

The proposed rule change for the most part eliminates the complex manual adjustments currently made by FICC's Operations Department with regard to the forward margin debit obligations and credit entitlements of repo broker members of the Government Securities Division ("GSD") of FICC.[3] When GSD initially implemented its blind-brokered repurchase agreement ("repo") service, it operated a system whereby the majority of members submitted trade data in a single batch file at the end of each day. The batch file submission process made it virtually impossible for repo brokers, that expect to net out of their position as middlemen in brokered repos, to timely determine the existence of trades on which they had positions, contact the appropriate counterparties, and correct trade details. As a result, any erroneous submissions on the part of a dealer counterparty resulted in a forward margin assessment to the repo broker. Realizing that a repo broker should always be flat from a net-settlement position perspective, FICC granted repo brokers relief from the forward margining process by providing a look through to the dealer counterparties for purposes of assessing forward margin obligations.[4] However, the look through involves a manual adjustment process that requires complex calculations inconsistent with FICC's overall management policy.[5]

FICC has determined that it will no longer provide a look through to relieve repo brokers from forward margin obligations. Subsequent to the events of September 11, 2001, FICC decided to eliminate all operations functions that require complex manual adjustment or input as a way to reduce risk in all operations processes. In addition, almost all repo broker activity is now submitted to FICC on an interactive, real-time basis that allows brokers to readily rectify any outstanding data submission errors during the day. For these reasons, FICC is proposing to modify the forward margin adjustment process to require the repo brokers to satisfy their forward margin obligations including both paying forward margin debits and receiving forward margin credits.

Going forward, FICC will apply the following parameters with respect to the forward margin obligations of repo brokers. Debits and credits up to a predetermined dollar amount cap will be automatically collected or paid as applicable by the repo brokers as is the case for all other netting members.[6] Debits and credits in excess of the cap will be subject to hybrid processing, whereby the dollar amount up to the cap will always be collected or paid in its entirety by the broker, amounts over the cap ("excess debits" or "excess credits") will be financed by GSD at the discretion of FICC.

The following is an example of hybrid processing for a broker with an excess debit. First, the Operations Department will request that the affected repo broker pay the excess debit to FICC. In the event that the repo broker is unable to pay the excess debit, the Operations Department, in consultation with the Credit Risk Department, will determine whether it is appropriate for FICC to finance the excess debit. If FICC finances the excess debit, the broker will be charged a financing fee, representing the interest amount that FICC will be charged by the clearing bank, and the member will be subject to an administrative fee.[7] GSD will collect the calculated interest amount from the repo broker on the subsequent business day. GSD will also reserve the right in certain situations to assess the forward margin amounts in excess of the dollar amount cap by looking through to the dealer, as is done by the current manual process.[8] All extensions of financing by

---

[9] 15 U.S.C. 78q–1.

[10] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] Securities Exchange Act Release No. 49242 (February 12, 2004), 69 FR 8251.

[3] Forward margin is a component of a netting member's daily funds-only settlement obligation. Forward margin is a mark-to-market payment on forward-settling positions. It is passed through in the form of cash from the debit side to the credit side. The amounts are reversed on the following day with interest collected from the credit side and paid through to the debit side.

[4] FICC, in a prior rule filing, amended its rules to allow management to look through brokered repo transactions in order that repo brokers were not left with debit or credit obligations caused by erroneous submissions on behalf of the dealers. Securities Exchange Act Release No. 38603 (May 9, 1997), 62 FR 27088 (May 16, 1997) (File No. SR–GSCC–96–12). In accordance with FICC's risk strategy at the time, the risk management process worked most effectively if a repo broker was netted out of its positions as a middleman. However, with the advent of real time trade matching and the ready ability of brokers to rectify dealer submission errors, GSD believes that risk management initiatives are better served by using the parameters outlined in this filing.

[5] On each business day, the Operations Division routinely adjusts the overall funds-only settlement obligation of a repo broker that has a forward margin debit or credit. If the repo broker has an overall credit forward margin, GSD will reduce its aggregate funds-only credit obligation or increase its aggregate funds-only debit entitlement by an amount equal to the forward margin credit. Conversely, if the repo broker is in an overall debit forward margin position, GSD will reduce its aggregate funds-only debit obligation or increase its funds-only credit entitlement by an amount equal to the debit; however, it then will apply that amount to the uncompared dealer (the dealer who failed to submit or submitted erroneously).

[6] The FICC Membership and Risk Management Committee will determine, based on historical data and risk considerations, what the debit and credit cap will be for forward margin debits and credits. The Committee has approved an initial cap of $2 million.

[7] This fee will be designed to cover FICC's cost of arranging financing and will be filed before implementation.

[8] FICC will continue to look through to the dealer counterparty for purposes of assessing forward

FICC will be secured by the clearing fund deposit of the repo broker.

In applying the hybrid processing to excess credits, the Operations Department in consultation with the Credit Risk Department will determine whether it is appropriate to pass through the excess credit to the repo broker. To the extent that GSD does not pass through to the broker all or a portion of its calculated excess credit, GSD will calculate an interest amount tied to the rate of interest earned by GSD on its overnight cash investment on such unpaid excess credit and will pay this interest amount to the repo broker on the subsequent business day. The proposed rule change will require some manual adjustments when the hybrid approach is used, but these instances will occur infrequently and will not rise to the complexity of the current process.

III. Discussion

Section 17A(b)(3)(F) of the Act requires, among other things, that the rules of a clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions.[9] FICC's look-through rule was established to eliminate the forward margin debits and credits of repo broker members of GSD when their dealer counterparties failed to timely submit trade data or submitted incorrect data. The transition to real time trade submission from end of day batch trade submission has significantly reduced the likelihood that repo brokers will be assessed forward margin and in FICC's view has rendered the look-through rule and its attendant manual adjustments unnecessary. Under the proposed rule change, forward margin will be collected from repo brokers or financed by GSD, but FICC will retain the right to look-through to the dealer counterparties when necessary. Accordingly, by significantly reducing the amount of manual processing with regard to forward margin debit obligations and credit entitlements without affecting FICC's ability to collect forward margin, the proposed rule change should help FICC to devote more resources to promoting the prompt and accurate clearance and settlement of securities transactions.

IV. Conclusion

On the basis of the foregoing, the Commission finds that the proposed rule change is consistent with the requirements of the Act and in particular with the requirements of section 17A of the Act and the rules and regulations thereunder applicable.

It is therefore ordered, pursuant to section 19(b)(2) of the Act, that the proposed rule change (File No. SR–FICC–2003–06) be and hereby is approved.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[10]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. E4–2296 Filed 9–21–04; 8:45 am]

BILLING CODE 8010–01–P

margin obligations in cases of a systemic outage where any non-submission by one counterparty versus a repo broker exceeds $1 billion.

[9] 15 U.S.C. 78q–1(b)(3)(F).

[10] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–50391; File No. SR–NASD–2004–090]

Self-Regulatory Organizations; National Association of Securities Dealers, Inc.; Order Approving Proposed Rule Change and Amendment No. 1 Thereto Relating to the Nasdaq Closing Cross

September 15, 2004.

On June 9, 2004, the National Association of Securities Dealers, Inc. ("NASD"), through its subsidiary, the Nasdaq Stock Market, Inc. ("Nasdaq"), filed with the Securities and Exchange Commission ("Commission"), pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1] and Rule 19b–4 thereunder,[2] a proposed rule change to establish auxiliary procedures for administering the Nasdaq Closing Cross on certain significant trading days. On July 23, 2004, Nasdaq amended the proposed rule change.[3] The proposed rule change, as amended, was published for comment in the **Federal Register** on August 2, 2004.[4] The Commission received no comments on the proposal. This order approves the proposed rule change, as amended.

The proposed rule change would establish auxiliary procedures for administering the Nasdaq Closing Cross on days when significant trading volume is expected ("significant trading days"). There are three components of the Nasdaq Closing Cross: (1) The creation of Market On Close ("MOC"), Limit on Close ("LOC") and Imbalance Only ("IO") order types; (2) the dissemination of an order imbalance indicator; and (3) Closing Cross processing in the Nasdaq Market Center at 4 p.m. that executes the maximum number of shares at a single, representative price that is the Nasdaq Official Closing Price. On significant trading days, the proposed auxiliary procedures would permit Nasdaq: (i) To set earlier times for the end of the order entry periods for IO, MOC, and LOC orders set forth in NASD Rule 4709(a); (ii) to set an earlier time for the order modification and cancellation periods for IO, MOC, and LOC orders set forth in NASD Rule 4709(a); (iii) to set an earlier time for the dissemination times and frequencies for the order imbalance indicator set forth in NASD Rule 4709(b); and (iv) to adjust the threshold values set forth in NASD Rule 4709(c)(2)(D) to no greater than twenty percent.

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 association.[5] The Commission believes that the proposed rule change is consistent with section 15A(b) of the Act,[6] in general, and furthers the objectives of section 15A(b)(6),[7] 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 regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, 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 believes that the proposed auxiliary procedures will allow Nasdaq greater flexibility in the administration of the Nasdaq Closing Cross and help Nasdaq maintain a fair and orderly market during the close on significant trading days.

For the foregoing reasons, the Commission finds that the proposed rule change, as amended, is consistent with the requirements of the Act and rules and regulations thereunder applicable to a national securities

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* letter from Mary M. Dunbar, Vice President and Deputy General Counsel, Nasdaq, to Katherine A. England, Assistant Director, Division of Market Regulation, Commission, dated July 22, 2004 ("Amendment No. 1"). In Amendment No. 1, Nasdaq restated the proposed rule change in its entirety.

[4] *See* Securities Exchange Act Release No. 50087 (July 26, 2004), 69 FR 46195.

[5] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[6] 15 U.S.C. 78*o*–3(b).

[7] 15 U.S.C. 78*o*–3(b)(6).

association, and, in particular, section 15A(b) of the Act.[8]

It is therefore ordered, pursuant to section 19(b)(2) of the Act,[9] that the proposed rule change (SR–NASD–2003–090), as amended by Amendment No. 1, is approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[10]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. E4–2295 Filed 9–21–04; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–50398; File No. SR–NSCC–2004–05]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending the By-Laws of the National Securities Clearing Corporation

September 16, 2004.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] notice is hereby given that on September 7, 2004, the National Securities Clearing Corporation ("NSCC") filed with the Securities and Exchange Commission ("Commission") the proposed rule change described in items I, II, and III below, which items have been prepared primarily by NSCC. The Commission is publishing this notice to solicit comments on the proposed rule change from interested parties.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change consists of changes to the By-Laws of the National Securities Clearing Corporation ("NSCC") to provide for indemnity for non-director members of NSCC board committees.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, NSCC 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. NSCC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of these statements.[2]

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In order to help assure the fair representation of the users of NSCC, the NSCC board of directors has delegated significant responsibilities to the NSCC Equity Operations and Planning Committee, the NSCC Fixed Income Operations and Planning Committee, and the NSCC Membership and Risk Management Committee and has appointed to these committees, in addition to directors, non-director NSCC-user representatives.[3]

The purpose of the proposed rule change is to revise NSCC's By-Laws to specify that non-director members of NSCC board committees will be indemnified in the same manner as NSCC directors and officers.

NSCC believes that the proposed rule change is consistent with the requirements of section 17A of the Act[4] and the rules and regulations thereunder applicable to NSCC because the proposed change strengthens NSCC's board committee structure and thereby helps NSCC provide its participants with fair representation in the administration of its affairs.

(B) Self-Regulatory Organization's Statement on Burden on Competition

NSCC perceives no adverse impact on competition by reason of the proposed rule change.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments from NSCC participants or others have not been solicited or received on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective upon filing pursuant to section 19(b)(3)(A)(iii) of the Act[5] and Rule 19b–4(f)(3)[6] thereunder because the proposed rule is concerned solely with the administration of NSCC. At any time within 60 days of the filing of such rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

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–NSCC–2004–05 on the subject line.

Paper Comments

- Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609.

All submissions should refer to File Number SR–NSCC–2004–05. 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, 450 Fifth Street, NW., Washington, DC 20549. Copies of such filing also will be available for inspection and copying at the principal office of NSCC and on NSCC's Web site at *http://www.nscc.com/legal*. All

[8] 15 U.S.C. 78*o*–3(b).

[9] 15 U.S.C. 78s(b)(2).

[10] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] The Commission has modified the text of the summaries prepared by NSCC.

[3] The changes to the NSCC By-Laws are modeled on the current indemnification provisions contained in the By-Laws of both the Fixed Income Clearing Corporation and Emerging Markets Clearing Corporation. The Depository Trust Company has filed a proposed rule change similar to this proposed rule change. Securities Exchange Act Release No. 50399 (September 16, 2004) (File No. SR–DTC–2004–09).

[4] 15 U.S.C. 78q–1.

[5] 15 U.S.C. 78s(b)(3)(A)(iii).

[6] 17 CFR 240.19b–4(f)(3).

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–NSCC–2004–05 and should be submitted on or before October 13, 2004.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[7]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. E4–2292 Filed 9–21–04; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–50395; File No. SR–NSCC–2003–09]

Self-Regulatory Organizations; National Securities Clearing Corporation; Order Approving Proposed Rule Change To Amend the Procedure for Determining Intraday Mark-to-the-Market Payments

September 16, 2004.

I. Introduction

On May 20, 2003, the National Securities Clearing Corporation ("NSCC") filed with the Securities and Exchange Commission ("Commission") proposed rule change SR–NSCC–2003–09 pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act").[1] On October 20, 2003, NSCC filed an amendment to the proposed rule change. Notice of the proposal was published in the **Federal Register** on March 8, 2004.[2] No comment letters were received. For the reasons discussed below, the Commission is approving the proposed rule change.

II. Description

NSCC is amending Procedure XV (Clearing Fund Formula and Other Matters) to give NSCC more flexibility in determining the intraday mark-to-the market amount it will collect from its members.

NSCC Rule 15 (Financial Responsibility and Operational Capability) provides that NSCC may obtain such adequate assurances of a member's financial responsibility and operational capability as NSCC may at any time or from time to time deem necessary or advisable in order to protect NSCC, Settling Members, Municipal Comparison Only Members, Fund Members, Insurance Carrier Members, creditors, or investors.

Currently, Procedure XV describes the criteria for determining which positions in high risk/volatile issues NSCC will require additional mark-to-the-market payments for and provides specific formulas that are used to determine additional deposit amounts. Generally, NSCC assesses on an intraday basis an additional mark-to-the-market charge to a member when the member maintains a position in a security where the intraday exposure to NSCC is in excess of 10% of the member's excess net capital. In addition, with respect to illiquid unsettled positions, NSCC may request additional collateral if the member's net unsettled position in any one security is greater than 25% of the security's average daily volume.

NSCC is replacing the formulas currently reflected in its procedures with a more generalized provision to give NSCC the flexibility to determine what amount, if any, should be collected based on conditions that exist at that time.[3] In addition, the reference to NSCC's authority to make such charges is being corrected to reflect NSCC Rule 15, Section 4.

III. Discussion

Section 17A(b)(3)(F) of the Act requires that the rules of a clearing agency be designed to assure the safeguarding of funds and securities for which it is responsible.[4] The Commission finds that NSCC's proposed rule change is consistent with this requirement because it should permit the safeguarding of funds and securities for which NSCC is responsible by permitting NSCC to more appropriately collect collateral to cover its exposure from its members' unsettled positions.

IV. Conclusion

On the basis of the foregoing, the Commission finds that the proposed rule change is consistent with the requirements of the Act and in particular Section 17A of the Act and the rules and regulations thereunder.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act, that the proposed rule change (File No. SR–NSCC–2003–09) be and hereby is approved.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[5]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. E4–2294 Filed 9–21–04; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–50374; File No. SR–PCX–2004–63]

Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change and Amendment No. 1 Thereto by the Pacific Exchange, Inc. Relating to a Proposed Listing Fee Schedule for Exchange Traded Funds and Closed-End Funds

September 14, 2004.

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 August 9, 2004, the Pacific Exchange, Inc. ("PCX" 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 PCX. The PCX submitted Amendment No. 1 to the proposal on September 3, 2004.[3] 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 PCX, through its wholly-owned subsidiary PCX Equities, Inc. ("PCXE"), is proposing to amend its Schedule of Fees and Charges ("Schedule") in order to adopt new listing fees specifically for listing Exchange-Traded Funds ("ETFs") and Closed-End Funds ("CEFs") (collectively, "Funds") on the PCXE and trading on the Archipelago Exchange ("ArcaEx"), a facility of the PCXE.[4] The PCX proposes to implement

[7] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] Securities Exchange Act Release No. 49353 (March 2, 2004), 69 FR 10789.

[3] Additional factors that NSCC may use in determining intraday mark-to-the-market requirements include but are not limited to (1) Percent of total security float, (2) average daily security volume, (3) position size (quantity and value), (4) portfolio concentration, and (5) industry/sector concentration.

[4] 15 U.S.C. 78q–1(b)(3)(F).

[5] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* letter from Tania Blanford, Regulatory Policy, PCX, to Nancy J. Sanow, Assistant Director, Division of Market Regulation, Commission, dated September 1, 2004, and accompanying Form 19b–4 ("Amendment No. 1"). Amendment No. 1 replaced the original filing in its entirety.

[4] ETFs include unit investment trusts, portfolio depository receipts and trust issued receipts designed to track the performance of the broad

Continued

these fees effective for listings, and listing applications pending, as of June 21, 2004. The text of the proposed rule change appears below; proposed additions are *italicized*.

* * * * *

SCHEDULE OF FEES AND CHARGES FOR EXCHANGE SERVICES

[PCX equities: listing fees]

Administrative Listing Fees:*	
Application Processing Fee	$500.00
Funds	*$500.00 for all applications to list Fund(s) submitted at the same time by a Fund issuer or "family," regardless of the number of Funds to be listed*[1]
Company Name Change	$250.00
Change in Par Value	$250.00
Original Listing Fees:**	
Common Stock, dually listed with the NYSE, AMEX or Nasdaq NM	$10,000.00
Common Stock, not dually listed	$20,000.00
Additional Classes of Common Stock	$2,500.00
Preferred Stock, Warrants, Debit Instruments, Purchase Rights, Units.	$2,500.00
Funds	*$20,000 for the first Fund listed by a Fund issuer or "family;" no fee for subsequent additional Funds listed by the same Fund issuer or "family".*

*This is a non-refundable, fixed charge for review of listing applications. Issues approved for listing will have this charge credited towards the Original Listing Fee *or, if the Fund issuer of "family" is not subject to an original listing fee, towards the applicable annual maintenance fee(s) due for the Fund or Funds listed.*

[1] *Fund "families" are those with a common investment advisor or investment advisors, which are "affiliated persons" as defined under the securities laws. A "family" also includes trust-issued receipts such as Holding Company Depositary Receipts (known as HLDRS*SM*) that have a common initial depositor or initial depositors that are "affiliated persons" as defined under the securities laws.*

**The Initial Listing fees are fixed and are not charged by the number of shares listed.

* * * * *

Additional Shares Listing Fee:[2]	
Per share	$.0025
Minimum charge (per application)	$500.00
Maximum charge (per application)	$7500.00
Maximum charge (per year)	$15,000.00
Annual Listing Maintenance Fee (Payable January of each year following):	
For one issue, dually listed with the NYSE, AMEX or Nasdaq NM	$1,000.00
For each additional issue	$500.00
Minimum (per year)	$1,000.00
Maximum (per year)	$5,000.00
For Funds:	

Aggregate Total Shares Outstanding	*Annual Maintenance Fee*
Less than 10 million	*$5,000*
10 million to less than 30 million	*$10,000*
30 million to less than 50 million	*$15,000*
50 million to less than 100 million	*$20,000*
100 million to less than 250 million	*$30,000*
250 million to less than 500 million	*$40,000*
500 million to less than 750 million	*$50,000*
750 million to less than One billion	*$60,000*
Greater than One billion	*$80,000*

[2] *This fee does not apply to Funds.*

* * * * *

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 PCX included statements concerning the purpose of and basis for the proposed modifications to the fee schedule. The text of these statements may be examined at the places specified in Item IV below. The PCX 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

The PCX proposes to adopt new listing fees specifically for Funds. The proposed fees include a non-refundable application processing fee, a one-time

stock or bond market, stock industry sector, and U.S. Treasury and corporate bonds, among other things. CEFs are a type of Investment Company registered under the Investment Company Act of 1940 that offers a fixed number of shares. Their assets are professionally managed in accordance with the CEF's investment objectives and policies, and may be invested in stocks, fixed income securities or a combination of both.

original listing fee per Fund issuer or "family," [5] as defined, and an annual maintenance fee based on the aggregate total shares outstanding of the Funds listed by the same Fund issuer or "family." The remaining portions of the current Schedule would continue to apply to Funds, except for the additional shares listing fee.

The PCX believes there are several reasons to adopt listing fees specifically for Funds. First, PCXE's current Schedule does not explicitly provide for listing fees for these types of securities. Accordingly, the PCX believes the amended Schedule would provide guidance and clarity to issuers and the public regarding the appropriate applicable fees for Funds. Second, the PCX believes, in most cases, proposed fees would substantially decrease the listing fees that Fund issuers and Fund "families" would otherwise pay under the current Schedule. As such, the PCX believes the proposed fees would enable PCXE to compete more effectively for listings. The PCX also believes the lower proposed fees would also be beneficial for issuers. Finally, the PCX believes reduced listing fees for Funds would remove the financial impediment to listing created by high fees, thus providing Fund issuers and Fund "families" with a greater choice of listing venues.

Summary of Current and Proposed Fee Changes

(a) Application Processing Fees

Currently, the Schedule provides for a $500 application processing fee, which applies generally to all listings applications including Funds. While this fee is non-refundable, it is credited towards the original listing fee upon approval for listing. PCX proposes to create an application processing fee specifically for Funds, which would allow a single application fee of $500 for applications submitted at the same time by a Fund issuer or Fund "family," regardless of the number of Funds to be listed. Thus, a Fund issuer or Fund "family" which seeks to list multiple Funds at the same time would incur a total application fee of $500. Subsequent applications from the same Fund issuer or "family" to list one or more Funds would incur a separate $500 application fee at that time.

Similar to the general application processing fee, the application processing fee for Funds would be non-refundable and credited towards the original listing fee, if any, upon approval of the listing, or, if the Fund issuer or "family" is not subject to an original listing fee, towards the applicable annual maintenance fee(s) due for the Fund or Funds listed.

(b) Original Listing Fees

Currently, the original listing fee is based on whether a Fund or "family" is dually listed on the New York Stock Exchange, Inc. ("NYSE"), the American Stock Exchange LLC ("Amex"), or Nasdaq National Market ("NNM"). Thus, if a Fund is dually listed, the original listing fee would be $10,000 per Fund; otherwise, the original listing fee would be $20,000 per Fund. This fee would apply to each individual Fund listed, regardless of the timing or number of Funds listed by an individual Fun issuer or "family" of funds.

The PCX proposes a one-time original listing fee of $20,000 specifically for the first Fund listed by a Fund issuer or Fund "family"—including those with one or more Funds listed as of June 21, 2004—would not incur an original listed fee, regardless of whether one or more previously listed Funds are no longer listed on PCXE.

This proposed fee would apply regardless of whether the Fund(s) lists in conjunction with an initial public offering, transfers from another marketplace, concurrently lists on another marketplace, or is listed on another exchange or market.

(c) Annual Maintenance Fees

Currently, the annual maintenance fees are fixed and based on whether the Fund is dually listed on the NYSE, Amex, or NNM. If a Fund is dually listed, the maintenance fee would be $1,000 per Fund; otherwise, the maintenance fee would be $2,000 per Fund. These fees apply regardless of the number of Funds listed by the issuer. Moreover, annual maintenance fees are not incurred in the year of listing; rather, they are payable beginning in the first full calendar year following the year of listing.

The PCX proposes to adopt annual maintenance fees specifically for Funds based on the aggregate total shares outstanding of the Funds listed by the same Fund issuer or Fund "family," as follows:

Aggregate total shares outstanding	Annual maintenance fee
Less than 10 million	$5,000
10 million to less than 30 million	10,000
30 million to less than 50 million	15,000
50 million to less than 100 million	20,000
100 million to less than 250 million	30,000
250 million to less than 500 million	40,000
500 million to less than 750 million	50,000
750 million to less than One billion	60,000
Greater than One billion	80,000

As previously stated, annual maintenance fees would be assessed beginning in the first full calendar year following the year of listing. The aggregate total shares outstanding would be calculated based on the total shares outstanding as reported by the Fund issuer or Fund "family" in its most recent periodic filing with the Commission or other publicly available information. For example, if a single Fund issuer or "family" listed ten Funds during calendar year 2001 with an aggregate of 120 million shares outstanding, and subsequently listed a single Fund in 2002 with 130 million shares outstanding, then listed a single Fund in 2003 with 400 million shares outstanding, that issuer would not incur an annual maintenance fee for 2001, but would incur annual maintenance fees of $30,000 for 2002 (based on an aggregate of 120 million total shares outstanding), $40,000 for 2003 (based on an aggregate of 250 million total shares outstanding) and $50,000 for 2004 (based on an aggregate of 650 million total shares outstanding). Annual maintenance fees would not be pro-rated or reduced for Funds that delist for any reason.

The annual maintenance fees would apply regardless of whether any of these Funds are listed elsewhere.

(d) Implementation

The PCX proposes that these proposed fees become effective retroactive for all listings, and listing applications pending, as of June 21, 2004.

2. Statutory Basis

The Exchange believes that the proposal, as amended, is consistent with Section 6(b) of the Act,[6] in general, and Section 6(b)(4) of the Act,[7] in particular, in that it provides for the equitable allocation of reasonable dues, fees and

[5] Fund "families" are those with a common investment advisor or investment advisors that are "affiliated persons" as defined under the securities laws. A "family" also includes trust-issued receipts such as Holding Company Depositary Receipts (known as HLDRS℠) which have a common initial depositor or initial depositors which are "affiliated persons" as defined under the securities laws.

[6] 15 U.S.C. 78f(b).

[7] 15 U.S.C. 78f(b)(5).

other charges among its members and other persons using its facilities.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change, as amended, will impose 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 Fee Schedule Modifications 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 Exchange consents, the Commission will:

A. By order approve the proposed modifications, 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, 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 e-mail to *rule-comments@sec.gov*. Please include File No. SR–PCX–2004–63 on the subject line.

Paper Comments

- Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609.

All submissions should refer to File No. SR–PCX–2004–63. 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 communication 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, 450 Fifth Street, NW., Washington, DC 20549–0609. Copies of such filing will also be available for inspection and copying at the principal office of the PCX. 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–PCX–2004–63 and should be submitted on or before October 13, 2004.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[8]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 04–21276 Filed 9–21–04; 8:45 am]

BILLING CODE 8010-01–M

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Aviation Proceedings, Agreements Filed the Week Ending September 10, 2004

The following Agreements were filed with the Department of Transportation under the provisions of 49 U.S.C. 412 and 414. Answers may be filed within 21 days after the filing of the application.

Docket Number: OST–2004–19088.

Date Filed: September 8, 2004.

Parties: Members of the International Air Transport Association.

Subject: PTC23 EUR–J/K 0116 dated 10 September 2004, TC23/TC123 Europe-Japan, Korea, Expedited Resolution 002w r1, Intended effective date: 15 January 2005.

Andrea M. Jenkins,

Program Manager, Docket Operations, Federal Register Liaison.

[FR Doc. 04–21249 Filed 9–21–04; 8:45 am]

BILLING CODE 4910–62–P

[8] 17 CFR 200.30–3(a)(12).

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Notice of Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits Filed Under Subpart B (Formerly Subpart Q) During the Week Ending September 10, 2004

The following Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits were filed under Subpart B (formerly Subpart Q) of the Department of Transportation's Procedural Regulations. (See 14 CFR 301.201 *et seq.*) The due date for Answers, Conforming Applications, or Motions to Modify Scope are set forth below for each application. Following the Answer period DOT may process the application by expedited procedures. Such procedures may consist of the adoption of a show-cause order, a tentative order, or in appropriate cases a final order without further proceedings.

Docket Number: OST–2004–13937.

Date Filed: September 10, 2004.

Due Date for Answers, Conforming Applications, or Motion to Modify Scope: October 1, 2004.

Description: Application of Cool Tours, Inc. d/b/a San Juan Aviation, requesting a waiver from the revocation for dormancy to conduct scheduled passenger operations as a commuter air carrier.

Docket Number: OST–2004–19109.

Date Filed: September 10, 2004.

Due Date for Answers, Conforming Applications, or Motion to Modify Scope: October 1, 2004.

Description: Application of Casino Airlines, Inc. dba City Airlines requesting authority to engage in scheduled passenger operations as a commuter air carrier and to operate scheduled daily flights between Dallas, TX (Love Field—DAL) to Lake Charles Regional, LA (Lake Charles Regional—LCH) flying two (2) BAe Jetstream 100 aircraft.

Andrea M. Jenkins,

Program Manager, Docket Operations, Federal Register Liaison.

[FR Doc. 04–21244 Filed 9–21–04; 8:45 am]

BILLING CODE 4910–62–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Public Notice of Availability of a Finding of No Significant Impact (FONSI)/Record of Decision (ROD) on a Final Environmental Assessment (FEA) for the Proposed Federal Action at Toledo Express Airport, Swanton, OH

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of availability.

SUMMARY: The FAA is issuing this notice to advise the pubic of the availability of the FONSI/ROD on an FEA for a proposed Federal action at Toledo Express Airport, Swanton, Ohio. The FONSI/ROD states that the proposed project is consistent with the National Environmental Policy Act of 1969 and will not significantly affect the quality of the environment. Therefore, the preparation of an Environmental Impact Statement (EIS) is not required.

The FEA evaluated Toledo Express Airport's proposal to implement measure LU–13, the purchase of Swanton Township School, of the amended Final Part 150 Noise Compatibility Program and approval of federal funds through the Airport Improvement Program to purchase the Swanton Township School located at 12035 Airport Highway (State Route 2) in Swanton Township, Lucas County, Ohio.

The FEA and the FONSI/ROD are available for review during normal business hours at the following locations: Toledo-Lucas County Port Authority, Toledo Express Airport, 11013 Airport Highway, Swanton, OH 43558; and FAA Detroit Airports District Office, 11677 South Wayne Road, Suite 107, Romulus, MI 48174.

Due to current security requirements, arrangements must be made with the point of contact prior to visiting these offices.

FOR FURTHER INFORMATION CONTACT: Mr. Kevin Mulcaster, FAA Great Lakes Region, Detroit Airports District Office, 11677 South Wayne Road, Suite 107, Romulus, MI 48174 (734) 229–2915.

Issued in Detroit, Michigan, August 24, 2004.

Irene Porter,

Manager, Detroit Airport District Office, FAA, Great Lakes Region.

[FR Doc. 04–21299 Filed 9–21–04; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE–2004–76]

Petitions for Exemption; Summary of Petitions Received

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petitions for exemption received.

SUMMARY: Pursuant to FAA's rulemaking provisions governing the application, processing, and disposition of petitions for exemption part 11 of Title 14, Code of Federal Regulations (14 CFR), this notice contains a summary of certain petitions seeking relief from specified requirements of 14 CFR, dispositions of certain petitions previously received, and corrections. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of any petition or its final disposition.

DATES: Comments on petitions received must identify the petition docket number involved and must be received on or before October 12, 2004.

ADDRESSES: You may submit comments [identified by DOT DMS Docket Number FAA–200X–XXXXX] by any of the following methods:

- Web Site: *http://dms.dot.gov.* Follow the instructions for submitting comments on the DOT electronic docket site.
- Fax: 1–202–493–2251.
- Mail: Docket Management Facility; U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, Room PL–401, Washington, DC 20590–001.
- 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.
- Federal eRulemaking Portal: Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.

Docket: For access to the docket to read background documents or comments received, go to *http://dms.dot.gov* at any time or to 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.

FOR FURTHER INFORMATION CONTACT: Tim Adams (202) 267–8033, Sandy Buchanan-Sumter (202) 267–7271, Office of Rulemaking (ARM–1), Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85 and 11.91.

Issued in Washington, DC, on September 15, 2004.

Anthony F. Fazio,

Director, Office of Rulemaking.

Petitions for Exemption

Docket No.: FAA–2004–18676.
Petitioner: Quest Diagnostics, Inc.
Section of 14 CFR Affected: 14 CFR 91.207(d)(4).
Description of Relief Sought: To allow Quest Diagnostics, Inc. to operate certain aircraft without testing the emergency locator transmitter for the presence of a sufficient signal radiated from its antenna.

[FR Doc. 04–21240 Filed 9–21–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Aviation Rulemaking Advisory Committee Meeting

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of public meeting.

SUMMARY: This notice announces a public meeting of the FAA's Aviation Rulemaking Advisory Committee to discuss airport issues.

DATES: The meeting will be held on October 6, 2004, 9:30 a.m. EDT.

ADDRESSES: The meeting will be held at the Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC, 20591, Room 9ABC.

FOR FURTHER INFORMATION CONTACT: Caren Waddell, Office of Rulemaking, ARM–200, FAA, 800 Independence Avenue, SW., Washington, DC 20591, telephone (202) 267–8199, e-mail *caren.waddell@faa.gov.*

SUPPLEMENTARY INFORMATION: The referenced meeting is announced pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463; 5 U.S.C. App. II).

The agenda will include:

- ARFF Requirements Working Group Status Report.
- Discussion/approval of ARFF Requirements Working Group draft recommendation to ARAC.
- Other business.

Attendance is open to the interested public but will be limited to the space available. The public must make arrangements to present oral statements at the meeting. Written statements may be presented to the committee at any time by providing 25 copies to the Assistant Chair or by providing the copies at the meeting.

If you are in need of assistance or require a reasonable accommodation for the meeting, please contact the person listed under the heading **FOR FURTHER INFORMATION CONTACT**. In addition, sign and oral interpretation, as well as a listening device, can be made available at the meeting if requested 10 calendar days before the meeting. Arrangements may be made by contacting the person listed under the heading **FOR FURTHER INFORMATION CONTACT**. Meeting attendees must bring a valid photo I.D. and will be expected to comply with FAA security procedures while in the building.

Issued in Washington, DC, on September 15, 2004.

Anthony F. Fazio,

Executive Director, Aviation Rulemaking Advisory Committee.

[FR Doc. 04–21248 Filed 9–21–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Government/Industry Aeronautical Charting Forum Meeting

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of public meeting.

SUMMARY: This notice announces the bi-annual meeting of the Federal Aviation Administration's Government/Industry Aeronautical Charting Forum (ACF) to discuss informational content and design of aeronautical charts and related products, as well as instrument flight procedures policy and criteria.

DATES: The ACF is separated into two distinct groups. The Instrument Procedures Group will meet October 25 and 26, 2004 from 9 a.m. to 4:30 p.m. The Charting Group will meet October 27 and 28, 2004 from 9 a.m. to 4:30 p.m.

ADDRESSES: The meeting will be held at the Advanced Management Technology Incorporated (AMTI), 1515 Wilson Blvd., Suite 1100, Arlington, VA 22209.

FOR FURTHER INFORMATION CONTACT: For information relating to the Instrument Procedures Group, contact Thomas E. Schneider, Flight Procedures Standards Branch, AFS–420, 6500 South MacArthur Blvd., P.O. Box 25082, Oklahoma City, OK. 73125; telephone (405) 954–5852; fax: (405) 954–2528. For information relating to the Charting Group, contact Richard V. Powell, FAA, Office of System Operations & Safety, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267–8790, fax: (202) 493–4266.

SUPPLEMENTARY INFORMATION: Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463; 5 U.S.C. App. II), notice is hereby given of a meeting of the Government/Industry Aeronautical Charting Forum to be held from October 25–October 28, 2004, from 9 a.m. to 4:30 p.m. at the Advanced Management Technology, Incorporated, 515 Wilson Blvd., Suite 1100, Arlington, VA 22209.

The Instrument Procedures Group agenda will include briefings and discussions on recommendations regarding pilot procedures for instrument flight, as well as criteria, design, and developmental policy for instrument approach and departure procedures.

The Charting Group agenda will include briefings and discussions on recommendations regarding aeronautical charting specifications, flight information products, as well as new aeronautical charting and air traffic control initiatives.

Attendance is open to the interested public, but will be limited to the space available. The public must make arrangements by October 7, 2004, to present oral statements at the meeting. The public may present written statements and/or new agenda items to the committee by providing a copy to the person listed in the **FOR FURTHER INFORMATION CONTACT** section by october 7, 2004. Public statements will only be considered if time permits.

Issued In Washington, DC, on September 16, 2004.

Richard V. Powell,

Co-Chair, Government/Industry, Aeronautical Charting Forum.

[FR Doc. 04–21300 Filed 9–21–04; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Laboratory Accreditation Program Approval

AGENCY: Federal Highway Administration, DOT.

ACTION: Notice.

SUMMARY: The Federal Highway Administration (FHWA) announces that it will use the National Cooperation for Laboratory Accreditation (NACLA) Recognition process for determining whether an accreditation program is comparable to the American Association of State Highway and Transportation Officials' (AASHTO) Accreditation Program for use in quality assurance procedures for laboratories performing sampling and testing of materials used in the construction of Federal-aid highways on the National Highway System. In order for the accreditation program to be considered comparable, the accreditation body must be recognized by NACLA with a scope that includes the "Technical Requirements for Construction Materials Testing."

FOR FURTHER INFORMATION CONTACT: Mr. Michael Rafalowski, Office of Pavement Technology (HIPT–10), (202) 366–1571; Mr. Harold Aikens, Office of Chief Counsel, (HCC–30), (202) 366–0791, Department of Transportation, Federal Highway Administration, 400 Seventh Street, SW., Washington, DC 20590–0001. Office hours are from 8 a.m. to 4:30 p.m., e.s.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access

An electronic copy of this document may be downloaded using a modem and suitable communications software from the Government Printing Office's Electronic Bulletin Board Service at (202) 512–1661. Internet users may reach the Office of the Federal Register's home page at *http://www.archives.gov/fedreg* and the Government Printing Office's web page at *http://www.gpoaccess.gpo.gov/nara.*

Background

In order to meet the quality assurance requirements for construction found in 23 CFR 637.209(a)(2), (3), and (4), laboratories performing sampling and testing of materials used in the construction of Federal-aid highway projects on the National Highway System must be accredited by the AASHTO Accreditation Program or a comparable laboratory accreditation program approved by FHWA. This notice announces that the FHWA will use the NACLA Accreditation Body Recognition Procedure and Technical Requirements for Construction Materials Testing, NISTIR 7012, as the criteria for the approval of comparable laboratory accreditation programs. The NACLA Recognition procedures are available at the following URL: *http://www.nacla.net/MRA/RecognitionProcedure.pdf.* The Technical Requirements for Testing Construction Materials is available at

the following URL: *http://ts.nist.gov/ts/htdocs/210/gsig/pubs/ir7012.pdf.*

Before accreditation bodies will be approved by the FHWA, these bodies will be evaluated against the NACLA recognition procedures, the Technical Requirements for Construction Materials Testing, and must be recognized by NACLA with the Technical Requirements for Construction Materials Testing listed in its scope. Additionally, to meet the quality assurance requirements in 23 CFR 637.209(a)(2), (3), and (4), the laboratories must have been successfully assessed using the technical requirements and the laboratories scope of accreditation and must indicate that the laboratory was assessed according to the requirements in NISTR 7012.

The NACLA is a membership organization that has been incorporated since May 1998 for the purposes of recognizing the competency of laboratory accreditation programs. The FHWA has been a member of the organization from its inception and involved in the development and implementation of the recognition procedures and development of the Technical Requirements for Construction Materials Testing.

Authority: 23 U.S.C. 109, 114, and 315; 23 CFR 637; 49 CFR 1.48(b)

Issued on: September 14, 2004.

Mary E. Peters,

Federal Highway Administration.

[FR Doc. 04–21239 Filed 9–21–04; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Federal Railroad Administration, DOT.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 and its implementing regulations, the Federal Railroad Administration (FRA) hereby announces that it is seeking approval of the following information collection activities. Before submitting these information collection requirements for clearance by the Office of Management and Budget (OMB), FRA is soliciting public comment on specific aspects of the activities identified below.

DATES: Comments must be received no later than November 22, 2004.

ADDRESSES: Submit written comments on any or all of the following proposed activities by mail to either: Mr. Robert Brogan, Office of Safety, Planning and Evaluation Division, RRS–21, Federal Railroad Administration, 1120 Vermont Ave., NW., Mail Stop 17, Washington, DC 20590, or Ms. Debra Steward, Office of Information Technology and Productivity Improvement, RAD–20, Federal Railroad Administration, 1120 Vermont Ave., NW., Mail Stop 35, Washington, DC 20590. Commenters requesting FRA to acknowledge receipt of their respective comments must include a self-addressed stamped postcard stating, "Comments on OMB control number 2130-New. Alternatively, comments may be transmitted via facsimile to (202) 493–6230 or (202) 493–6170, or e-mail to Mr. Brogan at *robert.brogan@fra.dot.gov*, or to Ms. Steward at *debra.steward@fra.dot.gov*. Please refer to the assigned OMB control number or collection title in any correspondence submitted. FRA will summarize comments received in response to this notice in a subsequent notice and include them in its information collection submission to OMB for approval.

FOR FURTHER INFORMATION CONTACT: Mr. Robert Brogan, Office of Planning and Evaluation Division, RRS–21, Federal Railroad Administration, 1120 Vermont Ave., NW., Mail Stop 17, Washington, DC 20590 (telephone: (202) 493–6292) or Debra Steward, Office of Information Technology and Productivity Improvement, RAD–20, Federal Railroad Administration, 1120 Vermont Ave., NW., Mail Stop 35, Washington, DC 20590 (telephone: (202) 493–6139). (These telephone numbers are not toll-free.)

SUPPLEMENTARY INFORMATION: The Paperwork Reduction Act of 1995 (PRA), Pub. L. 104–13, sec. 2, 109 Stat. 163 (1995) (codified as revised at 44 U.S.C. 3501–3520), and its implementing regulations, 5 CFR part 1320, require Federal agencies to provide 60-days notice to the public for comment on information collection activities before seeking approval by OMB. 44 U.S.C. 3506(c)(2)(A); 5 CFR 1320.8(d)(1), 1320.10(e)(1), 1320.12(a). Specifically, FRA invites interested respondents to comment on the following summary of proposed information collection activities regarding: (i) Whether the information collection activities are necessary for FRA to properly execute its functions, including whether the activities will have practical utility; (ii) the accuracy of FRA's estimates of the burden of the information collection activities, including the validity of the methodology and assumptions used to determine the estimates; (iii) ways for FRA to enhance the quality, utility, and clarity of the information being collected; and (iv) ways for FRA to minimize the burden of information collection activities on the public by automated, electronic, mechanical, or other technological collection techniques or other forms of information technology (*e.g.*, permitting electronic submission of responses). *See* 44 U.S.C. 3506(c)(2)(A)(i)–(iv); 5 CFR 1320.8(d)(1)(i)–(iv). FRA believes that soliciting public comment will promote its efforts to reduce the administrative and paperwork burdens associated with the collection of information mandated by Federal regulations. In summary, FRA reasons that comments received will advance three objectives: (i) Reduce reporting burdens; (ii) ensure that it organizes information collection requirements in a "user friendly" format to improve the use of such information; and (iii) accurately assess the resources expended to retrieve and produce information requested. *See* 44 U.S.C. 3501.

Below is a brief summary of proposed new information collection activities that FRA will submit for clearance by OMB as required under the PRA:

Title: Post-Traumatic Stress in Train Crew Members After a Critical Incident.

OMB Control Number: 2130—New.

Abstract: Nearly 1,000 fatalities occur every year in this country from trains striking motor vehicles at grade crossings and individual trespassers along the track. These events can be very traumatic to train crew members, who invariably are powerless to prevent such collisions. Exposure of train crews to such work-related traumas can cause extreme stress and result in safety-impairing behaviors, such as are seen in Post-Traumatic Stress Disorder or Acute Stress Disorder. Most railroads have Critical Incident Stress Debriefing (CISD) intervention programs designed to mitigate problems caused by exposure to these traumas. However, they are quite varied in their approach, and it is not certain which components of these programs are most effective. The purpose of this collection of information is to identify "best practices" for CISD programs in the railroad industry. By means of written and subsequent oral interviews with train crew members that will each take approximately 45 minutes, the proposed study aims to accomplish the following: (1) Benchmark rail industry best practices of CISD programs; (2) establish the extent of traumatic stress disorders

due to grade crossing and trespasser incidents in the rail industry (not by region or railroad) and identify at-risk populations; and (3) evaluate the effectiveness of individual components of CISD programs. It should be noted that only the components of CISD programs will be evaluated, not an individual railroad's overall intervention program.

Affected Public: Train crew members.

Respondent Universe: 2,000 train crew members.

Frequency of Submission: One-time.

Estimated Annual Burden: 3,000 hours.

Status: Regular Review.

Pursuant to 44 U.S.C. 3507(a) and 5 CFR 1320.5(b), 1320.8(b)(3)(vi), FRA informs all interested parties that it may not conduct or sponsor, and a respondent is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Authority: 44 U.S.C. 3501–3520.

Issued in Washington, DC, on September 15, 2004.

Kathy A. Weiner,

Director, Office of Information Technology and Support Systems, Federal Railroad Administration.

[FR Doc. 04–21243 Filed 9–21–04; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Waiver Petition Docket Number FRA–2003–17989]

Canadian Pacific Railway; Supplementary Notice of Waiver Request; Notice of Public Hearing; and Extension of Comment Period

On July 19, 2004, FRA published a notice in the **Federal Register** announcing Canadian Pacific Railway Company's (CPR) request to be granted a waiver of compliance from certain provisions of the Railroad Operating Practices regulations, 49 CFR part 218, regarding blue signal protection of workers, on behalf of themselves and their U.S. subsidiaries the Delaware & Hudson and the Soo Line Railroads. *See* 68 FR 43047. Specifically, CPR seeks to permit train and yard crew members, and utility employees to remove and replace batteries in two-way end-of-train telemetry devices (EOT), while the EOT is in place on the rear of the train the individual has been called to operate, without establishing any blue signal protection.

Both §§ 218.25 and 218.27 require blue signal protection when workers are on, under, or between rolling equipment on main track or other than main track. Section 221.16 of title 49, Code of Federal Regulations, permits inspection of an EOT which is on a train standing on a main track after establishing contact with the engineer in charge of the movement, but does not authorize removal or battery replacement. Section 218.22(c)(5) specifically identifies those functions that may be performed by a utility employee without providing the blue signal protection required by 49 CFR part 218. One of the enumerated functions is the inspection, testing, installation, removal or replacement of an EOT device.

FRA has determined that removing or replacing a battery in an EOT, while the device is in place on the rear of a train, requires blue signal protection for a utility employee since this task is a service and repair to the device and does not constitute the inspection, testing, installation, removal or replacement of the device. Therefore, the only way a utility employee can legally remove or replace the EOT battery, without establishing blue signal protection, is to remove the EOT from the rear of the train and perform the battery work outside the area normally protected by the blue signal.

CPR contends that safety would be enhanced if the individual was allowed to perform the battery work without removing the device from the rear of the train. Exposure to injury is greatly reduced because the individual is handling a small NiCad battery, as opposed to lifting the EOT device that weighs 32–34 pounds. It is CPR's position, supported by the BNSF waiver (FRA Docket No. 2001–10660), that changing EOT batteries *in situ* requires less time, places the employee in less immediate danger, and creates less physical strain than removing and replacing the entire EOT. CPR sought to make it clear that this waiver request is intended to cover only train and yard employees working on their own assigned equipment and properly assigned transportation utility employees. It is not intended to cover mechanical or other employees who clearly require blue flag protection to work in or under equipment.

The plain language of the definition of "worker," contained in § 218.5, excludes members of train and yard crews from the blue signal protection provisions, contained in 49 CFR part 218, except when assigned to inspect, test, repair, or service railroad rolling equipment that is not part of the train or yard movement they have been called to operate. Thus, in light of the express exception to the definition of "worker" contained in § 218.5, the blue signal protection provisions simply do not apply to situations involving the replacement of EOT batteries by train and engine employees on equipment they are called to operate. Accordingly, FRA concludes that CPR's request for a waiver to permit train and yard crew members to perform such duties on equipment they are called to operate should be dismissed as unnecessary. Any party seeking the legal basis for this conclusion should submit their request to FRA's Office of Chief Counsel, Federal Railroad Administration, RCC–10, Mail Stop 10, 1120 Vermont Avenue, NW., Washington, DC 20005. FRA will communicate separately with BNSF concerning Docket No. 2001–10660.

As a result of the comments received by FRA concerning this waiver petition, FRA has determined that a public hearing is necessary before a final decision is made on this petition. Accordingly, a public hearing is hereby set to begin at 9 a.m. on October 13, 2004, at the Federal Railroad Administration, 1120 Vermont Avenue, NW., Washington, DC 20005, in the 7th floor conference room. Interested parties are invited to present oral statements at this hearing.

The hearing will be informal and will be conducted in accordance with FRA's Rules of Practice (49 CFR part 211.25) by a representative designated by FRA. FRA's representative will make an opening statement outlining the scope of the hearing, as well as any additional procedures for the conduct of the hearing. The hearing will be a non-adversarial proceeding in which all interested parties will be given the opportunity to express their views regarding this waiver petition, without cross-examination. After all initial statements have been completed, those persons wishing to make a brief rebuttal will be given an opportunity to do so in the same order in which initial statements were made.

FRA further extends the comment period in this proceeding through October 22, 2004, and reserves the right to announce a further extension of the comment period exclusively for the purpose of receiving post-hearing submissions should that appear appropriate in the judgment of the chair based on testimony received and questions posed by the FRA panel. All communications concerning these proceedings should identify the appropriate docket number (*e.g.*, Waiver Petition Docket Number FRA–2003–17989) and must be submitted to the Docket Clerk, DOT Docket Management Facility, Room PL–401 (Plaza Level),

400 7th Street, SW., Washington, DC 20590. All written communications concerning these proceedings are available for examination during regular business hours (9 a.m.–5 p.m.) at the above facility. All documents in the public docket are also available for inspection and copying on the Internet at the docket facility's Web site at *http://dms.dot.gov.*

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78). The Statement may also be found at *http://dms.dot.gov.*

Issued in Washington, DC on September 15, 2004.

Grady C. Cothen, Jr.,

Acting Associate Administrator for Safety.

[FR Doc. 04–21242 Filed 9–21–04; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

Notice of Application for Approval of Discontinuance or Modification of a Railroad Signal System or Relief From the Requirements of Title 49 Code of Federal Regulations Part 236

Pursuant to Title 49 Code of Federal Regulations (CFR) Part 235 and 49 U.S.C. 20502(a), the following railroad has petitioned the Federal Railroad Administration (FRA) seeking approval for the discontinuance or modification of the signal system or relief from the requirements of 49 CFR Part 236 as detailed below.

Docket Number FRA–2004–18962

Applicant: Burlington Northern and Santa Fe Railway, Mr. William G. Peterson, Director Signal Engineering, 4515 Kansas Avenue, Kansas City, Kansas 66106.

Burlington Northern and Santa Fe Railway seeks approval of the proposed modification of the traffic control system, on the two main tracks at Albia, Iowa, milepost 303.7, on the Nebraska Division, Ottumwa Subdivision. The proposed changes consist of the conversion of the Appanoose County Railroad power-operated switch lead to hand operation, equipped with an electric lock; relocation of westward absolute signal 1WA–1WB to the west of the electric lock and railroad bridge; and removal of absolute signal 5WA–5WB and its associated approach signal. The electric lock and its unlock circuit will be located outside of the remaining OS circuit.

The reason given for the proposed changes is that train crews always take power-operated switch on hand when switching with the Appanoose, and by removing the power switch and installing an electric lock in its place, it will create a more efficient operation.

Any interested party desiring to protest the granting of an application shall set forth specifically the grounds upon which the protest is made, and include a concise statement of the interest of the party in the proceeding. Additionally, one copy of the protest shall be furnished to the applicant at the address listed above.

All communications concerning this proceeding should be identified by the docket number and must be submitted to the Docket Clerk, DOT Central Docket Management Facility, Room PL–401 (Plaza Level), 400 7th Street, SW., Washington, DC 20590–0001. Communications received within 45 days of the date of this notice will be considered by the FRA before final action is taken. Comments received after that date will be considered as far as practicable. All written communications concerning these proceedings are available for examination during regular business hours (9 a.m.–5 p.m.) at the above facility. All documents in the public docket are also available for inspection and copying on the internet at the docket facility's Web site at *http://dms.dot.gov.*

FRA wishes to inform all potential commenters that anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78) or you may visit *http://dms.dot.gov.*

FRA expects to be able to determine these matters without an oral hearing. However, if a specific request for an oral hearing is accompanied by a showing that the party is unable to adequately present his or her position by written statements, an application may be set for public hearing.

Issued in Washington, DC, on September 15, 2004.

Grady C. Cothen, Jr.,

Acting Associate Administrator for Safety.

[FR Doc. 04–21241 Filed 9–21–04; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF THE TREASURY

Fiscal Service

Surety Companies Acceptable on Federal Bonds: Correction—National Union Fire Insurance Company of Pittsburgh, PA and the Insurance Company of the State of Pennsylvania

AGENCY: Financial Management Service, Fiscal Service, Department of the Treasury.

ACTION: Notice.

SUMMARY: This is Supplement No. 1 to the Treasury Department Circular 570; 2004 Revision, published July 1, 2004, at 69 FR 30224.

FOR FURTHER INFORMATION CONTACT: Surety Bond Branch at (202) 874–1033.

SUPPLEMENTARY INFORMATION: The underwriting limitation for National Union Fire Insurance Company of Pittsburgh, PA and The Insurance Company of the State of Pennsylvania which were last listed in Treasury Department Circular 6570, July 1, 2004, revision, at 69 FR 40248 and 69 FR 40243 as $541,777,000 and $40,094,000 respectively, are hereby corrected to read $551,428,000 and $42,851,000 respectively, effective today.

Federal bond-approving officers should annotate their reference copies of the Treasury Circular 570, 2004 Revision, to reflect this change.

The Circular may be viewed and downloaded through the Internet at *http://www.fms.treas.gov/c570.* A hard copy may be purchased from the Government Printing Office (GPO) Subscription Service, Washington, DC, Telephone (202) 512–1800. When ordering the Circular from GPO, use the following stock number: 769–004–04926–1.

Questions concerning this Notice may be directed to the U.S. Department of the Treasury, Financial Management Service, Financial Accounting and Services Division, Surety Bond Branch, 3700 East-West Highway, Room 6F07, Hyattsville, MD 20782.

Dated: September 14, 2004.

Vivian L. Cooper,

Director, Financial Accounting and Services Division, Financial Management Service.

[FR Doc. 04–21227 Filed 9–21–04; 8:45 am]

BILLING CODE 4810–35–M

Federal Register

Wednesday,
September 22, 2004

Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 16 and 118

Prevention of *Salmonella* Enteritidis in Shell Eggs During Production; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16 and 118

[Docket Nos. 1996P–0418, 1997P–0197, 1998P–0203, and 2000N–0504]

RIN 0910–AC14

Prevention of *Salmonella* Enteritidis in Shell Eggs During Production

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to require shell egg producers to implement measures to prevent *Salmonella* Enteritidis (SE) from contaminating eggs on the farm. We are taking this action because of the number of outbreaks of foodborne illnesses and deaths caused by SE that are associated with the consumption of shell eggs that have not been treated to destroy this pathogen. We expect that the requirements that we are proposing in this rule, if finalized as proposed, will result in a significant decrease in the number of SE-contaminated eggs produced on farms. Ultimately, we expect that the proposed requirements in this rule will generate public health benefits through a decrease in the numbers of SE-associated illnesses and deaths caused by consumption of shell eggs.

DATES: Submit written or electronic comments by December 21, 2004.

Submit written comments on the information collection provisions by October 22, 2004. See sections III.C and VI.C of this document for the proposed compliance dates of a final rule based on this document.

ADDRESSES: You may submit comments, identified by [Docket Nos. 1996P–0418, 1997P–0197, 1998P–0203, and 2000N–0504], by any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.
- E-mail: *fdadockets@oc.fda.gov*. Include [Docket Nos. 1996P–0418, 1997P–0197, 1998P–0203, and 2000N–0504 and RIN number 0910–AC14] in the subject line of your e-mail message.
- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]: Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and Docket No. or Regulatory Information Number (RIN) for this rulemaking. All comments received will be posted without change to *http://www.fda.gov/dockets/ecomments*, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/dockets/ecomments* and/or the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Rebecca Buckner, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 5100 Paint Branch Pkwy. College Park, MD 20740, 301–436–1486.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Highlights of the Proposed Rule
II. Background
A. *Salmonella* and SE Infection
1. Salmonellosis
2. SE
3. SE and Eggs
4. Mechanism of *Salmonella* Contamination in Eggs
5. Infectious Dose
B. U.S. Egg Industry
C. Federal Egg Safety Regulatory Agencies and Authorities
D. Current Federal Egg Safety Measures for Shell Egg Production and Retail
1. Refrigeration of Shell Eggs
2. Labeling of Shell Eggs
3. The FDA Food Code
4. Egg Safety Education Efforts
E. The SE Risk Assessment
F. Advanced Notice of Proposed Rulemaking on SE in Eggs
G. Egg Safety Public Meetings
H. Current On-Farm Practices
1. The Layers Study
2. Voluntary Egg Quality Assurance Programs (QA)
I. Petitions to the Agency
1. Center for Science in the Public Interest
2. Rose Acre Farms, Inc.
3. United Poultry Concerns, Inc., and the Association of Veterinarians for Animal Rights
III. The Proposal to Require SE Prevention Measures for Egg Production
A. Rationale for Proposal
B. Shell Egg Producers Covered by Proposed 21 CFR Part 118
C. Proposed Compliance Dates for Shell Egg Producers of Various Sizes
D. Definitions
E. The SE Prevention Measures
1. Chicks and Pullets
2. Biosecurity
3. Rodents, Flies, and Other Pest Control
4. Cleaning and Disinfection
5. Refrigeration of Shell Eggs Stored More Than 36 Hours
F. Indication of the Effectiveness of the SE Prevention Measures: Testing
1. Environmental Testing for SE
2. Egg Testing for SE
G. Sampling and Testing Methodology for SE
1. Sampling of the Poultry House Environment
2. Egg Sampling
H. Laboratory Methods for Testing for SE
I. Administration of the SE Prevention Measures
J. Recordkeeping Requirements for the SE Prevention Measures
1. Records That Egg Producers Are Required to Maintain
2. General Requirements for Records Maintained by Egg Producers
3. Length of Time Records Must Be Retained
4. Offsite Storage of Records
5. Official Review of Records
6. Public Disclosure of Records
7. Comment Solicitation on Recordkeeping Measures
K. Enforcement of On-Farm SE Prevention Measures for Shell Eggs
L. Legal Authority
M. Response to Comments Related to On-Farm SE Prevention Measures
N. Transportation of Shell Eggs
IV. Handling and Preparation of Eggs by Retail Establishments
A. Inappropriate Handling of Raw Shell Eggs by Food Preparers
B. SE and Highly Susceptible Populations
C. The FDA Food Code
D. Request for Comments
E. Response to Comments Related to Retail Standards
V. Preliminary Regulatory Impact Analysis (PRIA)
A. Introduction
B. Need for Regulation
C. Economic Analysis of Potential Mitigations: Overview
1. Measuring Benefits
2. Measuring Costs
3. Coverage of the Analysis
D. Summary of Costs and Benefits of Regulatory Options and the

Proposed Rule
1. No New Regulatory Action
2. Classification of SE-Positive Eggs as Restricted or SE Positive
3. HAACP
4. The Proposed Rule
5. More Extensive On-Farm SE Prevention Measures
6. Less Extensive On-Farm SE Prevention Measures
7. Retail SE Prevention Measures
E. Benefits and Costs of Potential SE Prevention Measures: Detailed Analysis
1. On-Farm SE Prevention Measures
2. Administrative Measures
3. Summary of On-Farm SE Prevention and Administrative Measures
4. Retail Provisions
F. Summary of Benefits and Costs of the Proposed Rule
1. Coverage
2. Provisions in the Proposed Rule
3. Summary of Costs and Benefits
4. Analysis of Uncertainty
VI. Initial Regulatory Flexibility Analysis
A. Introduction
B. Economic Effects on Small Entities
1. Number of Small Entities Affected
2. Costs to Small Entities
C. Regulatory Options
1. Exemption for Small Entities
2. Longer Compliance Periods
D. Description of Recordkeeping and Recording Requirements
E. Summary
VII. Unfunded Mandates
VIII. Federalism
IX. Environmental Impact
X. Paperwork Reduction Act of 1995
XI. Comments
XII. References
Appendix to the PRIA A: Costs of Alternative Testing and Diversion Scenarios
Appendix to the PRIA B: The Expected Cost of Testing and Diversion
Appendix to the PRIA C: Distributions Used in the Analysis of Uncertainty

I. Highlights of the Proposed Rule

In this proposed rulemaking, FDA is proposing egg safety SE prevention measures for egg production. This proposal is significant because a farm-to-table risk assessment of *Salmonella* Enteritidis (SE) in eggs identified implementation of on-farm prevention measures as a very important step that could be taken to reduce the occurrence of SE infections from eggs. Voluntary quality assurance programs for egg production have led to meaningful reductions in SE illnesses already. However, these programs are not always uniformly administered or uniformly comprehensive in their prevention measures.

Moreover, the most recent data from the Centers for Disease Control and Prevention (CDC) show that SE illnesses have essentially remained steady for the past several years. In 2001, CDC estimated that 118,000 illnesses were caused by consumption of SE-contaminated eggs. Accordingly, we believe that additional interventions are warranted. The proposed on-farm SE prevention measures and a more detailed rationale for these measures are found in section III of this document.

Following are the proposed SE prevention measures: (1) Provisions for procurement of chicks and pullets, (2) a biosecurity program, (3) a pest and rodent control program, (4) cleaning and disinfection of poultry houses that have had an environmental sample or egg test positive for SE, and (5) refrigerated storage of eggs at the farm. Moreover, a cornerstone of the proposal is a requirement that producers test the environment for SE in poultry houses. If the environmental test is positive, we are proposing that egg testing for SE be undertaken, and that if an egg test is positive, eggs be diverted from the table egg market to a technology or process that achieves at least a 5-log destruction of SE for shell eggs, or the processing of egg products in accordance with the Egg Products Inspection Act. As part of the SE prevention measures, we are proposing that producers identify a responsible person to administer the prevention measures at each farm. We also are proposing recordkeeping requirements for environmental and egg sampling and testing and for egg diversion. Finally, we are proposing that if a producer has 3,000 or more laying hens and all eggs at a farm are to be given a treatment that will achieve at least a 5-log destruction of SE or processed into egg products, then only the proposed refrigeration requirements would apply. The proposed rule would not apply to producers who sell all of their eggs directly to consumers or producers with fewer than 3,000 laying hens.

We also are soliciting comment on whether we should include additional requirements in the final rule, particularly in two areas. First, should we expand the recordkeeping requirements to include a written SE prevention plan and records for compliance with the SE prevention measures? Second, should the safe egg handling and preparation practices in FDA's 2001 Model Food Code (as outlined in section IV.D of this document) be federally mandated for retail establishments that specifically serve a highly susceptible population (e.g., nursing homes, hospitals, day care centers)? These issues are discussed in more detail in the following relevant sections of this document.

II. Background

A. Salmonella and SE Infection

1. Salmonellosis

Salmonella microorganisms are ubiquitous and are commonly found in the digestive tracts of animals, especially birds and reptiles. Human illnesses are usually associated with ingesting food or drink contaminated with *Salmonella*, although infection also may be transmitted person to person through the fecal-oral route where personal hygiene is poor or by the animal-to-man route (Ref. 1).

The disease salmonellosis is the result of an intestinal infection with *Salmonella* and is characterized by diarrhea, fever, abdominal cramps, headache, nausea, and vomiting. Symptoms of salmonellosis usually begin within 6 to 72 hours after consuming a contaminated food or liquid and last for 4 to 7 days. Most healthy people recover without antibiotic treatment; however, the infection can spread into the bloodstream, then to other areas of the body such as the bone marrow or the meningeal linings of the brain. This infection can lead to a severe and fatal illness (Ref. 2). The complications associated with an infection are more likely to occur in children, the elderly, and persons with weakened immune systems. In addition, about 2 percent of those who recover from salmonellosis may later develop recurring joint pains and arthritis (Ref. 3).

Salmonellosis is a serious health concern. It is a notifiable disease, i.e., physicians and health laboratories are required to report cases (single occurrences of illness) to local health departments in accordance with procedures established by each State. These cases are then, in turn, reported to State health departments, and the *Salmonella* isolates[1] are referred to State Public Health laboratories for serotyping. Each case and each serotyped isolate is reported to CDC. These reports are made only for diagnosed cases of *Salmonella* infection.

A case of illness is confirmed as salmonellosis only if an isolate is confirmed by a laboratory as being

[1] When a physician sees a patient and suspects that the patient has a case of salmonellosis, the physician may obtain a patient's specimen (e.g. stool) for analysis. The specimen is sent to the laboratory to be tested to identify and confirm any *Salmonella* that may be present. Thus, the laboratory obtains the actual specimen of *Salmonella*.

Salmonella. Although all cases may not be confirmed, all confirmed cases are associated with isolates of *Salmonella*. Reported cases are likely to represent only a small portion of the actual number of illnesses that occurred because of the following reasons: (1) Ill individuals do not always seek care by medical professionals, especially if the symptoms are not severe; (2) medical professionals may not establish the cause of the illness but may simply treat the symptoms; and (3) medical professionals do not always report *Salmonella* cases to public health officials. CDC used updated information and data from a FoodNet population study to estimate that there are 38 cases of salmonellosis for every one that is reported (Ref. 4). This estimate was central to updating an estimate of the burden of salmonellosis. The overall burden of salmonellosis in 2001 was estimated to be 1,203,650 cases, including 14,000 hospitalizations, and 494 deaths (Refs. 4 and 5).

CDC surveillance data list close to 600 different *Salmonella* serotypes (a group of related microorganisms distinguished by their antigens) that have caused illness in the United States. Following are the four serotypes most frequently reported as causing illness: (1) *Salmonella enterica* serotype Typhimurium, (2) *Salmonella enterica* serotype Enteritidis (*Salmonella* Enteritidis or SE), (3) *Salmonella enterica* serotype Newport, and (4) *Salmonella enterica* serotype Heidelberg (Ref. 6). These microorganisms are found in poultry, eggs, and other foods.

2. SE

Currently, SE is one of the most commonly reported serotypes of *Salmonella*. SE accounted for only about 5 percent of the number of all reported *Salmonella* isolates in 1976. However, in 1985, 1990, 1994, and 1999, SE constituted 9.8 percent, 20.6 percent, 26.3 percent, and 16.3 percent, respectively, of all *Salmonella* isolates (Ref. 6). The rate of SE isolates reported to CDC increased from 0.6 per 100,000 population in 1976 to 3.6 per 100,000 in 1996 (Ref. 7). In 2001, the isolation rate of SE was 2.0 per 100,000 population and the contribution of SE (corrected for underreporting) to total salmonellosis was estimated to have been 213,046 illnesses, including 2,478 hospitalizations, and 87 deaths (Refs. 4 and 5).

In 1985, the States reported 26 SE-related outbreaks (i.e., occurrences of 2 or more cases of a disease related to a common source) to CDC; by 1990 the number of SE-related outbreaks reported to CDC had increased to 85. In 1995 there were 56 confirmed outbreaks of SE infection, in 2000 there were 50 and in 2002 there were 32 (Ref. 8).

3. SE and Eggs

In the mid-1980s, CDC made an epidemiological and laboratory association between eggs and *Salmonella* outbreaks. Shell eggs are now the predominant source of SE-related cases of salmonellosis in the United States where a food vehicle is identified. A food vehicle is identified in approximately half of the outbreaks of illness associated with SE. Between 1990 and 2001, an average of 78 percent of vehicle-confirmed SE outbreaks were egg associated (Ref. 9). These eggs were typically raw or undercooked. Although CDC can estimate the number of egg-associated SE illnesses as a percentage of all SE illnesses, the proportion of domestically acquired salmonellosis that is attributable to SE in eggs is difficult to estimate. The estimates have a broad range of uncertainty around them because of the variable nature of both foodborne disease outbreaks and investigations. However, the basic surveillance information on the number of reported SE cases and outbreaks is readily available and does not require further estimation. Although there are other sources of SE, actions to improve egg safety are the single most effective way to reduce the overall number of SE infections and outbreaks.

CDC has described several SE outbreaks that occurred between 1996 and 1998 and were associated with raw or undercooked eggs (Ref. 7).

- In November 1997, 91 persons who consumed broccoli with Hollandaise sauce at a Las Vegas restaurant became ill. Investigation showed that the Hollandaise sauce was prepared with pooled shell eggs, cooked to a temperature inadequate to kill SE, and then held at room temperature for several hours prior to service.
- In August 1997, 12 persons developed culture-confirmed cases of SE after consuming cheesecake prepared in a private residence in Los Angeles, CA. The cheesecake contained raw egg whites and egg yolks that were heated in a double boiler until slightly thickened. The California Department of Health Services and Department of Food and Agriculture investigated the farm that supplied the eggs and isolated SE from manure samples and from pooled egg samples.
- In October 1997, 75 persons at 7 different events in the District of Columbia developed salmonellosis after consuming lasagna supplied by the same commercial manufacturer. Cultures of leftover lasagna yielded SE. Investigation revealed that all of the lasagnas consumed at the different events were prepared from the same egg-cheese mixture. A traceback investigation led to farms at which 5 of 13 poultry houses had environmental samples positive for SE.

From 1990 to 2001, 14,319 illnesses were attributed to SE associated with shell eggs. Of those illnesses, 10,406 occurred during 1990 through 1995 and 3,913 occurred during 1996 through 2001 (Ref. 9). In 2002, there were 32 outbreaks of SE illness, and the SE isolation rate (illnesses per 100,000 population) was 1.77 (Ref. 8). Progress has been made and there has been a decrease in SE incidence since the mid-1990s, in part due to egg quality assurance (QA) programs, informing and educating consumers and retailers on proper handling, and nationwide regulations to keep eggs refrigerated. However, these gains are still far short of the public health and foodborne illness gains required to meet Healthy People 2010 goals. Healthy People 2010 sets forth significant and achievable goals, namely a 50 percent reduction in both outbreaks and salmonellosis from foodborne contamination (corresponding to a 50 percent reduction from the 2000 goals for SE outbreak reduction and a 50 percent reduction in salmonellosis in general) (Ref. 10). We estimate that the largest gains towards our public health goals will be achieved through implementation of this rule. The incidence of SE in the United States remains much higher than in the 1970s (1976 SE isolation rate = 0.56) (Ref. 11), and the decrease in reported cases of SE illness since 1999 has appeared to slow or stop compared to decreases seen in the mid-1990s (Ref. 9). Because progress in reducing the number of illnesses and outbreaks appears to have greatly slowed or stopped, we believe the additional preventive measures, proposed herein, for shell eggs may be needed to reduce further the incidence of SE illnesses and meet our public health goals.

4. Mechanism of *Salmonella* Contamination in Eggs

Previously, *Salmonella* contamination of shell eggs was thought most likely to be caused by trans-shell penetration of bacteria present in the egg's environment. The surface of an egg can become contaminated with any microorganism that is excreted by the laying hens. In addition, contact with nesting materials, dust, feedstuff, shipping and storage containers, human beings and other animals may be a source of shell contamination. The

likelihood of trans-shell penetration increases with the length of time that the eggs are in contact with contaminating materials.

While environmental contamination is still a route for *Salmonella* contamination, SE experts now believe that the predominant route through which eggs become contaminated with SE is the "transovarian" route. Though the mechanism is still not well understood, SE will infect the ovaries and oviducts of some egg-laying hens, permitting transovarian contamination of the interior of the egg while the egg is still inside the hen (Refs. 12 and 13). The site of contamination is usually the albumen (the egg white).

It is believed that only a small number of hens in an infected flock shed SE at any given time and that an infected hen may lay many uncontaminated eggs (Ref. 14). Nonetheless, it has been estimated that of the 47 billion shell eggs consumed annually as table eggs (eggs consumed as shell eggs, as opposed to eggs that are used to make egg products), 2.3 million are SE-positive, exposing a large number of people to the risk of illness (Ref. 15).

5. Infectious Dose

In general, the greater the numbers of microorganisms ingested, the greater the likelihood of disease. The likelihood of disease also is contingent on the virulence of the microorganism and the susceptibility of the host (Ref. 16). However, there is evidence that the infectious dose (i.e., amount of microorganisms capable of causing disease) for SE can be very low. For example, in a 1994 outbreak attributed to consumption of SE-contaminated ice cream, the highest level of contamination found in the implicated ice cream was only six microorganisms per half-cup (65 gram) serving (Ref. 17). Another report, using a different method of measurement, determined that the infective dose per serving was 25 microorganisms (Ref. 18). These reports indicate that low-level contamination of some foods with SE can lead to illness. It is generally believed that SE-contaminated eggs initially contain only a few SE microorganisms (less than 20 (Ref. 19)), which may be sufficient to cause illness.

B. U.S. Egg Industry

On a per capita basis, Americans consume about 234 eggs per year (Ref. 20). U.S. production is relatively stable and has increased only slightly, from about 60 billion eggs in 1984 to 67.3 billion eggs in 1998 (Ref. 21). Generally, about 70 percent of the edible shell eggs produced are sold as table eggs while the remainder are processed into liquid, frozen or dried pasteurized egg products. The majority of egg products are destined for institutional use or further processing into foods such as cake mixes, pasta, ice cream, mayonnaise, and bakery goods.

Geographically, commercial egg production in the western United States is concentrated in California, and in the eastern United States is centered in Ohio, Indiana, Iowa, and Pennsylvania. Other States in which major producers are located include Texas, Minnesota, and Georgia. Over 4,000 farm sites have 3,000 or more egg-laying hens, representing 99 percent of all domestic egg-laying hens and accounting for 99 percent of total egg production. There are an additional 65,000 farms with fewer than 3,000 egg-laying hens, accounting for the balance of eggs produced (Ref. 22).

C. Federal Egg Safety Regulatory Agencies and Authorities

Federal authority to regulate egg safety is shared by FDA and the U.S. Department of Agriculture's Food Safety and Inspection Service (USDA's FSIS). In addition, USDA's Animal and Plant Health Inspection Service (APHIS) conducts a control program that certifies poultry breeding stock and hatcheries as SE-monitored and USDA's Agricultural Marketing Service (AMS) conducts a surveillance program to ensure proper disposition of restricted shell eggs.

FDA has jurisdiction over the safety of foods generally, including shell eggs, under section 201 of the Federal Food, Drug, and Cosmetic Act (the FFDCA) (21 U.S.C. 321). The Public Health Service Act (the PHS Act) (42 U.S.C. 201 *et seq.*) authorizes the FDA to make and enforce such regulations as "are necessary to prevent the introduction, transmission or spread of communicable diseases from foreign countries into the States * * * or from one State * * * into any other State" (section 361(a) of the PHS Act (42 U.S.C. 264(a)). Thus, under the FFDCA and the PHS Act, FDA has the authority to regulate a food when the food may act as a vector of disease, as in the case of SE-contaminated eggs.

USDA has primary responsibility for implementing the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031 *et seq.*). Under the EPIA, FSIS has primary responsibility for the inspection of processed egg products to prevent the distribution of adulterated or misbranded egg products.

This proposed rule is part of a joint and coordinated strategy by FDA and FSIS to more effectively address egg safety. Pursuant to this coordinated strategy, FDA is focusing its efforts on farm practices, and on food manufacturing plants, institutions, and restaurants. FSIS, in turn, is focusing its efforts on egg products plants and egg handlers. Both agencies are evaluating additional measures to improve egg safety, and FSIS intends to issue proposed rules in the near future for egg products plants and egg handlers, including egg handlers who operate in-shell pasteurization treatments. FDA and FSIS will continue to work closely together to ensure that our egg safety measures are consistent, coordinated, and complementary.

D. Current Federal Egg Safety Measures for Shell Egg Production and Retail

Currently, there are no Federal regulations to reduce the presence of SE in eggs during production. However, we recognize that some State or local agencies may have requirements in place addressing egg safety during production.

There are several Federal activities related to egg safety at the retail level. FSIS issued a final rule for refrigeration and labeling of eggs during transport and storage when packed for the ultimate consumer (63 FR 45663, August 27, 1998). In addition, FDA issued a final rule that requires labeling of eggs and refrigeration of eggs at retail establishments (65 FR 76092, December 5, 2000). Further, FDA's Food Code provides guidance to retail establishments on the handling and storage of potentially hazardous foods, such as shell eggs. Also, there have been egg safety education campaigns specifically tailored for the retail sector. The following sections describe these egg safety measures.

1. Refrigeration of Shell Eggs

The EPIA was amended in 1991 (Public Law 102–237) to require that shell eggs packed for the ultimate consumer be stored and transported under refrigeration at an ambient temperature (i.e., the air temperature maintained in an egg storage facility or transport vehicle) not to exceed 45 °F. The 1991 Amendments to the EPIA also require that labels on egg containers indicate that refrigeration of eggs is required. Subsequently, USDA's FSIS amended its regulations to require shell egg handlers to store and transport shell eggs packed in containers destined for the ultimate consumer under refrigeration at an ambient temperature of no greater than 45 °F (7.2 °C) (63 FR 45663). In the FSIS regulation, an egg handler is defined as any person, excluding the ultimate consumer, who engages in any business in commerce that involves buying or selling any eggs

(as a poultry producer or otherwise), or processing any egg products, or otherwise using any eggs in the preparation of human food. In 9 CFR 590.5, FSIS defines an ultimate consumer as any household consumer, restaurant, institution, or other party who has purchased or received shell eggs or egg products for consumption. This regulation became effective August 27, 1999.

FSIS' regulation does not require the ultimate consumer, including restaurants and institutions, to maintain shell eggs under refrigeration. Consequently, we concluded that it was necessary to require that shell eggs be kept refrigerated throughout retail distribution. On December 5, 2000, we published a final rule requiring that retail establishments, such as grocery stores, farm stands, restaurants, schools, and nursing homes, promptly refrigerate eggs upon receipt and store and display eggs at an ambient temperature of 45 °F (7.2 °C) or less (65 FR 76092).

2. Labeling of Shell Eggs

In an effort to inform consumers of the risks associated with consuming raw or undercooked eggs, we require that egg cartons carry safe handling instructions (21 CFR 101.17(h)). All eggs not specifically processed to destroy *Salmonella* must carry the following safe handling statement: "SAFE HANDLING INSTRUCTIONS: To prevent illness from bacteria: keep eggs refrigerated, cook eggs until yolks are firm, and cook foods containing eggs thoroughly."

3. The FDA Food Code

Through the Food Code, FDA endeavors to assist those local, State, tribal, and Federal governmental jurisdictions assuming primary responsibility for preventing foodborne illness and for licensing and inspecting establishments within the retail segment of the food industry. The Food Code, published by FDA, is not Federal law or regulation, and is not preemptive. Rather, it represents our best advice to States and local authorities to ensure that food at the retail level is safe, properly protected, and properly represented (i.e., is what it is purported to be). The Food Code provides guidance on food safety, sanitation, and fair dealing that can be uniformly adopted for the retail segment of the food industry. The document is the cumulative result of the efforts and recommendations of many contributing individuals with years of experience. These individuals represent a diverse group of regulators, educators, industry leaders, and consumer representatives acting through their agencies, companies, professional groups, or trade organizations.

Although the Food Code provisions are not Federal requirements, they are designed to be consistent with Federal food laws and regulations. The Food Code is written so that all levels of government can easily adopt the language of the Food Code into a legal requirement.

All segments of the food industry and Federal, State, and local governments share the responsibility to ensure food provided to the consumer is safe and does not become a vehicle for a disease outbreak or the transmission of communicable disease. By sharing in this responsibility, government and industry can ensure consumer expectations are met, and food is prepared in a sanitary environment, properly presented, and not adulterated.

The Food Code provides advice on how to prevent foodborne illness based on information obtained from CDC investigations. CDC has identified risk factors, such as unsafe sources, inadequate cooking, improper holding, contaminated equipment, and poor personal hygiene, which may lead to foodborne outbreaks. CDC further established five key public health interventions to protect consumer health: (1) Demonstration of knowledge, (2) employee health controls, (3) controlling hands as a vehicle of contamination, (4) time and temperature parameters for controlling pathogens, and (5) consumer advisories.

FDA revises sections of the Food Code every 2 years, and publishes the revision either as a supplement (most recently in 2003) to the existing edition or as a new edition (most recently in 2001), based on the extent of revision. Each new edition incorporates the provisions of supplements issued between editions. The next revision of the Food Code will be in 2005. Provisions relevant to egg safety can be found in the 2001 Food Code in sections 3–202.11, 3–202.13, 3–202.14, 3–302.13, 3–401.11, 3–603.11, and 3–801.11.

4. Egg Safety Education Efforts

Consumer food safety surveys conducted in 1993, 1998, and 2001 by FDA and FSIS suggested that consumers are less aware of or concerned about risks associated with eggs than they are of risks associated with other foods (Refs. 23 and 24). The data indicate that people are most likely to follow recommended practices when handling fish, somewhat less likely when handling meat or chicken, and much less likely to follow recommended practices when breaking eggs. In fact, the majority of people (65 percent) do not wash their hands with soap after breaking raw eggs (Refs. 23 and 24).

Comparing the 1998 survey findings with those of 1993, improvement in the safe handling of eggs by people 61 and older lagged considerably behind that of people 18 to 25 years old. The younger group showed a 42 percent improvement versus 9 percent for the older group. The 2001 survey showed no significant difference in consumers' egg-handling behavior from 1998 (Ref. 24).

In consideration of the survey findings, we developed a strategy for an education campaign on egg safety that targeted both the general public and at-risk populations. We began the campaign with the July 1, 1999, release of FDA's egg labeling and refrigeration proposed rule to take advantage of media and public interest in safe handling instructions for shell egg labels and refrigeration requirements for eggs at retail establishments. We prepared a video news release (VNR) to inform consumers of the proposed regulations and to alert them to the potential risks of, and steps to take to avoid, undercooked eggs. The VNR was released in conjunction with the July 1999 announcement of the proposed egg labeling and refrigeration rule.

To provide a basic source of print information for consumers on eggs and egg safety, we developed a fact sheet, "Food Safety Facts for Consumers: Playing It Safe With Eggs," which was released in July 1999. The fact sheet covers safe buying, handling, preparation, and storage of eggs and egg dishes, as well as information on how to avoid the hidden risks in foods that contain raw or lightly cooked eggs. A corresponding fact sheet was developed for food service personnel, entitled "Food Service Safety Facts: Assuring the Safety of Eggs and Egg Dishes Made From Raw, Shell Eggs," and was released in September 1999.

The consumer fact sheet was targeted to general consumers, especially parents of young children and older Americans. The food service fact sheet was targeted to institutional preparers of food for children, the elderly, and immunocompromised individuals. To reach the target audience, the fact sheets were distributed to the print and electronic media, 83,000 day care centers, 13,000 nursing home directors, school nurses, FDA field staff, extension agents, State and local health agencies, and food preparation trade associations. Both fact sheets are posted on FDA's Web site *www.foodsafety.gov*.

Egg safety information also is incorporated into other food safety

education initiatives. For example, the widely distributed English and Spanish Fight BAC! brochures produced by the public-private Partnership for Food Safety Education, of which FDA is a member, include safe egg cooking information. The Partnership's Virtual Toolbox, available on the *fightbac.org* Web site, features egg safety information prominently among a wide range of other education materials for use by health educators.

We initiated a second phase of the egg safety education campaign after publishing the final rules on safe handling labels and refrigeration at retail. Our strategy remained unchanged; we targeted the general public and at-risk populations. Our campaign message focused attention on the new labels on eggs, the potential for human sickness caused by bacteria from fresh eggs from any source, and the safety of eggs if selected, stored, and prepared properly.

In addition to the press information FDA distributed about the regulations, we prepared and distributed a range of consumer education materials, including a video news release; a public service announcement/flier sent to 600 publications specializing in health, food, elderly issues and parenting, as well as specialized health information providers, such as the National AIDS Clearinghouse and Hotline, the American Cancer Society and National Cancer Hotline, and the Arthritis Foundation; a consumer brochure; and a drop-in feature article in English and Spanish. All consumer education materials are available on our Web site.

We currently are distributing educational materials we developed for food service and food retail personnel incorporating existing FDA regulations and recommendations pertaining to egg safety. These materials consist of a brochure entitled "Assuring the Safety of Eggs and Menu and Deli Items Made From Raw, Shell Eggs—Information for Retail Food Stores and Food Service Operations," and a poster, "Key Temperatures for Egg Safety in Food Service Operations and Retail Food Stores." Initially, 250 copies each of the brochure and the poster were sent to State Egg Program Directors, State Food Service Program Directors, FDA Regional Food Specialists, and FDA Public Affairs Specialists in the field to use in generating demand for the information.

Since the initial mailing, orders have been steady. As of August 2004, approximately 202,000 posters and 246,000 brochures had been distributed. At least one State, Kentucky, ordered enough (22,000) to provide copies to each retail food store, food service establishment and food manufacturing firm in the State. In addition, the brochure, "Assuring the Safety of Eggs and Menu and Deli Items Made from Raw Shell Eggs—Information for Retail Food Stores and Food Service Operations," was mailed to 70,300 restaurants in September 2002.

Consumer information on safe handling of eggs is also included in two widely distributed FDA consumer publications, To Your Health: Food Safety for Seniors and the Fight BAC! Flyer (originally developed as a patient handout for the AMA/ANA/FDA/CDC/USDA health professional education kit, Kiagnosis and Management of Foodborne Illnesses). Distribution of consumer and foodservice educational materials continues at professional meetings and conferences, most recently the 2003–2004 meetings of the American Dietetic Association, American Public Health Association, Food Safety Summit, National WIC Association, American College of Physicians, National Restaurant Association, American Nurses Association, National Association of Area Agencies on Aging, National Wellness Conference, and International Association for Food Protection.

E. The SE Risk Assessment

In December 1996, FSIS and FDA, with representatives from other government agencies and academia, began a comprehensive risk assessment in response to an increasing number of human illnesses associated with the consumption of eggs (Ref. 15). Following are the objectives of the risk assessment: (1) Establish the unmitigated (without any SE-prevention measures risk of foodborne illness from SE, (2) identify and evaluate potential prevention strategies, (3) identify data needs, and (4) prioritize future data collection efforts.

A team of scientists developed a quantitative model to characterize the risks associated with the consumption of eggs contaminated internally with SE, using information obtained from academic, government, and industry sources, along with scientific literature. The risk assessment model consists of five discrete modules (Egg Production Module, Shell Egg Module, Egg Products Module, Preparation and Consumption Module, and Public Health Module) that may be used independently to evaluate the effect of variable changes during a particular stage of the farm-to-table continuum. However, the overall model encompasses the entire continuum, from the chicken through egg production, to egg consumption and human illness. The model predicted that using any one intervention (e.g., egg refrigeration or consumer egg safety education) could achieve a modest reduction in human SE illnesses, while using multiple interventions could achieve a more substantial reduction for those interventions tested (Ref. 15). Though on-farm mitigations, as such, were not specified in the risk assessment, various inputs to the model were tested for cooling and refrigeration of eggs, including cooling eggs immediately after lay. The SE risk assessment concluded that a broad-based policy, encompassing interventions from farm to table, is likely to be more effective in eliminating egg-associated SE illnesses than a policy directed solely at one stage of the egg production-to-consumption continuum.

F. Advance Notice of Proposed Rulemaking on Salmonella Enteritidis in Eggs

In the **Federal Register** of May 19, 1998 (63 FR 27502), FDA and USDA jointly published an advance notice of proposed rulemaking (ANPRM) seeking to identify farm-to-table actions that would decrease the food safety risks associated with eggs. The agencies requested comment on these egg safety actions. In section III.M of this document, we respond to comments related to on-farm measures to prevent SE contamination of eggs. We respond to comments related to retail standards to reduce the risk of egg-associated SE illnesses in section IV.E of this document.

G. Egg Safety Public Meetings

To address the public health problem of SE, FDA and FSIS decided to coordinate efforts in a farm-to-table approach. Consistent with each agency's legislative authority, FDA would address egg safety issues at the producer and retail levels and FSIS would address these issues at egg packers and processors. On March 30, 2000, and April 6, 2000, FDA and FSIS held public meetings in Columbus, OH, and Sacramento, CA, respectively, to gather information for reducing or eliminating the risk of SE in eggs. Comments on specific egg safety questions were solicited in a **Federal Register** document (65 FR 15119, March 21, 2000). Interested persons were given until April 20, 2000, to comment.

In an effort to expand the public process and build upon the two public meetings, FDA and FSIS held a public meeting (65 FR 42707, July 11, 2000) on July 31, 2000, in Washington, DC. The purpose of this meeting was to obtain

comments on the agencies' current thinking on approaches to ensure egg safety from farm to table. A document outlining the agencies' current thinking on on-farm egg safety standards, packer/processor egg safety standards, and retail egg safety standards was made available at the public meeting and on the agencies' food safety Web site *www.foodsafety.gov*. Interested persons were given until August 14, 2000, to comment.

We are responding to comments from the public meetings in Columbus, OH, and Sacramento, CA, and the current thinking meeting in Washington, DC in this document. We have responded to comments related to on-farm measures to prevent SE contamination of eggs in section III.M of this document and to comments on retail standards to prevent egg-associated SE illnesses in section IV.E of this document.

H. Current On-Farm Practices

Most of the information on current on-farm practices comes from the APHIS National Animal Health Monitoring System (NAHMS) Layers '99 Study (the Layers study) and information on voluntary egg QA programs.

1. The Layers Study

In 1999, NAHMS conducted a study addressing national table egg layers and SE (Refs. 25, 26, and 27). The aim of the study was to include information from States that account for at least 70 percent of the animal and farm population in the United States. Fifteen States (Alabama, Arkansas, California, Florida, Georgia, Indiana, Iowa, Minnesota, Missouri, Nebraska, North Carolina, Ohio, Pennsylvania, Texas, and Washington) were chosen to participate in the study. These 15 States represented 82 percent of the 1997 U.S. table egg layers. The States, and the operations surveyed within those States, were chosen from a ranking of table egg layers summarized in a 1997 National Agricultural Statistics Service (NASS) survey of egg layers and egg production. NASS maintains information on laying operations that have more than 30,000 hens; therefore, each operation participating in the Layers study had more than 30,000 laying hens, although all hens may not have been on one farm.

a. Production facilities. Egg laying operations varied considerably in size and style of poultry house. Of the farm sites surveyed by the Layers study, approximately 34 percent had fewer than 50,000 layers, 29 percent had 50,000 to 99,999 layers, 20 percent had 100,000 to 199,999 layers, and 17 percent had 200,000 or more layers. One-third of farm sites surveyed had only one layer house, while 16.5 percent had 6 or more layer houses.

Within a poultry house, style also varied. Approximately one-third of all poultry houses had six or more banks of cages. A bank is all cages between two walkways or between a walkway and a wall. Approximately 40 percent of houses had 4 or more vertical levels of cages, while approximately 25 percent had only one level. Less than 1 percent of all poultry houses were cage-free.

Manure handling varied with house style and also varied regionally. Houses with a manure pit at ground level with the house above (high rise) accounted for 63 percent of houses in the Great Lakes region and 48 percent of houses in the Central region. In the Southeast, 40 percent of farm sites flushed manure to a lagoon. Nonflush scraper systems were used on 44 percent of farms in the West region.

b. Chicks and pullets. When a poultry house is repopulated with new laying hens, most of the new layers come from a pullet raising facility. A pullet is defined in the Layers study as a chicken less than 20 weeks of age. Less than 10 percent of layer farms raised pullets at the layer farm site, although some layer farms had their own pullet raising facilities at other locations.

The vast majority (95 percent) of pullets in pullet raising facilities came as chicks from National Poultry Improvement Plan (NPIP) monitored breeder flocks. USDA's NPIP is a cooperative Federal-State-industry mechanism intended to prevent and control egg-transmitted, hatchery-disseminated poultry diseases. NPIP has different monitoring programs for many avian diseases and pathogens, including SE, and all flocks in the program must meet the qualifications for "U.S. Pullorum-Typhoid Clean" classification (9 CFR 145.23(b)). Therefore, the fact that the chicks were from NPIP-monitored breeder flocks does not mean that they were from certified "U.S. *S.* Enteritidis Monitored" breeder flocks (9 CFR 145.23(d)).

Many pullet raising facilities in the Layers Study had their own programs for SE monitoring. In the West region, 83 percent of farms obtained layers from SE-monitored pullet facilities, and 70 percent of layers on all farms came from SE-monitored pullet facilities. Pullet facilities used one or more of the following methods to monitor SE: (1) Dead chick/chick paper testing, (2) environmental culture, (3) bird culture, and (4) serology. Some pullet facilities used competitive exclusion products[2] and/or vaccines to protect pullets against SE.

c. Production. In 1997, the average flock was placed for its first production cycle at 17.5 weeks of age. Flocks in their first production cycle reached peak production around 29 weeks of age. At peak production, the average maximum number of eggs produced was 90 eggs per 100 hens per day. Induced molting was used on many farms (83 percent of farm sites) to increase the laying cycles of the hens. In the West and Southeast regions, 95 percent or more of farms molted birds, while in the central region just over half (57 percent) of the farms molted birds. On average, molted flocks ended production at 111 weeks of age, while nonmolted flocks ended production at 74 weeks of age.

d. Feed and water. Approximately half (48 percent) of layer houses used a chain feed delivery system. Well water was used for watering birds by 66 percent of farms. The percentage of farms that tested feed for SE varied regionally. For example, finished feed was tested for SE by 26 percent of farms in the central region, and 68 percent of farms in the West. Approximately 75 percent of farms in both the West and Southeast regions tested feed ingredients for SE.

e. Biosecurity. Approximately two-thirds of farms instituted biosecurity measures that did not allow visitors without a business reason to enter poultry houses. Sixty-two percent of farms allowed business visitors provided they had not been on another poultry farm that day. Most farms (76 percent) required that visitors wear clean boots. At the majority of farms, employees were required not to be around other poultry and not to own their own birds.

f. Pest control. The Layers study estimated that rodents and flies had access to feed in feed troughs on nearly all farms. Fly control was practiced on 90 percent of all farms; baiting was the most common form of fly control (72 percent of farms). Essentially all farms used some type of rodent control. Chemicals and baits were used by 93 percent of farms for rodent control. Professional exterminators were used on less than 15 percent of farms that used rodent control. Producers rated almost 30 percent of farms as having a moderate or severe problem with mice and almost 9 percent as having a moderate or severe problem with rats.

[2] Competitive exclusion is a strategy in which benign bacteria are introduced into the gut to prevent a pathogen from colonizing the gut by blocking all of the sites on the walls of the intestines where the pathogen would attach.

g. Depopulation practices. Depopulation of a poultry house is the most opportune time for a producer to thoroughly clean and disinfect the house. Most farms did some sort of cleaning between flocks. Essentially all farms emptied feeders, 91 percent emptied feed hoppers, 81 percent flushed water lines, 79 percent dry cleaned cages, walls, and ceilings, and 71 percent cleaned fans and ventilation systems. Approximately one-third of farm sites never cleaned or disinfected egg belts/elevators between flocks. Down time between flocks varied regionally; most farms had a down time of more than 11 days, although some were down for less than 4 days.

h. Testing for SE. A 1994 NAHMS survey of farms revealed that almost 16 percent of farms tested for SE. The Layers study showed that, in 1997, 58 percent of farms tested for SE. The number of farms testing for SE varied by region. In the Southeast, almost 84 percent of farms had an SE testing program, while in the West only 26 percent had an SE testing program. The number and regional distribution of farms doing testing for SE is very similar to the number and distribution of farms participating in an egg quality assurance (QA) program.

i. NAHMS Study Testing for SE. In 1994, NAHMS undertook its own survey for SE in layer houses. It found that 7 percent of layer houses were positive for SE, based on environmental sampling. Only 4 percent of houses with fewer than 100,000 laying hens were positive for SE, while 16 percent of houses with greater than 100,000 laying hens were SE-positive. The study indicated that the number of rodents, cleaning and disinfection procedures, biosecurity, and the age of the flock were all related to the SE status of the layer house.

2. Voluntary Egg QA Programs

The Layers study found that 51 percent of all farm sites participated in an egg QA program sponsored by a State or commodity group (e.g., United Egg Producers (UEP)). Based on this information, we estimate that approximately 50 percent of the eggs in the United States are produced under an egg QA program.

In 1992, Congress provided special funding to USDA to begin the SE Pilot Project (SEPP). The SEPP was one of the first egg QA programs in the United States. The pilot project phase operated for 2 years and then, in 1994, the SEPP became the PA Egg QA Program (PEQAP). Currently, there are several voluntary egg QA programs operated and administered by states or other organizations (Refs. 28, 29, 30, 31, and 32). The states that have programs include PA, MD, NY, OH, SC, AL, OR, CA and the New England region. The UEP has a program called the UEP "Five Star" Total QA Program (Ref. 33) and the United States Animal Health Association has a protocol entitled "National Standardized *Salmonella* Enteritidis Reduction Program for Eggs" (Ref. 34). In addition, certain egg companies operate an egg QA program within their own facilities (Ref. 26).

Currently the egg QA programs that exist are voluntary for producers. All programs have similar requirements but vary in how they implement these requirements. All programs require use of chicks from NPIP "U.S. *S.* Enteritidis Monitored" breeders or equivalent, biosecurity, rodent control, and cleaning and disinfection of poultry houses. Most programs require some environmental testing; the amount varies among programs from once to four or five times during the life of a flock. If an environmental test is SE-positive, several programs require egg testing, with diversion if the egg testing is SE positive. Several programs also have State government oversight and recordkeeping requirements. All existing QA programs have some educational programs for participants. There is data indicating that QA programs have been effective in reducing SE contamination in poultry houses (see discussion in section III) and the provisions in this proposal are modeled on those successful programs.

I. Petitions to the Agency

FDA has received several citizen petitions relevant to this proposed rulemaking.

1. Center for Science in the Public Interest

We received a petition from the Center for Science in the Public Interest (CSPI) (filed May 14, 1997, Docket No. 97P–0197) requesting, among other things, that FDA require programs to reduce the risk of SE for all egg producers. In support of its request, CSPI stated that SE in eggs is a serious health problem, illnesses caused by SE in the United States have increased, and consumers are at risk of illness from SE in raw or undercooked eggs. CSPI requested that producers be required to implement on-farm SE prevention programs using Hazard Analysis and Critical Control Point (HACCP) principles and modeled after the PEQAP program. CSPI also requested the following program components: (1) Chicks from SE-monitored breeder flocks, (2) environmental sampling for SE of chicks, pullets, and twice during the life of layers, (3) cleaning and disinfection of poultry houses if environmental tests are SE positive, (4) egg testing if the environment is positive with diversion of SE-positive eggs to pasteurization plants, (5) biosecurity, (6) rodent control program, (7) program to control SE in feed, and (8) refrigerated storage of eggs at 41°F to ensure that SE cannot multiply. In addition, CSPI requested that producers be required to keep records that would be verified by FDA to indicate compliance with SE prevention programs.

2. Rose Acre Farms, Inc.

We received a petition from Rose Acre Farms, Inc. (filed November 4, 1996, Docket No. 96P–0418) requesting, among other things, that we issue a regulation requiring "Best Practices" of egg producers. The petitioner stated that "best practices" are a set of procedures used by egg producers to control the presence of SE to the lowest level practical. Rose Acre Farms, Inc. suggested that the "best practices" might include: (1) Environmental testing of a poultry house for SE, (2) egg testing if the environmental testing is SE-positive, (3) cleaning and disinfection of poultry houses, (4) a program to reduce SE in feed, (5) vaccines, (6) rodent control, (7) biosecurity, (8) egg washing, (9) recordkeeping requirements, and (10) use of appropriate third parties to audit compliance with program elements. The petitioner requested that "best practices" programs be accredited individually by FDA and USDA. The petitioner also requested that eggs produced under an accredited program could never be deemed adulterated, regardless of the outcome of environmental testing or implication of a flock in a traceback.

In addition, Rose Acre Farms, Inc. requested that the agency place greater emphasis on consumer education and retail foodservice. The petitioner suggested that FDA revise the FDA Food Code to prohibit pooling of more than three shell eggs by any restaurant or foodservice institution. For egg dishes requiring pooling of more than three eggs, pasteurized product would have to be used.

3. United Poultry Concerns, Inc. and the Association of Veterinarians for Animal Rights

We received a petition from United Poultry Concerns, Inc., and the Association of Veterinarians for Animal Rights (filed April 14, 1998, Docket No. 98P–0203/CP1) requesting that FDA eliminate forced molting of laying birds in the United States. The petitioners requested that forced molting be

stopped because it is cruel. The petitioners also stated that the stress of forced molting promotes a systemic disease in birds in the form of SE that renders products derived from these birds a health risk to consumers.

In support of the request to stop forced molting because it promotes SE-infection in layers and renders products from these birds a health risk to consumers, the petitioners stated that forced molting impairs the immune response of laying hens, which invites colonization of the intestine and other organs by SE. The petitioners also cited studies that they believe demonstrate SE is shed in large numbers in the feces of infected, molted birds and spreads more rapidly among molted laying hens than among nonmolted ones. The petitioners stated that molted birds are more susceptible to SE infection from rodents, which have been shown to harbor SE in the poultry house environment. The petitioners also cited information that indicates feathers can carry SE and that molted birds engage in abnormal feather pecking because of the molting conditions.

United Poultry Concerns, Inc. and the Association of Veterinarians for Animal Rights also requested that forced molting be eliminated because the living conditions under which forced molting is conducted are inherently disease producing. The petitioners cited studies that indicate that concentrated confinement of birds in cages allows 48 square inches of living space per bird. The petitioners stated that the confined living space puts an additional stress on birds that lowers immune response and exacerbates an SE infection if present.

III. The Proposal to Require SE Prevention Measures for Egg Production

A. Rationale for Proposal

The incidence and geographical distribution of egg-associated SE illnesses have made SE a significant public health concern. Although there are Federal rules requiring refrigeration of shell eggs packed for the ultimate consumer (FSIS) and at retail (FDA) to limit the growth of SE that may be present, there are no Federal requirements to address the introduction of SE into the egg during production. The *Salmonella* Enteritidis Risk Assessment Team (Ref. 15) estimated that 1 in 20,000 eggs are contaminated with SE. Based on annual egg production (Ref. 20), this means that 3.3 million SE-contaminated shell eggs may be produced annually. Thirty percent of total egg production is used in egg products (Ref. 20), leaving an estimated 2.3 million SE-contaminated shell eggs that may reach the consumer. Therefore, interventions that can reduce the number of SE-contaminated eggs produced are warranted from a public health standpoint.

As discussed in section II.I of this document, several States and organizations have established voluntary egg QA programs that show great promise in reducing the incidence of egg-associated SE illnesses in specific regions of the country. Data from the PEQAP program show that after three years on the program the number of poultry houses that had environmental samples positive for SE decreased from 38 percent in 1992 to 13 percent in 1995 (Refs. 35 and 36). PEQAP data initially indicated that approximately 50 percent of the flocks in the program had environmental samples positive for SE at some time during flock life, whereas in 1996 approximately 15 percent of PEQAP flocks had environmental samples positive for SE at some time during flock life (Ref. 36). From 1992 to 1995, there was a decrease in the SE isolation rate in humans in the three-State region (NY, NJ, PA) that constitutes the market for PA's eggs. This decrease in isolation rate has been attributed to the PEQAP program and consumer education (Refs. 35 and 36).

Currently in the United States, only 50 percent (Ref. 26) of shell eggs are produced under voluntary egg QA programs and the regions that have voluntary egg QA programs are not necessarily the regions that have had recent outbreaks of SE illnesses (Ref. 9). Therefore, we have tentatively concluded that a proposal to require that producers of shell eggs for the table market, other than those producers whose eggs are treated or sold directly to consumers or who have fewer than 3000 laying hens, comply with all of the proposed SE prevention measures would exclude SE on the farm and, thus, remove sources of SE contamination of shell eggs.

B. Shell Egg Producers Covered by Proposed 21 CFR Part 118

The proposed requirements for SE prevention measures do not apply to producers who sell all of their eggs directly to consumers (e.g., roadside stand operators) or producers with fewer than 3,000 laying hens. Although we could have proposed to require these producers to implement SE prevention measures, we opted not to do so because the sales by these producers do not contribute significantly to the table egg market. In addition, we have no information indicating that an outbreak of SE illness has ever been caused by eggs sold directly from farmer to consumer or from a producer with fewer than 3,000 laying hens. We are soliciting comment on the exemption for producers with fewer than 3,000 laying hens and producers who sell all of their eggs directly to consumers. Specifically, should these producers be covered by some or all of the SE prevention measures?

We are proposing in § 118.1(a) (21 CFR 118.1(a)) that if you are a producer with 3,000 or more laying hens at a particular farm whose eggs are going to the table egg market (eggs consumed as shell eggs, rather than eggs used in egg products), and not all of your eggs receive a treatment as defined in § 118.3, then you must comply with all of the requirements in proposed part 118 for eggs produced on that farm. You may be selling your eggs to restaurants or other foodservice establishments where the presence of SE-contaminated eggs could cause a severe public health threat by striking many people at one time. In establishments where eggs are combined to make food items, one SE-contaminated egg can contaminate a dish that will be served to many people. Thus, it is necessary for you to use SE prevention measures on your farm to prevent SE contamination of your eggs and illness in consumers.

It is our understanding that it would be difficult for a producer to keep eggs produced from individual poultry houses on a farm separate from other eggs that may be handled differently. For example, a producer could not easily segregate eggs destined for a breaking plant from three poultry houses, which would not have to comply with the SE prevention measures, from eggs not destined for a breaking plant from two other poultry houses, which would have to follow all of the SE prevention measures. Furthermore, it would be difficult for the producer to maintain proper biosecurity for the two poultry houses subject to all of the SE prevention measures if there were three other poultry houses on the farm not employing the same biosecurity measures. Therefore, we have tentatively concluded that, unless all of the eggs from a particular farm receive a treatment as defined in § 118.3 or are sold directly to consumers, producers who have 3000 or more laying hens on that farm must comply with all of the requirements of proposed part 118 if the eggs are produced for the table egg market.

We are proposing in § 118.1(b) that if you are a producer who produces eggs on a farm that will all receive a treatment as defined in § 118.3 and you

have 3,000 or more laying hens, you must comply only with the refrigeration requirements for on-farm storage found in proposed § 118.4(e). As defined in proposed § 118.3, "treatment" means a technology or process that achieves at least a 5-log destruction of SE for shell eggs, or the processing of egg products in accordance with the Egg Products Inspection Act. It is important that the load of SE within a contaminated egg be kept low prior to treatment so that the level of kill given to that egg by the treatment will be sufficient. For example, if the in-shell pasteurization process for eggs is designed to reduce the level of SE in an egg by "x" logs, then the incoming SE load of that egg must be less than "x" logs for the treatment to be successful.

Refrigeration at 45 °F within 36 hours of laying has been shown to slow the multiplication of SE within an egg substantially and is discussed in section III.E.5 of this document. We have tentatively concluded that, prior to treatment for SE destruction, producers who have 3,000 or more laying hens must keep eggs under refrigeration at 45 °F maximum if they are held at the farm for more than 36 hours. Although we are not proposing to require that producers who treat all of their eggs to achieve the required destruction of SE comply with all of the SE prevention measures, we strongly encourage all egg producers to follow non-mandatory SE prevention measures during egg production.

C. Proposed Compliance Dates for Shell Egg Producers of Various Sizes

We are proposing that, if a producer has 50,000 or more laying hens, according to the requirements of proposed part 118, compliance would be required 1 year after the date of publication of the final rule in the **Federal Register**. Although producers who currently participate in voluntary QA programs may already have some of the provisions in place, we recognize that producers will need time to implement SE prevention measures, train individuals to implement the measures, and begin to incorporate them in their farm practices. We believe that 1 year from the date that any final rule is published is a realistic timeframe for producers that have 50,000 or more laying hens on farm to put measures in place.

We recognize that smaller producers (those with fewer than 50,000 but at least 3,000 laying hens) may need more time to comply with the requirements of proposed part 118. We tentatively have concluded that it is reasonable to allow for extended compliance periods for smaller producers. For smaller producers, compliance would be required 2 years after the date of publication of the final rule in the **Federal Register**.

D. Definitions

We are proposing in the introductory paragraph of § 118.3 that the definitions and interpretations of terms in section 201 of the FFDCA, unless these terms are redefined in this part, are applicable to these terms when used in proposed part 118.

We are proposing in § 118.3 that the term "biosecurity" means a program to ensure that there is no introduction or transfer of SE onto a farm or among poultry houses. As specified in proposed § 118.4(b), a biosecurity program includes, but is not limited to, limiting visitors to a farm, keeping animals and wild birds out of poultry houses, requiring personnel to wear protective clothing, and ensuring that equipment is not moved among poultry houses or, if it is so moved, that it is adequately cleaned before it is moved.

We are proposing in § 118.3 that the term "farm" means all poultry houses and the grounds immediately surrounding the poultry houses covered under a single biosecurity program. We intend the term "farm" to encompass an entire farming operation at a single geographic location. We do not intend to allow, by this definition, multiple "farms" covered by multiple biosecurity programs at a particular geographic site. If we did allow multiple farms at a geographic location, a producer could have part of the operation under SE prevention measures for eggs going to the table egg market and part of the operation under no such measures for eggs going to treatment. Such an outcome is contrary to our rationale set forth for proposed § 118.1(a).

We are proposing in § 118.3 that the term "flock" means all laying hens within one poultry house. We recognize that laying hens of different ages sometimes are placed in the same poultry house. Research has indicated that once SE is introduced into a poultry house it spreads among the laying hens in that house (Refs. 37 and 38).

We are proposing in § 118.3 that the term "group" means all laying hens of the same age within one poultry house. This term particularly applies to laying hens of the same age that comprise part of a multi-aged flock of laying hens within one poultry house.

We are proposing in § 118.3 that the term "induced molting" means molting that is artificially initiated. Induced molting is done to improve egg production and egg quality.

We are proposing in § 118.3 that the term "laying cycle" means: (1) The period of time that a hen begins to produce eggs until it undergoes induced molting or is permanently taken out of production; and (2) the period of time that a hen produces eggs between successive induced molting periods or between induced molting and the time that the hen is permanently taken out of production.

We are proposing in § 118.3 that the term "molting" means a life stage during which a hen stops laying eggs and sheds its feathers.

We are proposing in § 118.3 that the term "pest" means any objectionable animals or insects, including, but not limited to, birds, rodents, flies, and larvae. This is also the definition of "pest" found in 21 CFR part 110.

We are proposing in § 118.3 that the term "positive flock" means a flock that produced eggs that tested positive for SE and applies until that flock meets the egg testing requirements in proposed § 118.6 to return to table egg production.

We are proposing in § 118.3 that the term "positive poultry house" means a poultry house from which there has been an environmental test that was positive for SE during a laying cycle. A poultry house would be considered positive until it had been cleaned and disinfected, even if an environmental test is positive for SE prior to a molt and then is SE-negative at the post-molt environmental test. A negative environmental test after a molt does not invalidate the initial positive environmental test or necessarily indicate that SE is no longer present. Data from the PEQAP program have indicated that cleaning and disinfection procedures can decontaminate an SE-positive poultry house (Ref.39). Therefore, we have tentatively concluded that a poultry house that has had an SE-positive environmental test must be considered positive until it has been cleaned and disinfected according to proposed § 118.4(d).

We are proposing in § 118.3 that the term "poultry house" means a building, other structure, or separate section within one structure used to house poultry. We have also tentatively concluded that, for structures comprising more than one section containing poultry, each section must have biosecurity procedures in place to ensure that there is no introduction or transfer of SE from one section to another. In addition, each section must be enclosed and separated from the other sections. We interpret "enclosed and separated" to mean that sections must be separated from one another by walls. Thus, under this proposed

definition, producers would have to limit their designation of "sections" representing separate poultry houses to areas that are physically separate from one another. It would not be acceptable under this proposed rule to designate areas that are separated, for example, only by a walkway or a gate as separate poultry houses.

We are proposing in § 118.3 that the term "producer" means a person who maintains laying hens for the purpose of producing shell eggs for human consumption.

We are proposing in § 118.3 that the term "shell egg (or egg)" means the egg of the domesticated chicken. This differs from the definition of "shell egg" in the EPIA, because, unlike the EPIA definition, FDA's definition does not cover shell eggs of the domesticated turkey, duck, goose, or guinea. FDA is focusing its resources on domesticated chicken eggs because they have been associated with numerous outbreaks of foodborne illness.

We are proposing in § 118.3 that the term "treatment" means technologies or processes that achieve at least a 5-log destruction of SE for shell eggs or the processing of egg products in accordance with the EPIA. In 1997, we recommended to AMS, in response to an AMS request to FDA on criteria for shell egg pasteurization, that processors attain a 5-log reduction in *Salmonella* in shell eggs in order for the eggs to be considered "pasteurized." We recommended the 5-log lethality based on literature available at the time on naturally infected shell eggs that indicated, under most storage conditions, an intact shell egg could contain between 10^2 and 10^3 *Salmonella* organisms (Ref. 19). FDA then added a 2-log safety factor to arrive at the recommendation for a 5-log lethality. AMS published this standard in its **Federal Register** notice on official identification of pasteurized shell eggs (62 FR 49955, September 24, 1997).

We are soliciting comment on whether a 5-log reduction or an alternative approach to achieve an equivalent level of protection is still appropriate to ensure the safety of shell eggs. We intend to work with USDA to ensure that shell eggs and egg products are given adequate treatments to destroy SE.

E. The SE Prevention Measures

Data indicate that voluntary egg QA programs have contributed to a decrease in SE in poultry houses and a decrease in SE illnesses. The particular program (PEQAP) from which the data were gathered includes provisions for chick and pullet procurement, biosecurity, rodent control, refrigeration, cleaning and disinfection of poultry houses, and monitoring of the poultry house environment through testing for SE (Ref. 28). Although the individual provisions were not evaluated for their relative importance, the PEQAP results indicate that, when used together, the provisions resulted in a decrease in the prevalence of SE within a poultry house (Ref. 35). Thus, the agency tentatively concludes that SE prevention measures are necessary to reduce the incidence of SE illness from consumption of shell eggs, when the eggs are not treated to destroy SE.

All of the provisions of proposed § 118.4 apply to you if you are a producer with at least 3,000 laying hens, you produce shell eggs for the table market, and you do not sell all of your eggs directly to consumers or treat all of your eggs to destroy SE as defined in proposed § 118.3 (§ 118.1(a)). We are proposing in § 118.4 that shell egg producers described in § 118.1(a) develop and implement the following SE prevention measures: Provisions for procurement of chicks and pullets, a biosecurity program, rodent, fly and other pest control, cleaning and disinfection of poultry houses that have had an environmental or egg test positive for SE, and refrigerated storage of eggs at the farm.

We also are proposing in § 118.4 that the particular form that SE prevention measures take be specific to each farm and poultry house where eggs are produced. Depending upon whether there are multiple poultry houses on a farm and whether the poultry houses vary in house style and location, the SE prevention measures may vary among poultry houses. For example, one poultry house may require certain rodent and pest control measures that another poultry house may not require.

Further, we are proposing that if you are a producer under section § 118.1(a), you must comply with the environmental and egg testing requirements in §§ 118.5 and 118.6, the sampling and testing methodology requirements in §§ 118.7 and 118.8, the administration requirements in § 118.9, and the recordkeeping requirements in § 118.10. We will discuss our rationale for compliance with these requirements in the relevant sections of this proposed rule.

1. Chicks and Pullets

We are proposing in § 118.4(a) that you must procure chicks and pullets that came as chicks from breeder flocks that meet NPIP's standards for "U.S. *S.* Enteritidis Monitored" status or equivalent standards. The fact that SE can be transmitted via the transovarian route means that chicks can be born SE-positive (Refs. 35 and 40). Therefore, they may remain infected as pullets and be placed into poultry houses as layers already carrying SE and then contaminate their eggs and, in addition, pass SE on to other layers within the poultry house (Refs. 38, 41, and 42). We tentatively have concluded that it is necessary for you to procure chicks and pullets that came as chicks from breeding flocks that meet NPIP's standards for "U.S. *S.* Enteritidis Monitored" status (9 CFR 145.23(d)) or equivalent standards in order to prevent SE contamination of shell eggs from SE-positive chicks. Producers that procure pullets from a pullet-raising facility need to have an assurance that those pullets came as chicks from a breeder flock that meets NPIP's standards for "U.S. *S.* Enteritidis Monitored" status or equivalent standards.

USDA's NPIP is a cooperative Federal-State-industry mechanism for controlling certain pathogens and poultry diseases. NPIP has established "U.S. *S.* Enteritidis Monitored" standards (9 CFR 145.23(d)) from which the breeding-hatching industry may conduct a program for the prevention and control of SE. Participation in the plan is voluntary, except under 9 CFR part 82, subpart C, no hatching eggs or newly-hatched chicks from egg-type chicken breeding flocks may be moved interstate unless they are classified "U.S. *S.* Enteritidis Monitored" under NPIP or meet equivalent standards.

To be classified "U.S. *S.* Enteritidis Monitored," under 9 CFR 145.23(d), a flock and the hatching eggs and chicks produced must come from a "U.S. S. Enteritidis Monitored" flock, or meconium (first bowel movement) from chick boxes and a sample of chicks that died within 7 days after hatching must be examined and test negative for *Salmonella*. Throughout the life of a "U.S. *S.* Enteritidis Monitored" flock, environmental and blood samples are taken at specified times and examined for group D *Salmonella* (the group that includes SE). Breeder flocks may be vaccinated with an SE bacterin, provided that 350 birds remain unvaccinated until the flock is at least 4 months of age. Hatching eggs produced by the flock are collected as quickly as possible, sanitized or fumigated, and incubated in an approved hatchery. The flock must also meet feed, facilities, and transport requirements.

A flock is not eligible for the "U.S. *S.* Enteritidis Monitored" classification if SE is isolated from a specimen taken from a bird in the flock. Isolation of SE

from an environmental sample of a vaccinated or nonvaccinated flock necessitates bird testing. If bird testing reveals no SE contamination, then the flock qualifies for the classification. The classification may be revoked at any time if procedures are not followed.

We are aware that most producers purchase pullets from a pullet-raising facility to repopulate a poultry house. Some of these pullet-raising facilities have SE-monitoring programs (Ref. 25). We specifically request comment on whether we should include in any final rule based on this proposal, a requirement that producers certify that pullets they procure have come from a facility that has an SE-monitoring program. If so, what requirements should producers certify that a pullet-raising facility has met in order to ensure that the pullet raising facility has an adequate SE-monitoring program?

2. Biosecurity

We are proposing in § 118.4(b) that you develop and implement a biosecurity program. Biosecurity refers to procedures that must be instituted on farms to prevent SE from being transferred from the environment into the poultry house or among poultry houses. Biosecurity is a routine part of all existing egg QA programs and is aimed at preventing the horizontal spread of SE. According to the Layers study (Ref. 26), 66 percent of farm sites already practice some form of biosecurity, and poultry houses where visitors were not allowed were less likely to test positive for SE. The Swiss have identified control of the horizontal spread (i.e., cross contamination from layer to layer or poultry house to poultry house) of SE as a major success of their SE control program (Ref. 42). We have tentatively concluded that producers need to develop and implement a biosecurity program covering the grounds and all facilities, including poultry houses, for each egg farm in order to prevent the horizontal spread of SE.

As part of your biosecurity program, you must take measures to prevent cross-contamination among poultry houses and contamination of poultry houses from the environment. This includes, where practical, purchasing separate equipment for each poultry house within a farm because shared equipment can cause SE cross-contamination between poultry houses. For certain large pieces of equipment (e.g., manure removing equipment), we recognize that it is not practical to purchase separate pieces of equipment for each house. We also recognize that certain pieces of equipment are common to all houses (e.g., egg belts). In the Layers study, approximately one-half of the positive environments were identified by egg belt or elevator sampling (Ref. 27). You must keep egg belts, manure-removing equipment, and other similar pieces of equipment clean and ensure that these pieces of equipment are not sources of SE contamination that can be spread from one house to another.

A comprehensive biosecurity program must also include provisions to limit visitors to the farm and poultry houses and to ensure proper hygiene of personnel who do move among poultry houses. Proper hygiene includes the use of protective clothing that is changed as employees move between poultry houses and foot sanitizing stations or other appropriate means to protect against contamination. In addition, you must prevent stray poultry, wild birds, or other animals from entering into poultry houses or on the grounds. You must not allow employees to keep poultry at home. You must implement the biosecurity measures stated above to prevent spreading SE from one poultry house to another on contaminated clothing or spreading SE from the environment into a poultry house by allowing stray animals entrance into a poultry house or allowing employees to keep their own poultry, which may be carrying SE, at home.

3. Rodents, Flies, and Other Pest Control

We are proposing in § 118.4(c) that you must develop and implement a pest and rodent control program to control rodents, flies and other pests. Many of the comments that we received after the egg safety public meetings in Columbus, OH (March 30, 2000), and Sacramento, CA (April 6, 2000), stated that the most important SE prevention measure that can be taken within a poultry house is rodent and pest control.

Several investigators have found strong indications that mice are carriers of invasive SE in the poultry house (Refs. 43 and 44). Kreager (Ref. 45) has stated that the SE status of rodents in a poultry house is thought to be indicative of the status of the flock. In fact, data indicate that the environments of SE-contaminated flocks are usually infected with the same phage type of SE found in mice and eggs also in that environment (Ref. 39). According to Davison et al. (Ref. 46), a single mouse can produce 100 droppings per day, and each dropping can contain up to 230,000 SE organisms. Wray and Davies (Ref. 47) have stated that mice may shed *Salmonella* intermittently for up to 18 weeks and may infect chickens consuming the fecal matter. Mice may become infected with SE from contaminated manure and then may spread it to other poultry houses that were previously SE free (Refs. 46 and 47). A few mice in one house can proliferate to 10,000 or more during the life of a flock.

Henzler and Opitz (Ref. 48) found that a poultry house with a large rodent population was approximately four times more likely to have an SE-positive environment as a poultry house with a small rodent population. In the Layers study (Ref. 26), producers reported that they had a moderate to severe problem with mice on 30 percent of farms and a moderate to severe problem with rats on 9 percent of farms. Rats have also been shown to harbor SE and are important vectors because they can travel long distances (Ref. 47). Environmental testing for the Layers study (Ref. 27) indicated that poultry houses in which 20 or more mice were captured (equals a rodent index of 2 or 3, see discussion of rodent indexing later in this section) were 9 times more likely to contain SE than poultry houses with a lower rodent index.

In addition to rodents, flies have been shown to harbor SE within the poultry house environment. Several *Salmonella* species were found in houseflies and bronze dump flies collected at caged-layer facilities that produced eggs that were implicated as the food vehicle in two recent outbreaks of SE infections. SE was isolated from 2 of 15 pools of houseflies from these facilities (Ref. 49). Both flies and rodents are attracted to feed within the poultry house and, according to the Layers study, flies and rodents have access to feed troughs on nearly all farms.

These studies indicate that rodents and pests can harbor SE that can be transmitted to layers and possibly to their eggs, potentially resulting in SE illnesses from consumption of shell eggs. We tentatively have concluded that producers must develop and implement a program to control rodents, flies and other pests.

We are proposing to require, under § 118.4(c)(1), that you must monitor rodent populations through visual inspection and use of mechanical traps or glueboards or another appropriate method. The use of traps and glueboards is appropriate if placed at regular intervals throughout each poultry house, or wherever rodents are most likely to be caught (Ref. 46). Davison et al. (Ref. 46) recommend that 12 traps be set per poultry house, left for a week, and checked twice during that week. If no mouse is caught at the first check, the trap should be moved, but no more than 15 feet. One week of trapping gives

a good indication of the level of rodent infestation in a poultry house; this is called rodent indexing (Ref. 46). If 0 to 10 mice (less than 2 mice/day) are caught, the rodent index is low or equal to 1; if 11 to 25 mice are caught, the rodent index is moderate or equal to 2; if 26 or more mice are caught, the rodent index is high or equal to 3. A low rodent index indicates acceptable rodent control.

We are proposing to require that when monitoring indicates unacceptable rodent activity (a rodent index of 2 or higher as described in Davison et al. (Ref. 46)) within a poultry house, you must take appropriate action to reduce the rodent population. We are proposing that baiting and trapping are possible methods to reduce a rodent population, but may not be effective in all situations. Producers, aware of rodent situations in their individual poultry houses, should choose a method that will be effective in their houses. If rodenticides are used, you should take care to prevent chickens or other nonrodents from consuming the bait.

We also are proposing to require under § 118.4(c)(2) that you monitor for flies and other pests through spot cards, Scudder grills, sticky traps or some other appropriate method that indicates pest activity. Spot cards are index cards used to enumerate the number of flies that land within the card area by counting fly specks (Ref. 50). Sticky traps are used to count the number of flies stuck to the trap (Ref. 51). A Scudder grill or a fly grill is a wooden grill that is placed over natural fly concentrations. The number of flies that land on the grill in 30 seconds is counted (Ref. 52). Spot cards and sticky traps should be checked weekly, while Scudder grills give an instant measure of fly activity within a poultry house.

Axtell (Ref. 50) has suggested that 50 or fewer hits on a spot card or sticky trap per week indicates satisfactory fly control. A count of less than 20 on a Scudder grill likewise indicates satisfactory fly control (Ref. 52). If monitoring indicates pest infestation (i.e., levels that do not indicate satisfactory pest control, as described above) within a poultry house, producers must use appropriate methods to reduce the pest population within a poultry house.

You would be required, under proposed § 118.4(c)(3), to remove debris within a poultry house and vegetation and debris outside of a poultry house that may harbor rodents and pests. Maintenance of a section of crushed rock around the perimeter of a poultry house helps prevent rodents from burrowing near poultry house foundations. Where possible, poultry houses should be sealed against entrance by rodents and pests.

4. Cleaning and Disinfection

We are proposing in § 118.4(d) that you must develop procedures for cleaning and disinfection of a poultry house that include removal of visible manure, dry cleaning, followed by wet cleaning using disinfectants, and finally, disinfecting. Further, we are proposing to require that you clean and disinfect a positive poultry house prior to the addition of new laying hens to the house. It is important, once a poultry house has had an SE-positive environmental or egg test, that you make every effort to rid the environment of SE before new laying hens are placed into that house to prevent the SE problem from being perpetuated in the replacement flock. Schlosser et al. (Ref. 39) reported that 50 percent of the SE-positive houses that were cleaned and disinfected according to PEQAP specifications were SE-negative when subsequently sampled. PEQAP cleaning and disinfection procedures consist of dry cleaning, wet cleaning (soaking, washing, rinsing), disinfection, and possibly fumigation with formaldehyde (Ref. 39). In addition, the Layers study found that no poultry house tested positive for SE after wet cleaning (i.e., where cages, walls, and ceilings were washed) (Ref. 27). We tentatively have concluded that, if an environmental test or an egg test is positive for SE during the life of a group in a poultry house, producers must clean and disinfect that poultry house before new laying hens are added to the house.

You must develop procedures for cleaning and disinfection in case they should ever need to be implemented. The cleaning and disinfection must include removal of all visible manure from the poultry house. Manure is a reservoir of SE that has been shed by infected laying hens. You must begin the cleaning procedure with dry cleaning of the house to remove dust, feathers, and old feed. Then, you must wet clean the poultry house, including washing with detergents. Detergents must be used according to label instructions, followed by recommended rinsing procedures. Following cleaning, you must disinfect the poultry house with spray, aerosol, fumigation or another appropriate disinfection method.

We are aware of studies that indicate that wet cleaning may have a detrimental effect on the SE status of a poultry house. In the report by Schlosser et al. (Ref. 39) mentioned in the first paragraph of this section, it is noted that, while 50 percent of the houses went from SE-positive to SE-negative after wet cleaning, 28 percent of the houses went from SE-negative to SE-positive. It is not known whether this was a testing error or a result of the wet cleaning. In addition, a Danish study found a relationship between wet cleaning procedures and SE-positive pig herds (Ref. 53). The authors were unsure whether the cleaning procedures were actually contributing to the presence of SE in the pigs or if the study was biased. Because there is some evidence, though inconclusive, suggesting that wet cleaning may result in an SE-positive poultry house environment, we specifically request comment and data on this subject. Although we are requiring cleaning and disinfection only for houses that have had an environmental or egg test that was positive for SE, we recommend that you remove manure and dry clean poultry houses as a general management practice every time you depopulate a house, even when no SE was detected in the house or eggs.

5. Refrigeration of Shell Eggs Stored More Than 36 Hours

We are proposing in § 118.4(e) that you must store eggs at or below 45°F (7.2°C) ambient temperature if you hold them at the farm for more than 36 hours after laying. This proposed requirement is the only SE prevention measure that applies to all producers with 3,000 or more laying hens regardless of whether your eggs will receive a treatment.

As we described in the shell egg refrigeration and labeling proposed rule (64 FR 36492 at 36495, July 6, 1999), although fresh shell eggs provide an inhospitable environment for *Salmonella* and other microorganisms to multiply, the chemical and physical barriers against bacterial movement and growth in shell eggs degrade as a result of the time and temperature of holding. Consequently, as a result of degradation, SE, if present, has access to the nutrient rich yolk, which provides a favorable environment for growth of SE.

Studies have shown that SE, when inoculated into the albumen of whole shell eggs, multiplied to high numbers if the eggs were not properly refrigerated (Refs. 54, 55, and 56). One study investigated the effect of holding inoculated whole eggs at five different temperatures in the range of 4 °C (39 °F) to 27 °C (81 °F). The investigators found that the SE growth response was proportional to the temperature at which the inoculated eggs were held. The study demonstrated that SE inoculated in shell eggs can multiply to substantial levels if held at 10 °C (50 °F)

or higher for up to 30 days. The authors concluded that "because the number of SE present at the time an infected egg is laid is probably very low, egg storage at 4 °C (39 °F) could be expected to result in a smaller risk to the public health than higher storage temperatures" (Ref. 54). In studies by Humphrey (Ref. 55) and Bradshaw et al. (Ref. 56), no growth was observed in SE inoculated into whole shell eggs at 8 °C (46 °F) and 7 °C (45 °F), respectively. We find that the scientific evidence on the growth of SE in eggs shows that control of storage temperature of shell eggs can effectively prevent the multiplication of any SE present. We seek comment and data on the impact of refrigeration on eggs after they leave the farm, such as the possibility that the eggs may "sweat" when removed from refrigeration.

Although we believe that it is very important that eggs be placed into refrigerated storage as soon as possible after they are laid, we realize that this may not be practical for all producers. It may be several hours or longer after the eggs are laid before they are collected or picked up for transport. It may not be practical for producers to place eggs under refrigeration within several hours after they are laid. It would be reasonable, based on what we know about current practices and the risk of SE growth in unrefrigerated eggs, to establish a time limit for holding eggs under ambient temperature conditions. According to the Layers study (Ref. 26), almost half of the farm sites surveyed had egg pick-ups every 1 to 2 days. We believe that holding eggs under ambient temperature conditions for up to 36 hours would not result in excessive growth of any SE, if present (Ref. 54). If eggs will be held at the farm for more than 36 hours after they are laid, it is important to place them in an environment that will protect the yolk membrane from degradation and, thereby, prevent any SE that may be present from multiplying. We have tentatively concluded that if eggs will be stored for more than 36 hours after they are laid, producers, with 3,000 or more laying hens, must store them at an ambient temperature of 45 °F (7.2 °C) or lower.

We are soliciting comment and data on the 36-hour threshold that eggs may be held unrefrigerated at a farm. Is this time frame practical for producers with daily egg pickup? Is it practical to refrigerate eggs held at farms for less than 36 hours?

F. Indication of the Effectiveness of the SE Prevention Measures: Testing

In addition to implementing SE prevention measures in the poultry house environment, we have tentatively concluded it is also important that you do environmental testing as an indicator of whether your measures are working effectively.

1. Environmental Testing for SE

Under proposed § 118.1(a), § 118.5 would apply to you if you are a shell egg producer with 3,000 or more laying hens, you produce shell eggs for the table market but do not sell all of your eggs directly to consumers, and any of your eggs that are produced at a particular farm do not receive a treatment as defined in § 118.3. We are proposing in § 118.5 that you must conduct environmental testing for SE as an indicator of whether your SE prevention measures are working effectively. According to Schlosser et al. (Ref. 39), the Northeast Conference on Avian Diseases recommended that the poultry house environment (e.g., manure pits and egg machinery) be sampled by swabbing. This recommendation was made with the assumption that, if SE was found in the environment, there was a high probability that the laying hens in the house were infected. Sampling of manure in a poultry house is a simple screening method for determining if laying hens are shedding SE. Some studies have shown that manure sampling gives more consistent results than sampling of egg machinery (Ref. 39), although we recognize that sampling egg machinery may be preferable in certain poultry houses, and the Layers study identified almost one-half of environmental positives through sampling of egg machinery (Ref. 27). We tentatively have determined that environmental testing of the manure or egg machinery in a poultry house is an appropriate method for screening the environment for SE and should be used as one indicator of the effectiveness of your SE prevention measures.

Testing provides an opportunity for you to evaluate the SE status of your poultry houses and to take appropriate action if your measures are not preventing SE. Many of the comments we received in response to the public meetings in Columbus, OH, and Sacramento, CA, stated that environmental testing was an appropriate indicator of whether SE prevention measures are working effectively. In addition, most of the voluntary egg QA programs contain some level of environmental testing for SE to evaluate the effectiveness of the programs.

Information from an egg QA program with a testing protocol indicates that the highest numbers of positive environmental samples are found when laying hens are 40 to 45 weeks of age (Ref. 57). The Layers study (Ref. 27) found that flocks less than 60 weeks of age (younger flocks) were 5 times more likely to test positive for SE than older flocks. Accordingly, we are proposing in § 118.5(a) that environmental testing for SE be conducted for the flock in each poultry house when each group of laying hens making up that flock is 40 to 45 weeks of age. We are proposing in § 118.5(b) that environmental testing for SE also be conducted approximately 20 weeks after the end of any induced molting process. We propose to do this because the egg industry considers the time period approximately 20 weeks after the end of a molting process to be equivalent to the time period when layers are 40 to 45 weeks of age in an initial laying cycle.

An SE-positive environmental test at the 40 to 45 week time period notifies a producer that there is a problem with SE contamination. At this point, action can be taken to determine if there are SE-contaminated eggs and to keep SE-contaminated eggs produced by an SE-positive flock out of the table egg market. Additionally, a positive environmental test during the 40 to 45 week period (just after peak lay) gives a producer sufficient notice to make arrangements for cleaning and disinfection of the contaminated poultry house at depopulation. Therefore, we have tentatively concluded that you must perform environmental testing for SE on a poultry house when each group of laying hens in the flock in that house are 40 to 45 weeks of age and, if molted, approximately 20 weeks after the end of any molting process.

We tentatively have concluded in proposed § 118.5(a)(1) that, if an environmental test at 40 to 45 weeks for SE is negative, and your laying hens do not undergo induced molting, then you do not need to perform additional environmental testing on the poultry house, unless the flock in that poultry house contains multi-aged laying hens. If the flock contains multi-aged laying hens, you must test the environment of the poultry house when each group of hens in the flock is 40 to 45 weeks of age. We are establishing minimum testing requirements to serve as one indication of whether your SE prevention measures are working effectively, and we believe that one test per laying cycle is sufficient for that purpose. In addition, a representative

from the PEQAP program stated at a recent FDA/FSIS public meeting on egg safety (Washington, DC, July 31, 2000) that 75 percent of environmental positives will be caught with one environmental test (Ref. 58).

If an environmental test for SE is positive, we have tentatively concluded, under proposed § 118.5(a)(2), that you must review implementation of your SE prevention measures and begin egg testing within 24 hours of receiving notification of the positive environmental test, unless you divert eggs to treatment for the life of the flock in that poultry house. Review of the SE prevention measures is critical to ensure that they are being implemented properly and to eliminate improper implementation as a contributor to the SE-positive environment. We are proposing that you begin egg testing within 24 hours of receiving notification of an SE-positive environmental test in order to determine as quickly as possible whether SE-contaminated eggs are being marketed to consumers.

Further, we tentatively have concluded, in proposed § 118.5(b), that you must perform an environmental test for SE at approximately 20 weeks after the end of the molting process. Under proposed § 118.5(b)(1), if an environmental test is negative approximately 20 weeks after the end of a molting process, and your laying hens are not molted again, you do not need to perform additional environmental testing, for the reasons previously stated, on that poultry house, unless the flock in the poultry house contains multi-aged laying hens. If the flock contains multi-aged laying hens, the environment of the poultry house must be tested approximately 20 weeks after the end of the molting process of each group of hens in the flock in each poultry house.

Under proposed § 118.5(b)(2), if the environmental test for SE is positive at approximately 20 weeks after the end of a molting process, you must proceed in the same manner as described when the environmental test performed when laying hens are 40 to 45 weeks of age is positive for SE.

2. Egg Testing for SE

Under proposed § 118.1(a), § 118.6 would apply to you if you are a shell egg producer with 3,000 or more laying hens, you produce shell eggs for the table market but do not sell all of your eggs directly to consumers, and any of your eggs that are produced at a particular farm do not receive a treatment as defined in § 118.3. We are proposing in § 118.6 that if you have an environmental test that is positive for SE at any point during the life of a flock, you must perform egg testing for SE, unless you divert eggs to treatment as defined in § 118.3 for the life of the flock in the positive poultry house. If an environmental test is SE-positive, the flock in that environment may be producing SE-positive eggs. Studies have shown that infected laying hens that are shedding SE into the environment are not necessarily producing SE-contaminated eggs (Ref. 14). However, data from the SE Pilot Project (Ref. 39) showed that 50 percent of flocks with an SE-positive environment produced at least one positive egg in the time period studied. The prevalence of SE-positive eggs from flocks in SE-positive environments was estimated to be approximately 1 in 3,600 from data from the SE Pilot Project (Ref. 39). The SE Risk Assessment (Ref. 15) estimated the prevalence of contaminated eggs to be as high as 1 in 1,400 from "high risk" flocks with SE-positive environments. We have tentatively concluded that, in order to protect public health, you must begin testing eggs within 24 hours of receiving notification that you have an environmental test that is positive for SE, unless you choose to divert eggs to treatment as defined in § 118.3 for the life of the flock in the positive poultry house.

We are proposing in § 118.6(c) that you must conduct 4 egg tests on the positive poultry house; you must collect and test eggs as required by §§ 118.7 and 118.8, respectively, at 2-week intervals for a total of 4 tests. We are also proposing in § 118.6(c) that if all four tests are negative for SE, then you may continue to supply eggs to the table egg market. However, if any one of the four egg tests is positive for SE, we are proposing in § 118.6(d) that, upon receiving notification of an SE-positive egg test, you must divert all eggs from the positive flock for treatment as defined in § 118.3 until the provisions of § 118.6(c) are met. You may divert eggs from the positive flock to egg products processing or to a treatment that will achieve at least a 5-log destruction of SE for shell eggs. You may return to providing eggs to the table egg market if they have met the provisions of proposed § 118.6(c) (see discussion in section III.G.2 of this document) and continue to meet the provisions of proposed § 118.6(e), described in the following paragraph.

We are proposing in § 118.6(e) that, if you have had a positive egg test in a flock and later meet the number of negative egg tests required in § 118.6(c) and return to table egg production, you must conduct one egg test per month on that flock (see discussion in section III.G.2 of this document) for the life of that previously positive flock. Humphrey (Ref. 14) has suggested that laying hens that are infected with SE will produce SE-contaminated eggs sporadically. Therefore, we believe that it is important that a flock that previously has produced positive eggs be monitored throughout its life for production of SE-contaminated eggs. Under proposed § 118.6(e)(1), if the monthly egg test in paragraph (e) is negative for SE, you may continue to supply eggs to the table market. If any of the monthly egg tests in paragraph (e) are positive for SE, under proposed § 118.6(e)(2), you must divert eggs from the positive flock to treatment for the life of the flock or until the conditions in paragraph (c) of proposed § 118.6 are met.

The testing schemes described in the previous paragraphs could be the basis for a performance based regulatory scheme. We are soliciting comment and data on alternative regulatory schemes that would achieve the same public health protection as the set of measures we are currently proposing. One possibility is a requirement for a specified frequency of environmental testing for all producers, followed, if necessary, by egg testing and diversion. As long as producers were maintaining poultry houses that tested negative for SE, the SE prevention measures would be recommended but not required. However, some or all of the measures may be required of producers whose houses were contaminated with SE. We solicit comment on a testing-based regulatory scheme and combinations of the prevention measures that might achieve the same public health goals as the current proposal.

G. Sampling and Testing Methodology for SE

We are proposing in § 118.7 to require that you follow a scientifically valid sampling procedure when sampling for SE in the poultry house environment and in eggs. Your ability to accurately assess the SE status of a flock and its eggs is a factor of the sampling methodology used to detect SE in the environment and in eggs. To protect public health, it is important that when you perform environmental testing for SE, you take representative samples of the manure or other appropriate material in poultry houses and, when you perform egg testing, you randomly collect 1,000 eggs from a day's production.

1. Sampling of the Poultry House Environment

We are proposing in § 118.7(a) that you use a scientifically valid sampling procedure for conducting environmental sampling within each poultry house. Currently, drag swabbing methods are being used to sample manure in poultry houses in the voluntary State QA programs (Refs. 28, 29, 30, 31, and 32). Drag swabbing has been reported to be an effective and convenient method for determining the SE status of a flock in a poultry house (Ref. 59). Drag swabbing involves pulling a square gauze pad (approximately 4 x 4 inches) that has been moistened with canned, evaporated milk across the surface of manure. Information on drag swabbing generated for the CA Egg QA Program (CEQAP) indicates that a swab becomes saturated with manure after being dragged approximately 30 linear feet. (Ref. 60) and, therefore, in that program an individual swab is only dragged for 30 feet. Most other State programs drag a single swab the entire length of a row of cages within a poultry house regardless of the length of that row (Refs. 28, 30, 31, and 32). As only the one CEQAP study has been done on saturation of a drag swab, there is very little information on this subject.

Currently, two different sampling plans are being used to drag swab manure in poultry houses among the voluntary State egg QA programs. CEQAP has developed a statistical sampling plan for drag swabbing a poultry house based on an assumed level of contamination within that house. Based on this assumed level of contamination, the number of swabs necessary to give a particular probability of detecting SE can be determined. For example, if 10 percent of the area of a poultry house is contaminated with SE, taking 32 swabs would give a 96 percent probability of detecting SE in that house. For the CEQAP program, the total area of a poultry house is divided into 30-foot sections (the distance that they have determined it is valid to drag a single swab) and, in our example, 32 of those 30-foot sections would be randomly selected to be drag swabbed for SE. In this sampling plan, the assumed area of contamination can be altered to fit the conditions in a particular poultry house with consequent changes in the number of swabs that must be taken to retain a 95 percent or better probability of detecting any SE that may be present.

Alternatively, many of the other voluntary egg QA programs drag swab the entire length of every row of cages within a poultry house. Rows or banks of cages typically have a right and left side. Each side of a row is dragged with a fresh swab until all the rows have been sampled. One swab is used per side regardless of the length of that row. The number of drag swabs taken per house equals twice the number of rows in that house. In addition, there are houses with cages that are stair-stepped and can be eight cages high with a large manure pit beneath them. In houses such as these, the manure belts are usually sampled. In houses where the floors are constantly flushed with water, the floor in general is swabbed.

We are aware of the differences in the types of poultry houses within the United States and the challenges involved in sampling all houses representatively and consistently. We are specifically soliciting comment on the appropriateness of different methods of drag swabbing, including manure belt and floor swabbing, and egg machinery swabbing. We would like comments on the distance an individual swab should be dragged and whether or not it is necessary to drag every row of every house. We would also like comments on alternative methods of sampling (e.g., sampling of the air in a poultry house to detect SE) that could be utilized more uniformly in different styles of poultry houses. Based on comments received, we will consider what poultry house environmental sampling methods should be required in any final rule.

2. Egg Sampling

In § 118.5(a)(2)(B) and (b)(2)(B), we are proposing to require that you begin egg testing within 24 hours of receiving notification of a single SE-positive environmental test unless you divert eggs to treatment for the life of the flock in the poultry house. In § 118.7(b)(1), we are proposing that, when you conduct an egg test required under § 118.6, you randomly collect and test 1,000 eggs from a day's production. The 1,000-egg sample must be tested according to proposed § 118.8. You must randomly collect and test 4 1,000-egg samples at 2-week intervals for a total test of 4,000 eggs over an 8-week period. With this sampling scheme, there is approximately a 95 percent probability that a positive egg will be detected from a flock that is producing SE-contaminated eggs with a prevalence of 1 in 1,400 (Ref. 61). As mentioned previously, data have indicated that an SE-contaminated flock may be producing SE-contaminated eggs with a prevalence of 1 in 1,400 (Ref. 15). We are proposing that eggs be tested in 2-week intervals because infected flocks shed SE intermittently (Ref. 14). However, the false negative rate of the sampling scheme is sensitive to the assumption regarding the prevalence of SE-contaminated eggs (Ref. 61). We are soliciting comment on this assumption, as well as other scientifically valid egg sampling procedures.

In proposed § 118.7(b)(2) we have tentatively concluded that 1,000 eggs from a day's production should be tested per month for the life of a flock that has had an SE-positive egg test and then met the provisions of § 118.6(c) and returned to table egg production. We are requiring this monthly egg test for the life of the flock because infected layers shed SE intermittently (Ref. 14).

H. Laboratory Methods for Testing for SE

We are proposing in § 118.8(a) that you must test for SE in environmental samples according to the method "Detection of *Salmonella* in Environmental Samples from Poultry Houses" and in § 118.8(b) that you must test for SE in egg samples according to the preenrichment method described by Valentin et al. (Ref. 62). These methods, which are incorporated by reference, are required unless you test for SE in environmental and egg samples using other methods that are at least equivalent in accuracy, precision, and sensitivity in detecting SE. In the future, we intend to place the specified methods in FDA's Bacteriological Analytical Manual. After publication of this proposed rule, the environmental sampling method will be available on FDA's Internet Web site at *www.cfsan.fda.gov*.

The method for detecting SE in the environment that we are specifically proposing to allow, "Detection of *Salmonella* in Environmental Samples from Poultry Houses," is a pre-enrichment method followed by primary enrichment method. The basic procedure for culturing samples involves incubating pre-enriched samples in enrichment broth and then streaking samples of broth onto selective media. Following incubation of the samples on the selective media, any suspect colonies that have grown on the media are identified biologically and serologically. In general, this procedure should give results in 5 days following receipt of samples by the laboratory.

The method for detecting SE in egg samples that we are specifically proposing to allow is a pre-enrichment method. The basic procedure for culturing involves incubation of pools of 20 eggs, followed by enrichment in modified tryptic soy broth. Following incubation and enrichment, samples are subcultured and streaked onto media and any suspect colonies that have

grown on the media are identified biochemically and serologically. We specifically request comment on appropriate options for conducting and funding testing of SE detection methods through State and Federal programs.

I. Administration of the SE Prevention Measures

We are proposing in § 118.9 that one individual at each farm must be responsible for administration of the SE prevention measures. Oversight by one qualified individual is essential to the effective implementation of SE prevention measures for egg production. Because egg production operations tend to be small and may have frequent turnover in staff, it is particularly important that one individual have training equivalent to a standardized curriculum recognized by FDA (discussed in the following paragraphs) or be otherwise qualified through job experience to administer the SE prevention measures.

Proposed § 118.9 requires an individual to have the requisite training or experience to administer SE prevention measures. Training on SE prevention measures for egg production must be at least equivalent to that received under a standardized curriculum recognized by FDA. We anticipate that 2- or 3-day training sessions will be provided by an egg safety training alliance, modeled after the Seafood HACCP Alliance. The Seafood HACCP Alliance is a consortium consisting of representatives from Federal and State agencies, industry, and academia who have worked to create a uniform training program that will meet the requirements of the seafood HACCP regulations with minimal cost. It is our intention to develop an Egg Safety Alliance to create a core curriculum and training materials on SE prevention measures for egg production. It also is our intention to use the Egg Safety Alliance curriculum and materials as the standard against which other course curricula and materials may be judged.

We also are proposing in § 118.9 that job experience will qualify an individual to administer the SE prevention measures if such experience has provided knowledge at least equivalent to that provided through the standardized curriculum. We acknowledge that a course on SE prevention measures for egg production might not be necessary for an individual who has experience working on an egg farm and is well-versed in SE prevention during egg production. Where job experience has imparted a level of knowledge at least equivalent to what an individual would receive through the standardized curriculum, that individual would be considered qualified to administer the prevention measures under proposed § 118.9.

We are proposing in §§ 118.9(a) through (c) that the qualified individual designated under § 118.9 must develop and implement SE prevention measures for each farm, reassess and modify the prevention measures as necessary to ensure that the requirements of § 118.4 are met, and review all records created under § 118.10. We also are proposing that the individual does not need to have performed the monitoring or created the records being reviewed. We have tentatively concluded that the prevention measures need to be implemented and, if necessary, modified and reassessed by an individual who not only is knowledgeable about egg production but who also has been trained or is experienced specifically in SE prevention measures for egg production so that the individual will be able to recognize potential problems.

J. Recordkeeping Requirements for the SE Prevention Measures

We are proposing recordkeeping requirements related to environmental testing and egg testing for SE, diversion, and eggs going to treatment.

1. Records that Egg Producers Are Required to Maintain

Under proposed § 118.1(a), § 118.10 would apply to you if you are a shell egg producer with 3000 or more laying hens, you produce shell eggs for the table market but do not sell all of your eggs directly to consumers, and any of your eggs that are produced at a particular farm do not receive a treatment as defined in § 118.3. We are proposing in § 118.10(a)(1) that you must keep records indicating compliance with environmental and egg sampling performed under proposed § 118.7 and results of environmental and egg testing performed under proposed § 118.8 as required in proposed §§ 118.5 and 118.6. If applicable, you must also keep records indicating compliance with the egg diversion requirements of proposed § 118.6. These records may be handwritten logs, invoices, documents reporting laboratory results, or other appropriate records.

Maintenance of appropriate records is fundamental to evaluating the effectiveness of your SE prevention measures. As stated in section III.A of this document, the combined SE prevention measures, when implemented properly, have been shown to result in a decrease in the number of poultry houses with SE-positive environments (Ref. 39). We have tentatively concluded that in order for you and FDA to evaluate whether these measures are being effective, it is necessary for you to keep records documenting the results of environmental testing and, if applicable, egg testing. We are proposing in § 118.10(a)(2) that if egg testing reveals SE-positive eggs you must maintain records indicating compliance with the diversion requirements in § 118.6. Records of diversion will provide assurance to both you and FDA that eggs required to be diverted are not being marketed to consumers and, thereby, putting consumers at risk of illness from SE.

We are proposing in § 118.10(a)(3) that you must keep records indicating that all of the eggs at a particular farm will be given a treatment as defined in § 118.3, if you have 3,000 or more laying hens and you are not complying with the SE prevention measures other than refrigeration (i.e., you are a producer described in § 118.1(b)). These records may include a contract with an in-shell pasteurization facility or an egg-breaking facility. It is necessary that these records be maintained so that both you and FDA will have an assurance that the potential for SE contamination in eggs is being addressed through a treatment or through the SE prevention measures.

2. General Requirements for Records Maintained by Egg Producers

In proposed § 118.10(b), we describe general requirements for records that must be maintained. Proposed § 118.10(b)(1) and (b)(2) require that records contain your name, the location of your farm, and the date and time of the activity that the record reflects. Proposed § 118.10(b)(3) requires that the record include the signature or initials of the person performing the operation or creating the record. The record signing requirement will assure responsibility and accountability by the individual who performed the activity. Also, a signature or initials ensure that the source of the record will be known if any questions regarding the record arise.

Proposed § 118.10(b)(4) requires that data reflecting compliance activities be entered on a record by the person performing or observing the activity at the time it is performed or observed in order to increase accuracy. The record must contain the actual values observed, if applicable.

3. Length of Time Records Must Be Retained

Proposed § 118.10(c) requires you to maintain all records in accordance with proposed part 118 at your place of business, unless stored offsite under § 118.10(d), for 1 year after the flock to which the records pertain has been taken permanently out of production. You must maintain records for 1 year after a flock is no longer producing eggs for consumption to allow for annual inspection and to facilitate investigation if the eggs from that flock are implicated in an outbreak of a foodborne illness.

4. Offsite Storage of Records

Proposed § 118.10(d) allows for offsite storage of records 6 months after the date the records were created. This applies to all records required under proposed part 118. We recognize that, under the recordkeeping requirements of this part, there may be more records than available storage space in an egg production facility. Therefore, we are proposing that records may be stored offsite. You must be able to retrieve any records you store offsite and provide them at your place of business within 24 hours of a request for official review. We would consider electronic records to be onsite if they are available from an onsite computer, including records transmitted to that computer via a network connection.

5. Official Review of Records

Proposed § 118.10(e) requires you to have all records required by part 118 available for official review and copying at reasonable times. The agency's access to records required by proposed part 118 is essential to understand whether your SE prevention measures are working and whether you are complying with the regulations. Our authority to require these records, and to provide for agency access to them, is discussed elsewhere in this document.

6. Public Disclosure of Records

Proposed § 118.10(f) states that records required by proposed part 118 are subject to the disclosure requirements under 21 CFR part 20. In another FDA rulemaking that discussed public disclosure of required records (60 FR 65096 at 65139, December 15, 1995), we concluded:

> [R]ecords and plans should be protected to the extent possible in order to promote the implementation of HACCP across the seafood industry. FDA has concluded that the public will benefit from the protection of records because it will actually strengthen the HACCP system. So long as the legitimate public need to be able to evaluate the system can be met through other means, the confidentiality of HACCP records and plans generally will foster the industry's acceptance of HACCP. Even though HACCP may be mandatory under these regulations, in order for it to succeed, processors must be committed to it because they see value in it for themselves. Fear of public disclosure of matters that have long been regarded as confidential business matters could significantly undermine that commitment. FDA concludes, therefore, that it is in the public interest to foster tailored HACCP plans that demonstrate understanding and thought, rather than promote the use of rote plans and minimally acceptable standards due to fear of public disclosure.
>
> FDA understands that we cannot make promises of confidentiality that exceed the permissible boundaries established under FOIA, nor does the agency wish to do so in this case. The agency still does not expect that we will be in possession of a large volume of plans and records at any given moment. However, given the significant interest in this subject as conveyed by the comments, we have concluded that the final regulations should reflect the fact that the HACCP plans and records that do come into FDA's possession will generally meet the definition of either trade secret or commercial confidential materials* * *.

We are not aware of any circumstances that would warrant different consideration on issues related to disclosure of records for SE environmental and egg sampling and testing and for diversion of eggs than those required for seafood HACCP. Therefore, we intend to consider records that come into our possession under this rule as generally meeting the definition of either a trade secret or commercial confidential materials.

7. Comment Solicitation on Recordkeeping Measures

We are soliciting comment on whether we should require two additional recordkeeping measures beyond the proposed recordkeeping requirements for environmental and egg sampling and testing, and for diversion. This solicitation is being made to assess the importance of these additional recordkeeping measures for a comprehensive SE prevention plan, given their added costs. First, we are soliciting comment on whether we should require that you establish and maintain a written SE prevention plan. If required, this SE prevention plan would set forth a producer's plan to implement the regulation's prevention and testing measures, and the requirement for diversion if eggs test positive for SE. A written plan may aid in the planning and establishing of efficient, effective, and consistently implemented SE prevention measures by facility personnel.

A written SE prevention plan also would be helpful to FDA representatives who inspect an egg facility. A written copy of a plan specific to each farm would assist FDA in establishing a link between what agency representatives see during an inspection and the overall SE prevention measures used on that farm over a longer time period. SE prevention measures may be quite different among farms, given different facility design and size, and yet be equally effective in meeting FDA's requirements. Knowledge of the specific prevention measures taken on a farm, as discussed in an SE prevention plan, would assist FDA representatives in assessing compliance with the prevention measures.

The second recordkeeping measure about which we are soliciting comment relates to a requirement that you maintain records indicating performance and compliance in implementing your facility's specific SE prevention measures. In this document, we are specifically proposing to require records only for environmental and egg sampling and testing, and for diversion of eggs found to be SE positive. We are requesting comment on whether we should require other documents demonstrating your implementation of the SE prevention measures that could be considered by FDA in assessing your compliance efforts, particularly in light of an SE-positive environmental test. Such documents, for example, might include monitoring records and activity logs. In the absence of other records to demonstrate compliance with SE prevention measures, FDA representatives who inspect a facility will base their evaluation of compliance with the regulation on observations, your sampling, testing, and any diversion records, FDA testing, and any other relevant information.

FDA did not propose to require a written plan and monitoring and compliance records because of their added costs, which FDA estimates to be $14.7 million, an 18 percent increase in the rule's total costs. Considering the information in the previous paragraphs, we are soliciting comment on the cost-effectiveness of the inclusion of a recordkeeping provision for a written SE prevention plan and a provision requiring records demonstrating compliance with all SE prevention measures in any final rule based on this proposal.

We also are soliciting comment about whether we should consider requiring, in a final rule, that you register with FDA if you are a producer who must comply with all of the SE prevention measures, as described in proposed § 118.1(a). We would use the producer registration information to create a

database that we would use to efficiently conduct inspections and allocate inspection resources. When the provisions of this rule are finalized, FDA intends to conduct annual inspections of egg farms. Oversight through annual inspection is necessary to ensure that shell eggs are being produced under controls that will prevent SE contamination and reduce the likelihood that SE-contaminated eggs will cause foodborne illness. Therefore, we solicit comment on the efficacy of requiring that producers register the location and size of their business with FDA.

K. Enforcement of On-Farm SE Prevention Measures for Shell Eggs

As discussed in section III.L of this document, FDA is proposing these regulations under both the FFDCA and the PHS Act. Failure to comply with the on-farm requirements proposed in §§ 118.1 through 118.10 would subject a producer to the administrative remedies (i.e., diversion or destruction) in § 118.12 of the proposed rule. Further, we would consider a failure to comply with the SE prevention requirements in proposed §§ 118.1 through 118.9 to result in the shell eggs being adulterated under section 402(a)(4) of the FFDCA (21 U.S.C. 342(a)(4)). Causing the eggs to become adulterated would be a violation of section 301(b) of the FFDCA (21 U.S.C. 331(b)), which prohibits adulteration or causing adulteration of food in commerce. Also, the introduction or delivery for introduction of adulterated shell eggs into interstate commerce would be a prohibited act under section 301(a) of the FFDCA (21 U.S.C 331(a)). Enforcement of adulteration regulations under the FFDCA is conducted under sections 301, 302, 303, and 304 (21 U.S.C. 332, 333, and 334).

Section 361 of the PHS Act (42 U.S.C. 264) authorizes the Secretary of Health and Human Services (the Secretary), and by delegation FDA, to issue regulations that provide for the destruction of articles and for other measures that the Secretary determines are necessary to prevent the introduction, transmission, or spread of communicable diseases. FDA tentatively concludes that the SE on-farm prevention requirements can be efficiently and effectively enforced through administrative procedures under the PHS Act. Accordingly, FDA is proposing procedures in § 118.12 under which FDA or a State or locality may order the diversion or destruction of shell eggs that have been produced or held in violation of any of the regulations in §§ 118.1 through 118.10. Under proposed § 118.12, FDA or a State or locality may issue a written order to the person holding the shell eggs requiring that the eggs be diverted or destroyed.

The proposed regulations would provide for the diversion to a treatment that achieves at least a 5-log destruction of SE for shell eggs or for processing of the egg products in accordance with the EPIA. Because EPIA requires pasteurization of egg products, any *Salmonella* present would likely be eliminated, as it would if the eggs received a treatment that achieves at least a 5-log destruction of SE. The written order would identify the shell eggs that are affected, and the grounds for issuing the order. The written order would provide that, unless the order is appealed by either filing a written appeal or by requesting a hearing, the shell eggs must be diverted or destroyed within 10-working days of the receipt of the order.

The authority for the enforcement of section 361 of the PHS Act is provided, in part, by section 368 of the PHS Act (42 U.S.C. 271). Under section 368(a), any person who violates a regulation prescribed under section 361 of the PHS Act may be punished by imprisonment for up to 1 year and may be fined. Individuals violating a regulation issued under section 361 may be fined an amount up to $100,000 if death has not resulted from the violation or up to $250,000 if death has resulted (18 U.S.C. 3559 and 3571(c)). In addition, Federal district courts have authority to enjoin individuals and organizations from violating regulations implemented under section 361 of the PHS Act (*Califano* v. *Yamasaki*, 442 U.S. 682, 704–05 (1979); *United States* v. *Beatrice Foods Co.*, 493 F.2d 1259, 1271–72 (8th Cir. 1974), *cert. denied*, 420 U.S. 961 (1975)).

We are proposing to amend § 16.5 (21 CFR 16.5) by adding paragraph (a)(5) to clarify that the regulatory hearing procedures in 21 CFR part 16 do not apply to a hearing proposed under § 118.12 on an order for diversion or destruction of shell eggs under section 361 of the PHS Act. We intend for the administrative remedies in proposed § 118.12 to be the applicable informal hearing process for any order issued under such section.

Proposed § 118.12(b) requires that shell egg producers allow FDA representatives to inspect egg production establishments. FDA does not need to provide advance notice before an inspection, and an inspection may include, but is not limited to, egg and environmental sampling, review of records, and inspection of eggs and equipment.

Proposed § 118.12(c) provides that States and localities that are authorized to inspect or regulate egg production establishments may enforce proposed §§ 118.4 through 118.10 of the rule through inspections under § 118.12(b) and through the administrative remedies in § 118.12(a). Proposed § 118.12(c) also provides that those States or localities may follow the rule's hearing procedures, substituting, where necessary, the appropriate State or local officials for designated FDA officials. The State or local officials also may use comparable State or local hearing procedures as long as such procedures satisfy due process.

L. Legal Authority

FDA is proposing these regulations under the PHS Act and the FFDCA. FDA's legal authority under the PHS Act for the proposed regulations is derived from the provisions of sections 311, 361, and 368 (42 U.S.C. 243, 264, and 271) that relate to communicable disease. The PHS Act authorizes the Secretary to make and enforce such regulations as "are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States * * * or from one State * * * into any other State" (section 361(a) of the PHS Act). (See sec. 1, Reorg. Plan No. 3 of 1966 at 42 U.S.C. 202 for transfer of authority from the Surgeon General to the Secretary; see 21 CFR 5.10(a)(4) for delegation from the Secretary to FDA.) This proposed rule would not be the first regulation issued by FDA that relied upon the authority of the PHS Act to prevent the transmission of communicable disease. For more than 60 years, FDA has used the PHS Act as its legal authority (in whole or in part) to issue the following regulations:

- Regulations to control the interstate shipment of Psittacine birds (21 CFR 1240.65);
- Regulations on the source and use of potable water (21 CFR 1240.80 to 1240.95);
- Regulations to control the interstate and intrastate commerce of turtles (21 CFR 1240.62);
- Regulations to control the interstate shipment of molluscan shellfish (21 CFR 1240.60);
- Regulations to require pasteurization of milk and milk products (21 CFR 1240.61);
- Regulations to require a safe handling statement on cartons of shell eggs that have not been treated to destroy *Salmonella* microorganisms and to require refrigeration of shell eggs held

for retail distribution (parts 16, 101, and 115 (21 CFR parts 16, 101, and 115));

• Regulations governing blood and tissue products in intrastate and interstate commerce (parts 606, 640, 1270, and 1271 (21 CFR parts 606, 640, 1270, and 1271));

• Regulations to require HACCP systems for juice in interstate and intrastate commerce (part 120 (21 CFR part 120); and

• Regulations to prevent the monkeypox virus from being established and spreading in the United States (21 CFR 1240.63).

Furthermore, at least one court has supported FDA's use of its PHS Act authority to issue regulations to control communicable disease. *State of Louisiana* v. *Mathews*, 427 F. Supp. 174 (E.D.La. 1977), involved an FDA regulation issued under the PHS Act banning the sale and distribution of small turtles. Plaintiffs argued that the PHS Act only provided FDA with authority to ban individual lots of infected turtles that were shown to be health hazards and did not provide authority for FDA's broad ban on all small turtles. *Id.* at 175. The court rejected this argument, observing that "Congress has granted broad, flexible powers to federal health authorities who must use their judgment in attempting to protect the public health against the spread of communicable disease." *Id.* at 176. The court found that FDA's total ban was "permissible as necessary to prevent the spread of communicable disease." *Id.*

Plaintiffs in the case also challenged FDA's authority under the PHS Act to promulgate a rule applicable to intrastate commerce. *Id.* FDA had concluded that controlling the spread of disease from contaminated turtles required extending the ban to intrastate sales. *Id.* Specifically, FDA reasoned that contaminated turtles may be purchased in one State for use as a pet in another and that, without prohibiting intrastate sales, unlawful interstate sales would be difficult or impossible to stop. *Id.* The court found that the intrastate ban "is not only authorized by law, but under modern conditions of transportation and commerce is clearly reasonable to prevent the interstate spread of disease." *Id.*

In *Public Citizen* v. *Heckler*, 602 F. Supp. 611 (D.D.C. 1985), the court considered a request to compel the Department to act on a petition to ban all domestic sales of raw milk and raw milk products because of the risk of transmission of disease from such products. In ordering FDA to respond to the petition, the court found that the Department had authority to ban raw milk and milk products under the PHS Act: "Under both the [PHS] Act's authorization for regulations to control communicable diseases, and the [act's] provisions for the control of adulterated foods, the Secretary has both the authority and the heavy responsibility to act to protect the nation's health in situations such as this one." *Id.* at 613. (internal citations omitted). See *Public Citizen* v. *Heckler*, 653 F. Supp. 1229, 1242 (D.D.C. 1987) (ordering FDA to publish a proposed rule banning the interstate sale of all raw milk and raw milk products).

In addition to the PHS Act, FDA's legal authority to require on-farm prevention measures under proposed §§ 118.1 through 118.9 derives from sections 402(a)(4) and 701(a) of the FFDCA (21 U.S.C. 371(a)). Under section 402(a)(4) of the FFDCA, a food is adulterated "if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health." Under section 701(a) of the FFDCA, FDA is authorized to issue regulations for the FFDCA's efficient enforcement. A regulation that requires measures to prevent food from being held under insanitary conditions whereby either of the proscribed results may occur allows for efficient enforcement of the FFDCA. See, e.g., regulations to require HACCP systems for fish and fishery products (21 CFR part 123) and juice (part 120) and regulations to require a safe handling statement on cartons of shell eggs that have not been treated to destroy *Salmonella* microorganisms and to require refrigeration of shell eggs held for retail distribution (parts 101 and 115).

Salmonellosis is a communicable disease that results from intestinal infection with *Salmonella* and is characterized by diarrhea, fever, abdominal cramps, headache, nausea, and vomiting. Contaminated shell eggs are the predominant identified food source of SE-related cases of salmonellosis in the United States. Lack of adequate on-farm prevention measures for the production of shell eggs can lead to the presence of SE in shell eggs and increase the likelihood of human illness if the eggs are not treated or thoroughly cooked. Infection may also be transmitted from person to person and animal-to-person. The provisions in the proposed rule are necessary to prevent SE from entering the farm and to prevent SE, if present, from cross contaminating the layers or eggs on the farm. We tentatively conclude that a regulation to require on-farm measures is necessary to prevent the spread of communicable disease and to prevent shell eggs from being prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health.

Although the egg market is largely regional, it involves significant shipment of shell eggs from State to State. Moreover, shipment of SE contaminated eggs from one State to another has contributed to the geographical spread of disease outbreaks in the U.S. human population. For example, eggs from Pennsylvania were implicated in an outbreak of SE infection reported in Asbury Park, NJ, involving at least 47 persons (Ref. 63). Eggs from Maryland were implicated in an outbreak in Livonia, NY, where 12 patrons of a restaurant reported gastrointestinal illness linked to consumption of omelets made from pooled grade A eggs (*Id.*). Further, consumption of raw eggs was associated with an SE outbreak at a catered wedding reception in New York, where Caesar salad dressing was implicated as the cause of SE illnesses. The Caesar salad dressing, made with 18 raw shell eggs traced to a Pennsylvania producer, was left unrefrigerated for 2 hours at the catering establishment, held in an unrefrigerated truck until delivered, and served at the reception 4.5 hours later (Ref. 64).

If eggs are not produced using SE prevention measures, SE is more likely to be present in the shell eggs, thereby increasing the likelihood of human illness if the eggs are not treated or thoroughly cooked. We tentatively conclude that it is necessary for producers with 3,000 or more layers on a farm that do not sell all of their eggs directly to consumers and that produce for the table market shell eggs that do not all receive a treatment, to produce shell eggs using all of the proposed rule's measures to prevent the spread of communicable disease. We also tentatively conclude that only the refrigeration requirements of proposed § 118.4 would apply to producers that provide shell eggs to the table market but do not sell all of their eggs directly to consumers and have 3,000 or more layers at a farm, and whose eggs receive a treatment. We have previously explained, in section III.B of this document, why we are proposing to exempt producers who sell all of their eggs directly to consumers and who have fewer than 3,000 laying hens at a farm from the SE prevention measure requirements.

Activities that are intrastate in character, such as the production and final sale of shell eggs to a retail establishment or institution for ultimate consumption by the consumer within one State, are subject to regulation under section 361 of the PHS Act when intrastate regulation is necessary to prevent the interstate spread of disease (*State of Louisiana* v. *Mathews*, 427 F. Supp. 174, 176 (E.D.La. 1977)). We tentatively conclude that the on-farm SE prevention measures in proposed §§ 118.1 through 118.10 must also apply to producers of shell eggs who sell their eggs intrastate, other than directly to consumers. The record in this rulemaking demonstrates that shell eggs can function as a vehicle for transmitting foodborne illness caused by *Salmonella* (Refs. 7, 8, and 9). Similarly, the record (Ref. 65) demonstrates that consumers, including tourists and other travelers, are likely to purchase intrastate raw shell eggs or products made with them. These consumers subsequently take the eggs or products back to their home state where the eggs or products are consumed, or the consumers carry a communicable disease back to their home state as a result of such consumption, thereby creating the risk that foodborne illness may be spread from one State to another as a result of such consumption. Although producers do not ship such eggs across State lines, there have been interstate SE outbreaks associated with such eggs (Ref. 66).

We believe that a regulation to require on-farm SE prevention measures or shell eggs produced and sold within a State would reduce the risk of SE illness. We are concerned that if we do not require on-farm prevention measures for shell eggs that are produced and sold in one state, the regulations will not prevent the introduction of SE contaminated eggs into other states and, thus, will not prevent the introduction of salmonellosis from one State to another. We tentatively conclude that the spread of salmonellosis among states from SE-contaminated eggs cannot be adequately controlled without extending the on-farm requirements to producers of eggs whose eggs are shipped within one state.

We are proposing to use our authority under section 361 of the PHS Act to institute recordkeeping requirements. We have previously imposed recordkeeping requirements under section 361 of the PHS Act in regulations governing blood and tissue products (parts 606, 640, and 1270) and juice (part 120).

Regulations governing blood and blood components require that records be kept covering each step in the their collection, processing, compatibility testing, storage and distribution and documentation covering shipping temperature and donor information (examination results, tests, laboratory data, interviews, written consent, and health certification) (§§ 606.160 and 640.72).

Recordkeeping requirements are also included in FDA's Human Tissue Intended for Transplantation regulations in part 1270, which also include requirements that records be maintained relating to infectious disease tests, donors, and the receipt, distribution, and disposition of human tissue (§ 1270.35).

HACCP systems regulations for juice also require significant recordkeeping. The regulations generally require each juice processor with a food hazard that is reasonably likely to occur to maintain a written hazard analysis and HACCP plan (21 CFR 120.12). The regulations further require that such processors maintain records documenting the implementation of the sanitation standard operating procedures, the ongoing application of the HACCP plan, verification of the HACCP system, and validation of the HACCP plan or hazard analysis. *Id.*

Section 361 of the PHS act provides FDA with authority to issue regulations necessary to prevent the introduction, transmission, or spread of communicable disease. Recordkeeping requirements are necessary for FDA to ensure that producers follow the sampling, testing, and, if necessary, diversion requirements under proposed part 118 for the production of shell eggs. We are proposing environmental testing as an indicator of whether a producer's SE prevention measures are effective. Testing would provide information on the SE status of a poultry house and indicate the need to take appropriate action if the measures were not preventing SE. Under the proposed rule, a positive environmental test would necessitate review of the implementation of SE prevention measures and testing of eggs (unless all eggs in the poultry house are subsequently diverted for the life of the flock). Testing would reduce the number of SE-positive eggs that reach consumers by: (1) Improving the effectiveness of SE prevention measures by indicating when prevention measures are ineffective and need to be modified and (2) triggering diversion to treatment of SE-positive eggs.

Records of SE testing are needed to allow FDA to determine whether SE prevention measures are being implemented in an effective manner over time. Furthermore, FDA personnel may not be present when producers perform environmental sampling and collect eggs for testing. Records would allow FDA to verify that sampling is done in a scientifically valid manner and that the required testing is conducted. Records would also allow FDA to confirm test results and that producers are taking appropriate actions based on the results (e.g., reassessment, additional testing, diversion). The records would provide assurance, to both the producer and FDA, that the risk of SE-contaminated eggs being provided to consumers is being minimized, either through an SE-negative poultry house or diversion of SE-contaminated eggs.

In addition to having the authority under the PHS Act to require recordkeeping, we believe we also have the authority to require access to the records. Because the on-farm sampling, testing, and diversion requirements are necessary to minimize the risk of communication of salmonellosis, access to records that demonstrate a farm has followed such requirements in part 118 is essential to confirm compliance and achieve the full benefits of the rule. We also have the authority, under section 361 of the PHS Act, to copy the records when necessary. We may consider it necessary to copy records when, for example, our investigator may need assistance in reviewing a certain record from relevant experts in headquarters. If we are unable to copy the records, we would have to rely solely on our investigators' notes and reports when drawing conclusions. In addition, copying records will facilitate followup regulatory actions. Therefore, we have tentatively concluded that the ability to access and copy records is necessary to enforce the rule and prevent the spread of communicable disease. A failure to comply with the rule's records provisions would subject the producer to the administrative procedures under proposed § 118.12. In other relevant sections of this document, we explain in more detail the recordkeeping provisions that we believe are necessary and, because they are limited to what is necessary, that we believe do not create an unreasonable recordkeeping burden.

Under the PHS Act, the Federal, State, and local governments have a long tradition of cooperation. The PHS Act specifically recognizes cooperation between the Federal, State, and local governments as an important tool for public health officials. Previously, in the area of food safety, FDA has used portions of the PHS Act (e.g., sections 310 and 311 (42 U.S.C. 242 and 243)) that focus on Federal assistance to the States. The Conference for Food

Protection (CFP) and the Food Code are a result of Federal, State, and local cooperation and Federal assistance to States and localities under the PHS Act. Section 311 of the PHS Act not only recognizes Federal assistance to the States, but it also recognizes that States and localities may be able to assist the Federal Government. This section provides in part: "The Secretary is authorized to accept from State and local authorities any assistance in the enforcement of quarantine regulations made pursuant to this Act which such authorities may be able and willing to provide."

We believe that, under sections 311 and 361 of the PHS Act, there are several ways we could accept assistance from the States in the enforcement of the on-farm regulation. For example, FDA could accept State and local assistance in the inspection of shell egg farms and then use those inspections as the basis for detention and diversion or destruction under proposed § 118.12 (as discussed in section III.K of this document) or as the basis for an enforcement action under the FFDCA. Another option would be to authorize the States and localities to conduct inspections and enforce the on-farm requirements through the administrative enforcement remedies set out in proposed § 118.12, while FDA could hear appeals with judicial review available after FDA's decision. FDA also believes that sections 311 and 361 of the PHS Act authorize the agency to issue a regulation that would allow States and localities to enforce the SE prevention on-farm requirements themselves.

After examining these options, FDA has tentatively concluded that all except the last option (allowing States and localities to enforce the requirements themselves) would prove too cumbersome. FDA believes that a cooperative approach would be the most effective means to enforce the on-farm requirements. We are proposing a similar approach to the one chosen for the egg labeling and refrigeration regulations (parts 101 and 115). Specifically, FDA has tentatively decided to allow agencies of those States and localities that are able and willing to inspect or regulate shell egg producers, as authorized under sections 311 and 361 of the PHS Act, to enforce the SE prevention measures along with FDA. FDA recognizes that States and localities currently do this type of enforcement and has tentatively concluded that this option will be the most effective and efficient use of Federal, State, and local food safety resources. Accordingly, proposed § 118.12(c) provides that those States and localities that are able and willing are authorized under sections 311 and 361 of the PHS Act to enforce proposed §§ 118.1 through 118.10 using the administrative procedures in § 118.12, as set out in section III.K of this document. With respect to the hearing procedures, we recognize that many States and localities already have administrative procedures in place for hearings. The proposed regulation would allow them to use a similar hearing process as long as that process satisfies basic due process requirements.

FDA recognizes that some of these are new approaches to enforcement of food safety regulations, and is soliciting comments on this aspect of this proposed regulation. FDA is particularly interested in comments on how State, local, and Federal food safety authorities can best work together to ensure effective and efficient implementation and enforcement of food safety standards.

M. Response to Comments Related to On-Farm Prevention Measures

In this section, we are responding to comments that the agency received in response to the 1998 joint FDA/USDA ANPRM on *Salmonella* Enteritidis in eggs and in response to the public meetings on egg safety that the agency sponsored with USDA in Columbus, OH (March 30, 2000), Sacramento, CA (April 6, 2000) and Washington, DC (July 31, 2000). FDA/USDA received approximately 73 letters to the 1998 ANPRM (Docket No. 97N–0322), each containing one or more comments. We received approximately 370 letters to Docket No. 00N–0504 for the public meetings on egg safety, each containing one or more comments. Comments on both the ANPRM and the public meetings were received from egg farmers, egg packers, trade associations, consumers, consumer interest groups, animal interest groups, academia, State government agencies, and foreign government agencies. We are responding to comments received to these dockets to the extent that they are relevant to this proposal.

(Comment 1) A few comments stated that it is not necessary to establish regulations for egg safety because the risk of illness from an SE-contaminated egg is low. Comments referenced the SE Risk Assessment in stating that the risk of an egg being contaminated with SE is 0.005 percent. In addition, 30 percent of the 3.3 million eggs that are contaminated annually are used for the production of egg products that are pasteurized and, therefore, do not result in illness. Comments maintained that the risk of illness from the remaining 2.3 million SE-contaminated eggs is less than the risk from consuming other high-protein foods and, therefore, is acceptable and does not warrant Federal regulatory action.

(Response) We do not agree with these comments. We believe that the current risk of illness from consuming SE-contaminated eggs is still too high, especially when there are cost-effective measures that can be taken that will reduce the risk. In 2001, the isolation rate of SE was 2.0 per 100,000 population and the contribution of SE (corrected for underreporting) to total salmonellosis was estimated to have been 213,046 illnesses, including 2,478 hospitalizations, and 87 deaths (Refs. 4 and 5). We estimate that the cost to society of egg-associated SE illnesses in a year is $1.8 to 3.1 billion. (See discussion in the Preliminary Regulatory Impact Analysis in section V. of this document.)

As to the argument that eggs do not carry the same risk as other high protein foods (presumably meat and poultry), this is not a reason to ignore the risk from eggs. USDA has instituted HACCP programs to reduce the risk of foodborne illness from meat and poultry. Likewise, we are proposing measures in this proposed rule to reduce the risk of foodborne illness from eggs because there are practical steps that can be taken to reduce that risk. Consumers also are more aware of the risks associated with consuming undercooked meat and poultry than they are of the risks of consuming raw or undercooked eggs (Ref. 23). Thus, we disagree with this comment and believe that the risk of foodborne illness from consumption of SE-contaminated eggs is too high and warrants Federal regulatory action.

(Comment 2) Several comments stated that not enough is known about the ecology of SE to develop credible on-farm prevention measures. The comments further stated that the relationship between an environment that is contaminated with SE and an egg that is contaminated with SE has not been established and, therefore, it is not possible to develop appropriate SE prevention measures.

(Response) We do not agree with these comments. As stated in section III.E of this document, data from the SE Pilot Project have shown that certain measures (e.g., rodent and pest control, biosecurity, use of SE-monitored chicks, and cleaning and disinfection) have been effective in reducing the number of poultry houses with SE-positive environments (Ref. 39). When these measures were implemented, the number of positive houses decreased

from 38 to 13 percent over a 3-year period. Although we agree that more information is needed on the ecology of SE, we believe that prior experience from voluntary egg QA programs has indicated that there are preventive controls that can be implemented on a farm that will prevent SE contamination of eggs.

We agree that the exact relationship between an environment that is contaminated with SE and an egg that is contaminated with SE is not known. However, data from existing QA programs have indicated that, when a poultry house environment is contaminated with SE, the prevalence of SE-contaminated eggs is approximately 1 in 3,600 or, as estimated in the SE risk assessment, 1 in 1,400. A prevalence of SE-contaminated eggs of 1 in 1,400, or even 1 in 3,600, is unacceptable from a public health standpoint. Preventive measures have been developed to prevent the SE-contamination of poultry houses on a farm, which would reduce the production of SE-contaminated eggs that may cause foodborne illness. Therefore, it is appropriate that we take steps to ensure that producers are employing these preventive measures to reduce the prevalence of SE-contaminated eggs by proposing to require use of the SE prevention measures.

(Comment 3) One comment stated that on-farm prevention measures are not necessary because most of the outbreaks of SE illness can be attributed to improper food handling.

(Response) We do not agree with this comment. Although we are aware that many outbreaks of foodborne illness occur as a result of cross contamination during food handling, many egg-associated SE outbreaks have been traced back to eggs contaminated during production. In section II.A of this document, we discuss several outbreaks that were traced back to eggs from farms that had SE-positive environments at the time of traceback. In addition, the increase in egg-associated SE outbreaks in the mid-1980s occurred at the same time that transovarian contamination of SE in eggs was first being detected. Although proper handling by retailers and consumers can reduce egg-associated illnesses, it is important to take practical measures to prevent eggs from becoming contaminated with SE in the first place.

(Comment 4) Many comments maintained that induced molting of laying hens is cruel to the birds and contributes to SE contamination of eggs and, therefore, should be banned. In support of this position, these comments cited the information outlined in the petition from United Poultry Concerns, Inc., and the Association of Veterinarians for Animal Rights (described in section II.J of this document) and data on induced molting collected during the SEPP.

(Response) The issue of whether induced molting should be stopped because it is cruel to laying birds is outside the scope of this proposed rule. With regard to the assertion that induced molting should be banned because it contributes to SE contamination of eggs, we do not agree with that comment at this time. However, we seek comment, discussed below, on whether certain practices related to molting are appropriate to reduce SE contamination of eggs within a poultry house.

Several studies (described in section II.J of this document and (Ref. 67)) have been cited in comments as evidence for the claim that induced molting increases SE contamination of eggs and, thereby, SE illness in consumers. Comments have cited studies by Holt and coworkers that indicate that induced molting impairs the laying hens' immune systems and invites SE infection. While we agree that the previously mentioned studies have implications with regard to the health of laying hens, the studies do not address infection of eggs from these birds and, therefore, cannot be interpreted to conclude that induced molting increases SE contamination of eggs (Ref. 67).

The comments also cited studies by Holt and coworkers on the relationship between indigenous intestinal microflora and induced molting. These studies noted a difference in the kinetics of intestinal infection between molted and unmolted birds but did not link intestinal microflora to intestinal infection and did not discuss transmission of SE to eggs. Studies by Henzler and Opitz (Ref. 48) linking induced molting and rodents in the poultry house environment were cited in comments. Although research has indicated that rodents are an important factor in the epidemiology of SE in the poultry house, no evidence exists that correlates infected rodents to molting (Ref. 67).

Comments requesting that we ban induced molting cited a study by Holt (Ref. 68) linking stress in molted hens to transmission of SE within a poultry house. Possible stress during molting has been suggested as a cause for increased intestinal shedding of SE, which then increases transmission of SE within a poultry house, observed in the Holt study. However, the author of the study did not provide evidence to support the hypothesis that stress increases intestinal shedding of SE, which then increases transmission of SE within a poultry house. The author also suggested several other factors aside from induced molting that could result in increased transmission of SE to uninfected hens (Ref. 67).

The comments also cited a study by Bailey and coworkers (Ref. 69), as well as the Holt study (Ref. 68), that linked consumption of SE-contaminated feathers during molting with increased infection. Although feather consumption has been observed in molted hens, and some researchers have noted that this behavior could contribute to the spread of *Salmonella* in a poultry house, there is no evidence to suggest that the behavior is related to stress-induced colonization of SE in molted hens (Ref. 67).

According to the comments, the environment, such as crowded conditions, in which induced molting is conducted also encourages SE infection and multiplication. Although induced molting in crowded conditions may exacerbate transmission of SE, there is little or no evidence to suggest that molting in crowded conditions affects SE transmission any more than would molting or crowding independently.

The comments also cited studies by Holt (Ref. 68), by Nakamura, and by Seo and coworkers (Ref. 70) indicating that induced molting increases fecal shed of SE and that induced molting promotes horizontal transmission of SE within a poultry house. We agree that molting induced by withholding feed increases fecal shedding of SE in birds infected with SE in laboratory environments and increases horizontal transmission of SE among birds. Therefore, we question whether certain practices related to molting on a farm may be appropriate to reduce SE contamination of the environment and, thus, to decrease production of SE-contaminated eggs.

In addition to concerns we have already expressed, we note that most of the research conducted on induced molting was done in conditions that limit its applicability. Most studies have been done with single lines of specific pathogen-free chickens that have been exposed to a narrower range of microflora than commercial laying hens. Therefore, the pathogen-free chickens may be immunologically naïve and, consequently, may be more susceptible to serious infection than commercial laying hens. Studies also have been performed in controlled laboratory settings that do not accurately represent the conditions in a poultry house. Finally, molting experiments have typically relied on very high populations of a single, laboratory

modified, and propagated strain of SE. Behavior of single strains may not indicate behavior of populations of wild strains of SE.

The comments opposed to molting also have stated that field data, which was used in the SE risk assessment, from the SEPP indicated that molted birds lay more SE-contaminated eggs and, therefore, molting should be prohibited for public health reasons (Ref. 71). In addition, the comments maintained that statements made by Dr. John Mason indicated that forced molting caused increased SE-contamination of eggs.

We agree that the field data collected in the SEPP suggest a link between molting and production of SE-contaminated eggs. However, we have several concerns about the conclusiveness of these data. First, there may have been bias in sampling because flocks participating in the SEPP were chosen by producers who may have had a tendency to choose flocks that were known to be SE-positive in order to implement procedures that might change the SE status of those flocks. Therefore, these flocks may not be representative of all flocks. Second, the SEPP report indicates that the authors realized that differences in egg contamination that were being attributed to molting may also be a result of the age of the layers since only older flocks are molted. With regard to the statements made by Dr. John Mason, he has indicated that, when he made statements about forced molting causing increased SE-contamination of eggs, he was referring to information from the SEPP study and research discussed in the previous paragraphs (Ref. 72).

At this time we do not believe that we have adequate data upon which to rely for a final decision on the issue of the relationship between induced molting and SE contamination of the environment and of eggs. We know that research currently is being conducted that will address several of these data gaps. To discuss some of the research and address the data gaps, FDA sponsored an SE research meeting in Atlanta, GA, on September 8, 2000 (65 FR 51324, August 23, 2000). Ongoing research that was generated or discussed at the meeting includes projects on alternative diets for laying hens undergoing molting and an on-farm study to evaluate the effect of molting on SE in eggs.

We specifically request comment and data related to our discussion of induced molting. In view of the scientific data that suggest that molting by feed withdrawal may increase shedding of SE into the environment or eggs (Refs. 68, 70, and 71), we seek comment on the following potential prevention measures that we may consider for inclusion in any final rule: (1) The use of alternative diets to replace feed and water withdrawal to induce molting, (2) the use of competitive exclusion (defined in footnote 3 of this document) to reduce fecal shedding of SE during molting, (3) more frequent removal of manure during and immediately following molting, (4) alternative timing for environmental testing or additional environmental testing during or immediately following molting, and (5) a prohibition of molting in SE-positive houses. Depending upon the comments received, we will consider including provisions regarding molting in any final rule. These provisions may include, but are not limited to, the need for additional testing of molted flocks or restrictions on the manner in which a molt may be induced.

(Comment 5) Many comments addressed the use of vaccines for laying hens as an intervention against SE contamination of eggs. Several comments stated that vaccines against SE have been proven effective in field trials undertaken through PEQAP; flocks in the PEQAP program that were vaccinated against SE had significantly fewer environmental samples positive for SE than nonvaccinated flocks. In addition, no SE-positive eggs from a vaccinated flock were found during the 3-year study period. A few comments stated that vaccinating flocks against SE would have the most significant impact on SE prevention of any possible intervention. In addition, a few comments recommended vaccination for a flock placed in a poultry house if the previous flock in that house had a positive SE environmental test. Conversely, other comments stated that the data from the PEQAP study were inconclusive because too few flocks were included in the study.

(Response) We agree that vaccines show promise in reducing the prevalence of SE in laying hens. The PEQAP data indicate that the SE bacterin vaccines used in that program were 70 percent effective in reducing SE-positive environmental samples in flocks (Ref. 73). We find these data to be encouraging. In addition, field trials in ME showed that vaccination significantly reduced the mean fecal counts of vaccinated birds compared to nonvaccinated birds (Ref. 74). We are also aware that some existing egg QA programs require their participants to vaccinate replacement flocks that are being placed into a house that had an environmental SE-positive while the previous flock occupied that house.

However, we also agree that more information on the effectiveness of vaccines needs to be generated before we would mandate vaccination as an SE prevention measure. Although approximately 900 flocks participated in the vaccination field trials in the PEQAP study, less than 100 of those flocks were vaccinated (Ref. 73). Only seven poultry houses participated in the ME field trials, three of which contained vaccinated birds (Ref. 74).

Vaccines are also expensive and labor intensive; we estimate that vaccines cost 13.5 cents per layer, including labor (see discussion in the Preliminary Regulatory Impact Analysis in section V. of this document). Members of our national egg safety standards working group indicated that vaccines are only economically justified for heavily contaminated flocks. Since we know that cleaning and disinfection can decontaminate an SE-positive poultry house (Ref. 39), we do not believe that it is currently appropriate for the agency to propose to require that producers incur the additional cost of mandatory vaccines when cleaning and disinfection, biosecurity, and rodent and pest control may resolve the problem. We encourage producers to use vaccines in the case of persistent SE contamination within a poultry house or as prescribed by a veterinarian, but do not believe that we currently can justify mandating their use.

(Comment 6) A few comments maintained that there is no indication that feed or water has ever been associated with transfer of SE to laying hens and should not be included in the required SE prevention measures. However, one comment stated that potable water should be one of the SE prevention requirements, and several comments stated that SE-negative feed should be included in mandatory SE prevention measures.

(Response) Although we acknowledge that feed and water cannot be ruled out as potential sources of SE contamination in poultry houses, we believe provisions for feed and water are not necessary in the required SE prevention measures. We are proposing to establish minimum national SE prevention measures, and evidence of feed and water being the source of SE contamination of laying hens or shell eggs is rare.

Although SE contamination of feed has been documented by researchers, SE contaminated feed has not been implicated in the occurrence of SE in laying hens or in eggs in the United States. However, as the Layers study indicated, many producers perform

some testing of feed or feed ingredients for SE (Ref. 25). We encourage this as a general good management practice.

Water has not been directly implicated in the transfer of SE to laying hens and, therefore, we have not included it in the proposed provisions in proposed § 188.4. However, we encourage producers to ensure that their water meets the microbiological standards established by the Environmental Protection Agency for potable water.

(Comment 7) Several comments stated that routine, complete cleaning of poultry houses is not practical, particularly if the house is SE-negative. A few comments also maintained that wet cleaning and disinfection of poultry houses, while it may reduce SE, is not practical in colder months.

(Response) We agree that cleaning and disinfection of poultry houses is not warranted to reduce SE if the house is SE-negative. Although cleaning and disinfection of an SE-negative poultry house at depopulation may be prudent for the control of avian diseases, and dry cleaning and manure removal at depopulation are prudent practices in general, we do not have data and information that suggest that cleaning and disinfecting an SE-negative poultry house would reduce the incidence of SE-contaminated environments or SE-contaminated eggs. In § 118.4, we are proposing to require that, if an environmental test or an egg test is positive for SE, then you must clean and disinfect the poultry house before new laying hens are added to the house. If the environmental test is negative, then cleaning and disinfection is not needed to decontaminate the house of SE. However, we recommend manure removal and dry cleaning of poultry houses between occupation by laying flocks as a general good management practice.

We recognize that there are situations in which it may be difficult for producers to wet clean a poultry house (i.e., winter months, dirt floors). Data from a voluntary QA program (Ref. 39) and the NAHMS SE study (Ref. 27) indicate that wet cleaning is effective in decontaminating SE-positive poultry houses. However, as we discussed in section III.E.4 of this document, there are some studies in which wet cleaning may have resulted in some previously SE-negative poultry houses becoming positive. Even so, based on the totality of the information we presently have, we believe that wet cleaning results in an overall reduction in the number of SE-positive poultry houses sufficient to justify its inclusion in the required SE-prevention measures. We plan to consider comments we receive on the issue and any other new evidence before deciding whether to require wet cleaning in a final rule.

(Comment 8) One comment stated that FDA should address on-farm washing of eggs because certain producers wash eggs before they are sent to a packer/processor.

(Response) We do not agree with this comment. We are not aware that on-farm washing of eggs in an offline operation (i.e., an operation that sends its eggs elsewhere for processing for retail sale) is a widespread practice. The Layers study indicated that prewashing of eggs before processing was practiced on only 5 percent of farms (Ref. 26). We would discourage the practice unless producers follow the procedures for proper egg washing outlined by USDA in 7 CFR 56.76(e).

We request comment specifically on the prevalence of on-farm washing of eggs in offline operations. If comments indicate that prewashing of eggs on the farm is more prevalent than indicated in data the agency currently have, we may consider adding a provision for washing of eggs to the required SE-prevention measures.

(Comment 9) Several comments stated that egg testing and diversion should not be used as SE management tools and that these activities would just divert producers' attention away from practices that will reduce SE in poultry houses.

(Response) Although we agree that egg testing itself is not an SE management tool, diversion of eggs that may be contaminated with SE from the table egg market is a method of preventing consumer illness and may be considered an SE management tool. In addition, we do not agree that egg testing and diversion will divert producers' attention away from SE prevention measures. We are proposing to require egg testing only if the environmental test is SE-positive.

As stated previously, data have indicated that flocks in an SE-contaminated environment produce SE-contaminated eggs with greater than average prevalence (see comment 2 of this section). These contaminated eggs could reach the consumer and cause foodborne illness. It is an important public health precaution for a producer to begin egg testing upon finding that the poultry house environment is contaminated with SE. If egg testing reveals that SE-contaminated eggs are being produced by a flock, the eggs from that flock must be diverted to a treatment as defined in § 118.3. Diversion prevents foodborne illness that might occur had those contaminated eggs reached a consumer. Prevention of egg-associated foodborne illness is the goal of the provisions in this proposed rule. We are proposing, in § 118.6, egg testing protocols by which a producer who must divert eggs can return, after certain testing conditions are met, to producing eggs for the table egg market.

(Comment 10) A few comments stated that any requirements that mandated diversion of shell eggs to breaking facilities would be devastating to the Hawaiian egg industry because there are no egg breaking facilities in HI.

(Response) We recognize that HI presently has no egg breaking facilities to which eggs can be diverted. We will consider the status of egg breaking facilities in HI prior to issuing any final rule and seek further comment in this proposed rule on options for handling diverted eggs in HI.

(Comment 11) Many comments stated that environmental testing is appropriate to indicate whether SE prevention measures are working effectively; however, a few comments noted that other methods (e.g., egg yolk antibody testing) may prove to be equally effective as environmental testing and could also be used to gauge the effectiveness of SE prevention measures.

(Response) We agree with these comments. We have stated in the proposal that environmental testing must be used to evaluate the effectiveness of the SE prevention measures and have discussed various methods to sample manure in a poultry house. However, we have also solicited comment on alternative methods of sampling the environment that may be more uniform in different styles of poultry house than manure testing. We encourage the development of methods that are at least as indicative of SE contamination in a poultry house as manure testing and that are more rapid and less expensive.

(Comment 12) Several comments stated that any SE prevention measures required for producers should take into account regional differences in the egg industry.

(Response) We agree with the comments. In this proposed rule, we are proposing to require specific controls for SE prevention, but are not specifying the exact manner in which individual producers must comply with the provisions. Each producer must develop SE prevention measures that are appropriate for his unique situation, including regional differences. We recognize there are regional differences in the egg industry and anticipate that they will be reflected in the specific SE

prevention measures. For example, producers with different poultry house styles (e.g., open-sided versus enclosed) may choose to perform rodent control or cleaning and disinfection in different manners, as the most effective method may be differ depending on house style.

(Comment 13) A few comments requested that, if egg testing is required, the number of eggs tested be based on flock size.

(Response) We do not agree with this comment. We believe that it is reasonable to require that producers with 3,000 or more laying hens test a total of 4,000 eggs in 4 1,000-egg samples, should their poultry house be SE-positive. It is important that enough eggs be tested to achieve a certain level of assurance that SE is not present in the eggs (see discussion in section III.G.2 of this document and (Ref. 61)).

(Comment 14) Several comments requested that multiple environmental tests be required during the life of a flock to ensure that the maximum number of contaminated eggs is being diverted from consumption as table eggs.

(Response) In this proposed rule, we are establishing minimum environmental testing requirements as an indicator of the effectiveness of SE prevention measures. We do not agree that multiple environmental tests are necessary. This minimum testing requirement does not preclude producers from testing more frequently during the life of a flock. To reach the public health goal of reducing SE illnesses, we have proposed to require that producers use their resources towards implementing measures that will prevent SE contamination of eggs. These measures include use of chicks and pullets from SE-monitored breeder flocks, biosecurity, rodent and pest control, cleaning and disinfection of an SE-positive poultry house, and refrigerated storage of eggs held at a farm more than 36 hours. Testing alone does not reduce SE contamination of eggs. We believe that environmental testing can be a useful indicator of whether the SE prevention measures are working effectively. We believe one environmental test per laying cycle per flock in a poultry house is sufficient as an indicator of the efficacy of the prevention measures. (See discussion in section III.F.1 of this document.)

N. Transportation of Shell Eggs

To reach the goal of significantly reducing SE illnesses, egg safety measures must be put in place along the entire farm-to-table continuum. FDA is coordinating efforts with FSIS to cover the refrigeration of shell eggs throughout distribution. Refrigerated transport and storage of eggs packaged for the ultimate consumer and refrigerated storage of eggs at retail are already required by regulation (discussed previously in section II.D.1 of this document). In a future proposed rulemaking, FSIS may consider applying safety standards to the transport of eggs from packer to packer and from packer to egg products processing plant. In order to close any gaps in the farm-to-table continuum, FDA is seeking comment on whether to require refrigerated transport of shell eggs not already required by regulation or within USDA's jurisdiction; for example, transport of shell eggs from a farm or a packer to a food manufacturing facility. We will consider putting into place requirements similar to those we finalized for refrigerated storage of shell eggs at retail (i.e., transport of shell eggs at or below 45 °F ambient temperature).

IV. Handling and Preparation of Eggs by Retail Establishments

A. Inappropriate Handling of Raw Shell Eggs by Food Preparers

SE outbreak investigations show that outbreaks commonly occur when foods prepared with raw shell eggs are not properly handled by food preparers. Common inappropriate practices for foods containing SE-contaminated shell eggs include temperature abuse (e.g., failing to keep eggs and foods prepared with eggs refrigerated) and inadequate cooking. When shell eggs are combined to prepare a large volume of an egg-containing food which is subsequently temperature abused or inadequately cooked, these practices can cause illness in large numbers of people if any of the shell eggs were initially contaminated with SE.

Temperature abuse gives SE the opportunity to multiply, thereby increasing the number of viable microorganisms ingested, especially when eggs are consumed raw. Temperature abuse and consumption of raw shell eggs were associated with an SE outbreak at a catered wedding reception in New York, where Caesar salad dressing was implicated as the cause of SE illnesses. The Caesar salad dressing was made with 18 raw shell eggs, left unrefrigerated for 2 hours at the catering establishment, held in an unrefrigerated truck until delivered, and served at the reception 4.5 hours later (Ref. 64).

Incomplete cooking of raw shell eggs (e.g., soft-boiled, sunny-side-up, and soft-poached) also allows ingestion of viable microorganisms if any of the eggs were initially contaminated. In 1997, incomplete cooking of raw shell eggs was associated with an SE outbreak in Nevada where the consumption of Hollandaise sauce served in a restaurant was linked to SE illnesses. Review of the food handling practices showed that the sauce had been prepared from raw shell eggs that were combined, incompletely cooked, and held at room temperature for several hours before serving (Ref. 7).

We also are aware that many consumers eat foods containing raw or undercooked shell eggs. An FDA survey indicated that 53 percent of 1,620 respondents ate foods containing raw shell eggs at some time (Ref. 75). Raw shell egg-containing foods mentioned in this survey included cookie batter, homemade ice cream, homemade eggnog, Caesar salad, frosting, homemade shakes, homemade Hollandaise sauce, and homemade mayonnaise. The Menu Census Survey (1992 through 1995) (Refs. 76 and 77) showed that frosting accounted for 53 percent and salad dressing 19 percent of occasions when raw shell egg-containing products were consumed.

The 1996 to 1997 Food Consumption and Preparation Diary Survey (Ref. 77) showed that 27 percent of all egg dishes consumed were undercooked (described as being runny or having a runny yolk or runny white). On average, each person consumed undercooked shell eggs 20 times a year. Within the at-risk groups, women over 65 and children under 6 consumed undercooked shell eggs 21 times a year and 8 times a year, respectively. Moreover, consumer focus group research showed that many participants did not realize that certain foods, such as chocolate mousse or key lime pie, may contain raw or undercooked shell eggs and, therefore, are potentially hazardous (Ref. 78).

B. SE and Highly Susceptible Populations

Certain populations, such as children, the elderly, and immunocompromised individuals, are more likely to experience severe health problems from eating SE-contaminated eggs than the general population (Ref. 16). For example, CDC reported that 54 of the 79 deaths associated with outbreaks of SE between 1985 and 1998 were of individuals in nursing homes (Ref. 79). In addition, the agency found that the likelihood of dying from a foodborne illness contracted in a nursing home was 13 times higher than outbreaks in other settings. According to a U.S. General Accounting Office (GAO) survey of State regulatory officials, 24 states reported that they did not require food service operators that serve highly

susceptible populations to use pasteurized eggs for any food item that usually contains raw eggs or (2) is prepared by cracking, combining, and holding a number of eggs prior to cooking or after cooking and prior to service (Ref. 79). A 1998 Dietary Managers Association survey of 136 private nursing homes, hospitals, and other care facilities and 23 Air Force hospitals across the nation showed that 35 percent of these institutions use raw eggs to prepare batters for foods that may not be fully cooked, such as French toast (Ref. 79).

C. The FDA Food Code

As noted in section II.D.3 of this document, the FDA Food Code provides FDA's best guidance to state and local authorities and to retail industry on how to prevent foodborne illness, including special provisions for those establishments that serve a highly susceptible population. To date, 41 of 56 States and territories, representing 76 percent of the population, have adopted codes patterned after some version (1993 or later) of the FDA Food Code. Twenty-one of those States and territories (35.3 percent of the population) have adopted codes patterned after the 1999 FDA Food Code, and 2 (2.3 percent of the population) have adopted codes patterned after the 2001 version. Moreover, agencies in 11 of the 15 remaining States and territories that have not adopted a new code since 1993 are in the process of doing so, and many efforts at adoption are targeted for completion in 2003. Therefore, in 2003 and under the current system of state adoption, most state and local authorities, as well as retail industry, will be administering some aspects of FDA's best guidance as detailed in the FDA Food Code. The egg-relevant safe handling and preparation practices can be found in sections 3–202.11(C), 3–202.13, 3–202.14(A), 3–401.11(A)(1)(a) and (2), and 3–801.11(B)(1) and (2), (D)(1) and (2), and (E)(1) and (2) of the 2001 FDA Food Code.

D. Request for Comments

As noted previously, the incidence and geographical distribution of egg-associated SE illnesses have made SE a significant public health concern. As discussed in section II.A of this document, data from SE outbreaks show that outbreaks can occur when contaminated eggs are mishandled by food preparers. Furthermore, consumption data establish that some consumers, including highly susceptible populations, eat raw or undercooked eggs.

Many comments to the May 1998 ANPRM and year 2000 public meetings maintained that proper handling of shell eggs is an important measure that could reduce the incidence of foodborne illness. Some contended that we should mandate those provisions of the FDA Food Code related to egg safety. At the public meetings and in the current thinking document distributed at the July 2000 current thinking meeting, FDA presented a farm-to-table approach that proposed regulations to codify all egg-related provisions of the FDA Food Code. Given State and local government authority to manage retail food safety within their jurisdictions, FDA is now requesting comment on whether: (1) The current FDA Food Code system with State adoption and implementation achieves the desired public health outcome among high-risk populations or (2) the public health outcome for high-risk populations can only be achieved through mandatory Federal standards and, if so, how those standards would be best implemented. We consider high-risk populations to be those persons who are more likely than other people in the general population to experience foodborne disease because of the following reasons: (1) Immunocompromised, preschool age children, or older adults and (2) obtaining food at a facility that provides services such as custodial care, health care, or assisted living, such as a child or adult day care center, kidney dialysis center, hospital, or nursing home, or that provides nutritional or socialization services, such as a senior center.

If you contend that the desired public health outcome for high-risk populations can only be achieved through mandatory Federal standards, we specifically request comment on which, if any, of the following measures should be mandated for retail establishments that serve highly susceptible populations:

- Using raw eggs that are clean, sound, and meet the restricted egg tolerances for U.S. Consumer Grade B, which minimizes the entry of surface bacteria to the inside of eggs;
- Using raw eggs that have been transported under refrigeration, because refrigeration lengthens the effectiveness of the eggs' natural defenses against SE and slows the growth rate of SE;
- Using only egg products that have been pasteurized in accordance with USDA's requirements under 9 CFR 590.570, which are designed to kill or inactivate SE and other bacteria;
- Cooking raw eggs and raw egg-containing foods thoroughly, which kills viable SE that may be present;
- Substituting eggs treated to achieve at least a 5-log destruction of SE or pasteurized egg products for raw eggs in the preparation of foods, e.g., soft-boiled, poached, or sunny-side-up eggs, meringue, Caesar salad, hollandaise or Béarnaise sauce, homemade mayonnaise, eggnog, homemade ice cream, that will be served undercooked, which minimizes the risk of egg-associated SE illnesses in consumers of those foods; and
- Substituting eggs treated to achieve at least a 5-log destruction of SE or pasteurized egg products for raw eggs in the preparation of foods where eggs are combined, since combining raw eggs to prepare a large volume of food that is subsequently temperature-abused or inadequately cooked can cause illness in large numbers of people if any of the eggs were initially contaminated with SE.

If FDA were to require any of these measures, we would rely on section 361 of the PHS Act, just as we are relying on it for the requirements we are proposing in this document. (See section III.L of this document.)

E. Response to Comments Related to Retail Standards

(Comment 1) Several comments maintained that the agency should place a greater emphasis on the retail segment of the farm-to-table continuum because that is where the majority of the SE outbreaks occur, with the implicated food containing undercooked eggs.

(Response) We disagree with this comment. We do not believe that a greater emphasis should be placed on any one segment of the farm-to-table continuum, i.e., producer, packer, processor, or retail establishment. In this document, FDA is proposing requirements for the producer to produce safe eggs. As stated in section II.G of this document, FSIS will develop standards for the packer to maintain the safety of eggs, and for the processor to further enhance the safety of eggs. At retail, the FDA Food Code provides guidance on handling and preparing raw eggs to maintain or enhance egg safety. Additionally, we are seeking comment on whether we should require facilities that specifically serve a highly susceptible population to follow certain safe handling and preparation practices for raw eggs.

Most SE outbreaks occur at retail establishments because that is where the same food is served to large numbers of people. This does not mean that retail establishments cause the majority of SE outbreaks due to eggs. Rather, the cause is a combination of factors starting at the producer level, where the eggs may

become contaminated, and extending to the retail level, where inappropriate handling or preparation practices may not eliminate or minimize the impact of the contamination.

(Comment 2) Many comments supported Federally-mandated food safety education, training, and certification for retail food service managers and employees.

(Response) We agree that food safety education and training for retail food service managers and employees is necessary, and manager certification is a useful means of demonstrating food safety knowledge; however, FDA has not decided whether food safety training and certification should be Federally mandated. FDA has actively promoted industry food safety training and certification, and encouraged joint regulatory-industry-academia training initiatives.

Presently, there are a wide variety of industry management training and certification programs being offered by regulatory agencies, academic institutions, food companies, industry groups, professional associations, and third-party organizations. Most certification programs share a common desire to have the food manager certificate they issue universally recognized and accepted by others, especially by the increasing number of regulatory authorities that require food manager certification.

Certification programs vary in focus and primary mission of sponsors, organizational structures, staff resources, revenue sources, testing mechanisms, policies toward applicants and employers of food managers, and policies pertaining to such things as public information, criteria for maintaining certification, and the need for recertification. Where courses are offered, they vary in scope, content, depth and duration, quality of instructional materials, qualifications of instructors, and instructional approach (classroom, on-the-job, PC-based, home study, etc.). Where testing is a program component, varying degrees of attention are given to test construction and test administration as they relate to nationally accepted standards (reliability, validity, job analysis, subject weighting, cut scores, test security, etc.).

We believe in the utility of a mechanism for regulatory authorities to use in determining which certificates should be considered credible based on which certificate-issuing programs meet sound organizational and certification procedures and use defensible processes in their test development and test administration. Certified food protection managers are knowledgeable about the development, implementation and enforcement of specific policies, procedures, or standards aimed at preventing food borne illness. Specifically, they understand the concepts necessary for the identification of hazards, supervising or directing food preparation activities, coordinating training, and taking corrective action as needed to protect the health of the consumer. CFP recently has provided the standards and procedures necessary for the independent evaluation and accreditation of food protection manager certification programs. (The CFP, founded in 1971, is a non-profit organization designed to create a partnership among regulators, industry, academia, professional organizations, and consumers to identify problems, formulate recommendations, and develop and implement practices that ensure food safety.)

On May 28, 2002, the CFP entered into a cooperative agreement with the American National Standards Institute (ANSI) regarding the accreditation of certification bodies responsible for ensuring the food safety knowledge of all managers it certifies. (ANSI, a private non-profit organization, administers and coordinates the U.S. voluntary standards and conformity assessment system.)

On June 28, 2002, CFP published a revised version of "Standards for Accreditation of Food Protection Manager Certification Programs." These standards identify the essential components a Food Protection Manager Certification Program must meet for universal acceptance of its certificates. The standards have been developed after years of CFP research into, and discussion about, Food Protection Manager Certification Programs and are based on nationally recognized principles used by a variety of organizations providing certification programs for diverse professions and occupations.

In January 2003, ANSI assumed responsibility for accrediting certification bodies based on the CFP Standards for Accreditation of Food Protection Manager Certification Programs.

FDA has developed educational materials on safe egg handling and preparation practices for food preparers and anticipates making these materials widely available to all providers of food safety training or certification services. While these materials will address safe practices specific to eggs, we believe that all retail food service establishments should ensure that their managers and employees are properly trained in general safe food practices. We recommend that all retail food service establishments follow the management and personnel provisions in chapter 2 of the FDA Food Code, specifically sections 2–101, "Responsibility," 2–102, "Knowledge," and 2–103, "Duties." We further recommend that food regulatory officials recognize food managers who have been certified through an ANSI-accredited program as meeting the food safety knowledge requirement."

(Comment 3) One comment called for uniform recordkeeping requirements for retail establishments to facilitate traceback and recall activities.

(Response) In the FDA Food Code, FDA recommends the implementation of HACCP, of which recordkeeping is a vital component, in food establishments because it is a system of preventive controls that is the most effective and efficient way to ensure that food products are safe. Use of a HACCP system emphasizes the industry's role in continuous problem solving and prevention rather than relying solely on periodic facility inspections by regulatory agencies.

HACCP offers two additional benefits over conventional inspection techniques. First, it clearly identifies the food establishment as the final party responsible for ensuring the safety of the food it produces. HACCP requires the food establishment to analyze its preparation methods in a rational, scientific manner in order to identify critical control points (CCPs) where food safety hazards might occur and to establish critical limits and monitoring procedures. A vital aspect of the establishment's responsibility under HACCP is to establish and maintain records that document adherence to the critical limits that relate to the identified CCPs, thus resulting in continuous self-inspection.

Secondly, as recognized in the FDA Food Code, a HACCP system allows a regulatory agency to determine an establishment's level of compliance more comprehensively. A food establishment's use of HACCP requires development of a plan to prepare safe food. This plan and associated monitoring records must be shared with the regulatory agency so that the agency can verify that the HACCP plan is working. Using conventional inspection techniques, an agency can only determine conditions during the time of inspection, which provide a "snapshot" of conditions at the moment of the inspection. However, when evaluating an establishment using a HACCP approach, an agency can determine both current and past conditions. When regulatory agencies review HACCP

records, they have, in effect, the ability to look back through time. Therefore, a regulatory agency can better ensure that processes are under control. "HACCP Guidelines" are presented in annex 5 of the 2001 FDA Food Code.

In section III.J.8 of this document, we are seeking comment on whether we should require egg producers to maintain certain records.

(Comment 4) One comment stated that the risk of illness is not significantly increased if an egg is not fully cooked.

(Response) We do not agree with this comment. As stated in section IV.A of this document, SE outbreak investigations show that outbreaks can occur when foods prepared with SE-contaminated eggs are not appropriately handled by food preparers. Practices inappropriate for foods containing SE-contaminated eggs include temperature abuse (i.e., failing to keep the eggs and foods prepared with eggs refrigerated) and inadequate cooking. Combining raw eggs to prepare a large volume of an egg-containing food that is subsequently temperature abused or inadequately cooked can cause illness in large numbers of people if any of the raw eggs were initially contaminated with SE.

As discussed in section IV.A of this document, incomplete cooking of raw eggs (e.g., soft-boiled eggs, sunny-side-up eggs) can allow ingestion of viable microorganisms, including SE, if any of the eggs were initially contaminated. In 1997, incomplete cooking of raw eggs was associated with an SE outbreak in Nevada, where the consumption of Hollandaise sauce served in a restaurant was linked to SE illnesses. Review of the food handling practices showed that the sauce had been prepared from raw eggs that were combined, incompletely cooked, and held at room temperature for several hours before serving (Ref. 7). Another outbreak of SE illness in an Indiana nursing home was linked to the consumption of baked eggs. The baked eggs were prepared by combining 180 Grade A raw shell eggs, mixing with a whisk, and baking in a single pan at (an oven temperature of) 204 °C (400 °F) for 45 minutes to 1 hour. Investigators believed that inadequate cooking occurred because the mixture was not stirred while baked (Ref. 64).

(Comment 5) One comment asked that we cover rodent control and *Salmonella* monitoring in institutional and commercial kitchens as we would for producers as part of an on-farm SE prevention plan.

(Response) We disagree with this comment. As discussed in section IV.A of this document, SE outbreak investigations show that outbreaks occur when foods prepared with SE-contaminated eggs are not appropriately handled (i.e., temperature abuse, undercooking, combining more than one egg) by food preparers. Although the retail establishment environment may be the source for some foodborne illness outbreaks, this proposed regulation focuses on the control of SE in shell eggs, based on practices on the farm. We seek comment on whether we should extend the rule to address the contamination of eggs or other foods from food service environments serving a highly susceptible population.

Furthermore, we expect that all retail establishments will make sure that their facilities are clean and sanitary and do not contribute to the contamination of food being prepared or served. Although this proposal does not address rodents or other environmental factors of retail establishments that may cause food to become contaminated, we recommend that all retail establishments follow the physical facilities provisions in chapter 6 of the FDA Food Code, specifically in subsections 6–202.15, "Outer Openings—Protected," 6–202.16, "Exterior Walls and Roofs, Protective Barrier," 6–501.111, "Controlling Pests," and 6–501.112, "Removing Dead or Trapped Birds, Insects, Rodents, and Other Pests." Of course, the retail standards contained in the FDA Food Code are additions to basic sanitation practices already established by Federal and State regulations covering rodent control and environmental hazards.

(Comment 6) One comment recommended that food handlers be periodically tested for *Salmonella*, Listeria, and *Escherichia coli*.

(Response) We disagree with this comment. As discussed in section IV.A of this document, SE outbreak investigations show that outbreaks can occur as a result of SE-contaminated eggs being inappropriately handled by food preparers, including temperature abuse (i.e., failing to keep eggs and foods prepared with eggs refrigerated), inadequate cooking, and combining two or more eggs. While food preparers may be the source for some foodborne illness outbreaks, the scope of this proposed regulation addresses the prevention of SE in shell eggs and does not extend to contamination of eggs or other foods from other sources, such as food preparers. We expect that all retail establishments will ensure that the health, cleanliness, and hygienic practices of their employees do not contribute to the contamination of food being prepared or served. Although this proposal does not require that food service workers be tested for the presence of bacteria which may cause foodborne illness, we strongly recommend that all retail establishments follow the management and personnel provisions in chapter 2 of the 2001 FDA Food Code, specifically in section 2–201, "Disease or Medical Condition."

V. Preliminary Regulatory Impact Analysis (PRIA)

A. Introduction

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Reforms Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million, adversely affecting a sector of the economy in a material way, adversely affecting competition, or adversely affecting jobs. A regulation is also considered a significant regulatory action if it raises novel legal or policy issues. FDA has determined that this proposed rule is an economically significant regulatory action.

The Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121) defines a major rule for the purpose of congressional review as having caused or being likely to cause one or more of the following: an annual effect on the economy of $100 million; a major increase in costs or prices; significant adverse effects on competition, employment, productivity, or innovation; or significant adverse effects on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. In accordance with the Small Business Regulatory Enforcement Fairness Act, the Office of Management and Budget (OMB) has determined that this proposed rule, if it becomes final as proposed, would be a major rule for the purpose of congressional review.

B. Need for Regulation

Private markets operating within the framework of the legal system promote the health and safety of consumers. Limitations of both the marketplace and the legal system, however, can result in inadequate control of some health and

safety hazards, and reduce societal welfare.

In a perfectly competitive market in which consumers and producers both have full information, the optimal level of production of eggs will be provided at an optimal level of safety. In the egg market, however, consumers and producers do not have sufficient information on the SE status of particular eggs. In the case of SE-contaminated eggs, the lack of awareness and information about the risk suggests that an inefficiently high demand exists for eggs that are produced without using measures to prevent SE.[3] Since the demand for eggs is not sufficiently affected by safety considerations, the farmer's incentive to invest in safety measures is diminished. Consequently, the market does not provide the incentives necessary for optimal egg safety.

With sufficient information for consumers and producers, a legal system that awards compensation for harm done due to SE-contaminated eggs has the potential to remedy market imperfections by providing producers with incentives to provide the level of safety that is best for society. The legal system does not ensure the optimum level of shell egg safety because consumers who become ill due to SE contamination often do not know the reason for or source of their illness. Even in cases where consumers are aware that their illness was contracted from eggs, imperfect information makes it difficult to determine who is ultimately responsible for their illness.

In sum, the imperfect information about the risk associated with SE from particular shell eggs means that neither the legal system nor the marketplace is able to provide adequate economic incentives for the production of SE free eggs. The government may therefore be able to improve social welfare through targeted regulation. In what follows, we will look at the costs and benefits of the provisions in the proposed rule. We will also look at the costs and benefits of other measures to control SE that we considered, but did not include in the proposed rule.

C. Economic Analysis of Potential Mitigations: Overview

We considered many possible SE prevention measures. Because of the large number of provisions considered (and the large number in the proposed rule) we begin our analysis in this section with an overview of our methods of estimating the benefits and costs of the various measures to control SE in shell eggs. In section V.D of this document, we summarize the benefits and costs of the proposed rule and some leading regulatory options. In section V.E of this document, we present the detailed analysis of all of the SE prevention measures we considered (including those in and those not in the proposed rule).

1. Measuring Benefits

a. *Modeling benefits.* The primary benefit of the provisions in this proposed rule (and the other possible measures) would be an expected decrease in the incidence of SE-related illnesses. The benefits will be calculated using the following model:

Benefits = base line risk x prevention (C_1, C_2, C_3, * * *) x value of prevention

where,

Benefits = annual health benefits realized due to this proposed rule;

base line risk = the base line level of risk facing consumers today, expressed as the number of SE cases attributable to shell eggs;

prevention (C_1, C_2, C_3, * * *) = the prevention due to the implementation of a rule with components C_1, C_2, C_3, and so on; and

value of prevention = the social cost of one representative case of salmonellosis. This cost includes medical costs, the value of lost production, and the loss of welfare the individual experiences due to pain and suffering and lost leisure time.

We write the prevention component of the benefits equation in a general functional form rather than an additive form because combinations of the proposed rule's components (C_1, C_2, C_3, * * *) will usually not result in linear, proportional reductions of risk. Instead, we assume that some components are partial substitutes for one another while others complement each other.[4] The total risk reduction will not be the sum of the individual components; the effectiveness of the rule could be less than or greater than the sum of its parts.

b. *Base line risk from SE in eggs.* We estimated the reduction in SE illnesses by applying the percentage prevention to the base line number of illnesses. We estimated the base line levels of egg contamination and the number of human illnesses that result from such contamination.

The CDC passive surveillance system recorded 5,614 illnesses due to SE in 2001. Using the CDC multiplier (used to estimate total cases based on ratio of total to reported cases) of 38, we estimated the number of illnesses due to SE to have been 213,330 in 2001.[5] Because SE is not unique to eggs, not all of the 213,330 illnesses due to SE in 2001 can be attributed to domestic shell eggs. CDC estimates that 16 percent of the cases reported were acquired outside of the United States. Consequently, the base line level of domestic SE cases is 179,200. A total of 53 percent of all SE illnesses identified through outbreak surveillance are attributable to eggs. Where a vehicle of transmission was identified, 81 percent of outbreaks and 79 percent of illnesses identified through outbreaks were attributed to eggs. The midpoint of the lower bound (53 percent) and upper bound (79 percent) estimates is 66 percent, which we assume to be the mean percent of domestic SE illnesses attributable to eggs. Using these figures we calculate a lower bound estimate of 94,980 (53 percent x 179,200), and an upper bound estimate of 141,570 (79 percent x 179,200) cases due to SE in eggs. The CDC method generates a mean point estimate, based on 2001 data, of 118,270 (66 percent x 179,200) cases for 2001.

To estimate a base line level of risk for this proposed rule, we adjust the estimated number of cases downward to account for the projected effects of the refrigeration and labeling rule, which will reduce the number of cases in the coming years. We previously estimated that the refrigeration and labeling rule will reduce illnesses from shell eggs by 15 to 20 percent. We use the higher figure to ensure against double counting, so the net result is a new expected base line of 94,620 SE illnesses attributable to eggs and likely to be affected by this proposed rule.

Table 1 of this document illustrates how we arrived at our base line.

TABLE 1.—BASE LINE EGG-RELATED *Salmonella* ENTERITIDIS (SE) CASES

2001 Passive Surveillance Cases	5,614
Multiplier	38
Estimated SE Cases in 2001	213,330

[3] Many consumers may not know that many common methods of preparing eggs for consumption will not eliminate SE in a contaminated egg.

[4] An example of substitute components would be rodent poisons and traps. By themselves rodent poisons and traps may reduce the problem of SE contamination by X percent and Y percent respectively. However, when used together the effect on SE contamination will be somewhat less than X percent + Y percent (though still higher than each component alone).

When prevention measures are complements, the total prevention from using the two measures that reduce risk by A percent and B percent separately is greater than A percent + B percent.

[5] All data for the calculations in this paragraph and the following paragraph are from Meade (Ref. 4) and CDC (Refs. 5, 6, 7, and 9).

TABLE 1.—BASE LINE EGG-RELATED *Salmonella* ENTERITIDIS (SE) CASES—Continued

Cases From Outside the United States	-16%
Estimated Domestic SE Cases	179,200
Percent of SE Cases From Eggs	
Minimum	53%
Mean	66%
Maximum	79%
Egg related SE cases in 2001	
Minimum	94,980
Mean	118,270
Maximum	141,570
Adjustment for Refrigeration and Labeling rule	-20%
Future Egg Related SE Cases	
Minimum	75,980
Mean	94,620
Maximum	113,250

c. *Measuring the health benefits from preventing Salmonellosis.* i. *The economic impact of illness from SE in eggs.* Measuring the economic impact of illness due to the consumption of SE-contaminated eggs is a critical part of our analysis. It is therefore important that we include all of the effects of SE on human health. These effects include both monetary and non-monetary losses and are both acute and chronic in nature.

Epidemiological evidence suggests that SE leads to both acute and chronic illnesses. The acute illness that accompanies SE generally causes gastrointestinal symptoms. SE illness may also result in chronic arthritis (Ref. 81). Finally, SE can result in death, especially for the immunocompromised, children, and the elderly (Ref. 80).

ii. *The consequences of SE illness.* We outline the consequences of SE illnesses in table 2 of this document. Table 2 of this document includes the medical outcomes of SE illness, the duration of conditions acquired due to SE illness, and the probability of occurreuce for each condition with a given level of severity.[6]

We classify the gastrointestinal illness caused by SE illness as either mild, moderate, or severe. A mild case of SE is defined as a case that causes gastrointestinal symptoms, but is not severe enough to warrant visiting the doctor. An individual with a mild case of SE illness will be ill for 1 to 3 days. A moderate case of SE illness lasts for 2 to 12 days and is characterized as a case severe enough to necessitate a trip to the doctor or other health care professional. A severe case of SE illness results in hospitalization and typically lasts from 11 to 21 days.

TABLE 2.—CONSEQUENCES OF *Salmonella* ENTERITIDIS INFECTION

Condition and Severity	Outcome	Duration (Days per Year)	Percent of Cases
Gastrointestinal Illness			
Mild	No Physician Visit	1 to 3	90.7
Moderate	Physician Visit	2 to 12	8.1
Severe	Hospitalized	11 to 21	1.2
Arthritis			
Short-term	Waxing and Waning, Eventually Resolved	1 to 121	1.26
Long-term	Chronic Arthritis	365	2.40
Death	Death		0.04

We do not have direct estimates of the distribution of outcomes of SE illnesses separate from the outcomes of illnesses for all nontyphoidal *Salmonella*. In the absence of better information we assume that all *Salmonella* serovars will result in similar distributions of illness severity. We therefore use information that applies either to all 1,400,000 estimated annual cases of salmonellosis or to the 1,340,000 estimated annual foodborne cases of salmonellosis. Using general results for all diarrheal illnesses, CDC has estimated that 113,000 of the 1,400,000 *Salmonella* illnesses in 1997 could have resulted in physician office visits, a rate of 8.1 percent (113,000 ÷ 1,400,000) (Ref. 82). CDC also has estimated that foodborne *Salmonella* cases lead to about 15,600 hospitalizations per year, which is about 1.2 percent (15,600 ÷ 1,340,000) of annual foodborne cases (Ref. 4). We assume that the remaining 90.7 percent of gastrointestinal illness cases are mild.

SE may also result in reactive arthritis. This illness can manifest itself either as a relatively short-term bout of joint pain or as a chronic condition. Studies of outbreaks imply that short-term arthritis may last from 1 day to a total of 121 days. Chronic arthritis lasts from the time of onset until death. Overall, we estimate that 1 to 10 percent of SE infections lead to some form of arthritis. We expect two-thirds of these to be long-term and one-third to be short-term (Ref. 81).

The most severe potential result of SE infection is death. CDC estimates that 553 deaths occur due to foodborne *Salmonella* (Ref. 4). The estimate implies that about 0.04 percent (553 ÷ 1,340,000) of foodborne cases result in death.

iii. *Quality adjusted life years (QALYs).* The benefits from this regulation will be presented in both monetary and non-monetary terms. In section V.E of this document, the benefits will be expressed in illnesses and deaths averted by each regulatory provision under consideration. In the summary of benefits due to the regulation, we present both a cost effectiveness framework (cost per illness averted and cost per QALY saved) and a monetary benefits estimation.

One approach to estimating health benefits involves the use of QALYs. QALYs can be used to measure the loss of well being that an individual suffers due to a disease or condition. QALYs do not include the value of health expenditures caused by the condition in question; we estimate health expenditures separately.[7] QALYs range from 0 to 1 where 0 is equivalent to death and 1 is equivalent to perfect health.

A number of methods have been constructed to measure QALYs. One class of methods uses surveys to ask laypersons and doctors to use a QALY scale to estimate how much someone else who is afflicted with a given symptom or condition will suffer. This direct survey approach has been used widely, partly because surveys of QALY values for a large variety of symptoms and functional limitations have been

[6] We use recent data from CDC to estimate the relative prevalence of illnesses of different severities (Ref. 82). The expected duration of illness for each category of severity is taken from Zorn and Klontz (Ref. 81).

[7] Although some QALY estimates include the value of medical expenditures, particularly QALY estimates derived from survey data, the QALY estimates used in this study do not.

published (Ref. 81). An alternative method used by Cutler and Richardson uses regression analysis to estimate the effect of particular conditions on overall health status (Ref. 83). In our analysis, we use both methods where appropriate.[8]

In table 3 of this document, we present estimates of the number of quality adjusted life days (QALDs) lost due to SE. Total QALDs lost are derived by multiplying the estimated number of QALYs lost by 365. Then, to calculate the disutility per day, or one QALD, we divide by the average duration of the illness. Like QALYs, QALDs range from 0 to 1 where 0 is equivalent to death and 1 is equivalent to perfect health. We report the loss in QALDs since most of the illnesses associated with *Salmonella* Enteritidis last days rather than years. The QALD values listed for mild, moderate, and severe cases of SE infection were estimated by Zorn and Klontz using data from Kaplan, Anderson, and Ganiats (Ref. 81). This approach calculated that the acute effects of food poisoning (vomiting, diarrhea, and general gastrointestinal illness) lead to a loss of QALDs greater than 0.5 for each day of illness. Furthermore, these lost QALDs persist for 2 to 16 days. Thus, the total loss of QALDs from gastrointestinal illness is calculated to be 1.05 to 9.99.

TABLE 3.—LOST QUALITY ADJUSTED LIFE DAYS DUE TO *Salmonella* ENTERITIDIS

Severity	Disutility per Day (QALDs Lost)				Total QALDs Lost per Illness
	Functional	Symptom	Total	Average Days Ill	
Illness					
Mild	0.44	0.08	0.53	2	1.05
Moderate	0.44	0.08	0.53	7	3.68
Severe	0.53	0.09	0.62	16	9.99
Arthritis					
Short-term	--	--	0.22	25	5.41
Long-term	--	--	0.14	18,250	2,613.12

For arthritis, we used the regression of Cutler and Richardson (Ref. 83) The regression approach yields estimates of losses per day of 0.22 for short-term arthritis and 0.14 for long-term arthritis. We estimate that short-term arthritis results in a loss of 5.4 to 10.8 QALDs while long-term arthritis results in a loss of 2,613 to 5,223 QALDs.

We do not present the estimated QALYs saved for each provision considered in this analysis. Instead, we present benefits by provision in an "illnesses averted" metric for each option and provision. This practice allows us to calculate cost per illness averted by each provision. In the summary we present the result of alternate valuation methods that do and do not rely on QALY estimates. Since a large portion of the loss due to chronic reactive arthritis is due to pain and suffering not associated with direct medical expenditures, it is difficult to capture the full economic loss due to SE related arthritis without using QALYs or some other measure of morbidity effects. Benefits estimates not relying on QALY estimates will necessarily be significantly lower than estimates with QALYs. The results of all methods of valuation are presented in section V.E of this document.

iv. *Valuation of SE illnesses.* Table 4 of this document illustrates how we calculate the dollar value of a typical case of SE under different assumptions. The first column of table 4 of this document lists the type of ailment. The second and third columns of table 4 of this document are taken from tables 2 and 3 of this document. The health loss per case is calculated by multiplying the value of a QALY, scaled to the value of a single day, by the actual number of QALDs lost, and then discounting where appropriate (only values of chronic cases of reactive arthritis are affected by the discount rate). The values in this column will vary depending upon the particular assumptions about the value of a statistical life (VSL), QALY, and the discount rate. The assumptions about the different values for these parameters will be discussed in a following paragraph. The fifth column of table 4 of this document shows the annual medical costs of each condition that is caused by SE infection (long term reactive arthritis is the only condition where the afflicted will incur medical costs for more than a single year). The sixth column of table 4 of this document shows the weighted dollar loss per outcome caused by SE. The probability that a case of SE infection results in a given outcome (column 2) is multiplied by the sum of the average health and medical costs per case. These results will vary depending on the economic assumptions. The weighted dollar values in column 6 are summed to calculate the total expected loss associated with a typical case of SE. We present the range of estimates of dollar losses per case in table 5 of this document.

[8] The Cutler and Richardson approach has several advantages over the Kaplan, Anderson, and Ganiats approach. However, it is not clear that this approach is appropriate for valuing acute illnesses. Therefore the Kaplan, Anderson, and Ganiats approach is used for acute illnesses and the Cutler and Richardson approach is used for chronic conditions. See Scharff and Jessup for a discussion of the pros and cons of each approach (Ref. 84).

TABLE 4.—VALUING OF A TYPICAL CASE OF *Salmonella* ENTERITIDIS[1]

Type and Severity	Case Breakdown	Total QALDs Lost per Illness	Health Loss per Case	Medical Costs per Case	Weighted Dollar Loss per Case
Illness					
Mild	90.7%	1.05	$864	$0	$784
Moderate	8.1%	3.68	$3,025	$74	$250
Severe	1.2%	9.99	$8,208	$8,500	$203
Arthritis					
Short-Term	1.26%	5.41	$4,442	$100	$57
Long-Term	2.40%	2,613.12	$592,411	$531	$14,244
Death	0.04%	18,250.00	$5,000,000		$2,143
Total Expected Loss per Case					$17,682

[1] The value of a typical case will actually vary widely depending on assumptions about the VSL, QALY, and the discount rate. These figures are based on an assumption of VSL=$5 million, QALY=$300 thousand, and a discount rate of 7%.

[2] "Health Loss per Case" and "Weighted Dollar Loss per Case" for "Death" are calculated using a VSL=$5 million. If we use the QALD calculation, assuming the average victim of death due to SE loses 50 years of life, the Health Loss per Case is $4.14 million and the Weighted Dollar Loss per Case is $1,773.

Cost of illness estimates usually include the medical costs associated with SE. For example, Buzby et al. produced a summary of medical and other costs for U.S. salmonellosis cases (Ref. 80).[9] The figures they estimated include the lost productivity of workers due to salmonellosis. Because we estimate lost productivity separately, we must net out these costs.

For mild SE illnesses, we assume that most persons will not obtain medical services. The cost estimated for this category chiefly reflects lost productivity (Ref. 80).

For medical costs for those who contract moderate illnesses, we use figures from Williams (Ref. 85) updated with medical cost indices (Ref. 86). In 1996, the average total cost of treatment for a nonurgent medical problem, including physician's fees and medication, was $62. We adjust these numbers to account for the increased cost of medical care since 1996. The consumer price index (CPI) for medical services rose from 227.8 in 1996 to 272.5 in June 2001.

The data for the medical cost of a severe case of SE was obtained from the Health Cost and Utilization Project's (HCUP) Nationwide Inpatient Sample (NIS) (Ref. 87). Medical costs due to arthritis are based on Zorn and Klontz (Ref. 81). Zorn and Klontz estimated that short-term arthritis medical costs were approximately $100 per case. We estimate that long-term reactive arthritis costs had a present value of $5,370 in 1992.[10] We use the CPI for medical care in general to update this cost to current dollars. Between 1992 and June 2001, the CPI for medical care rose from 190.1 to 272.5 (Ref. 86).

FDA uses a range to estimate the value of an additional year of life to reflect the uncertainty in the literature. As a lower bound, FDA uses $100,000 per (quality-adjusted) statistical life year. Cutler and Richardson (Ref. 83) use a similar estimate, and Garber and Phelps (Ref. 88) conclude that estimates of the value of a life year are about twice the level of income, though they present a broad range to reflect uncertainty associated with risk aversion and discount rates. Updating Garber and Phelps' estimates suggests that $100,000 per life year is a reasonable estimate, given that median family income in 2002 was about $51,000 (Ref. 89). Moreover, this estimate is close to the estimate used in FDA's economic analysis of the regulations implementing the Nutrition Labeling and Education Act of 1990. To reflect other underlying literature, and following suggestions from other federal agencies, we begin with an estimate of the VSL of $6.5 million. This estimate is consistent with the survey by Aldy and Viscusi (Ref. 90) on the premium for risk observed in labor markets. Annualizing this value over 35 years at 3 percent and at 7 percent discount rates implies estimates of a value of an additional year of life of about $300,000 and $500,000. Therefore, calculations for estimated benefits will reflect three estimates of the value of a statistical life year (VSLY): $100,000, $300,000 and $500,000, for both of the methods of estimating gains in life years. Total benefits differ from mortality-related benefits by including the value of reduced morbidity and health care costs. Furthermore, FDA assumes values of a statistical life of $5 million and $6.5 million. This range of VSL estimates is consistent with one reasonable interpretation of studies of willingness to pay to reduce mortality risks. (Refs. 90 and 91) FDA uses the lower value to reflect the fact that many of the estimates of willingness to pay to reduce mortality risk from papers not surveyed by Aldy and Viscusi are relatively low.

In table 5 of this document, value of a typical case of SE under different assumptions is shown.

[9] As with the CDC data above, we assume that the characteristics of SE-related illnesses are similar to those of *Salmonella* in general.

[10] This is based on the fact that in 1992 there were $64.8 billion in costs due to arthritis, 24 percent of these costs were medical costs, and there were 40 million arthritis sufferers. This yields $389 per arthritis sufferer in direct medical costs. Discounted at 7 percent, the present value of medical expenditures for 50 years with reactive arthritis is $5,370.

TABLE 5.—VALUE OF A TYPICAL CASE OF *Salmonella* ENTERITIDIS UNDER DIFFERENT ECONOMIC ASSUMPTIONS

	Discount Rate=$3%		Discount Rate=7%	
	VSL[1]=$5 million	VSL=$6.5 million	VSL=$5 million	VSL=$6.5 million
VSLY[2]=$0	$2,646	$3,289	$2,464	$3,107
VSLY=$100 thousand	$11,885	—	$7,602	—
VSLY=$300 thousand	$30,363	$31,006	$17,879	$18,522
VSLY=$500 thousand	—	$49,484	—	$28,799

[1] VSL means value of a statistical life.
[2] VSLY value of a statistical life year.

The expected value of a typical case of SE varies greatly depending on the assumptions. The values when the QALY is taken out of the calculation are, as expected, the lowest, ranging from $2,464 per case to $3,289 per case. These values do not account for pain and suffering, which are a large part of the economic loss associated with chronic arthritis. The highest expected value for a case of SE, $49,484, occurs when we assume a VSL of $6.5 million, a QALY of $500 thousand, and a discount rate of 3 percent. The average of all of the values is $17,254 per case. This most closely corresponds to the assumption set where VSL = $5.0 million, QALY = $300 thousand, and the discount rate = 7 percent, which produces a value of $17,879 per case.

d. *Other benefits.* Pathogens other than SE have been associated with eggs. In particular, *Campylobacter* (Ref. 92) and non-SE *Salmonella* (Ref. 14) have been found on the shells of eggs. The presence of pathogens on the eggshell may be harmful to humans if one of two scenarios occurs. First, under certain conditions, pathogens may migrate through the shell of the egg to infect the egg's contents (Ref. 93). Second, eggshell contamination could result in the contamination of egg contents if eggs are broken in such a way that the shell of the egg comes into contact with the contents of the egg (Ref. 93).[11] Current USDA washing and sanitizing standards are designed to reduce pathogens on the exterior of the egg. Also, pathogen migration is unlikely given current USDA standards and industry practices.[12] Consequently, we do not expect benefits from the reduction of illnesses due to pathogens other than SE to be large.

[11] The use of centrifuges would cause this to occur.

[12] Most modern egg washing machines are spray-washers (63 FR 27502 at 27505, May 19, 1998). Migration of SE through the eggshell is more commonly associated with immersion washing (Ref. 94).

2. Measuring Costs

The measurement of costs is relatively straightforward. We measure costs based on the best available information from government, industry, and academic sources. Furthermore, we assume that total costs are typically the sum of the costs of individual provisions. What this assumption means is that, unlike benefits, the cost of one provision is generally independent of the cost of other provisions. Where economies of scope with respect to SE mitigation exist, we adjust the costs downward to account for the economies.[13]

3. Coverage of the Analysis

We estimate costs and benefits of potential prevention measures for all farms that produce eggs for distribution in retail markets. Because the proposed rule exempts very small farms (<3,000 layers) from all provisions, wherever the data permit we calculate costs and benefits separately for both very small farms and for larger farms (>3,000 layers). The separation of costs and benefits by size of farm allows us to estimate the total costs and benefits of the proposed rule, as well as the total costs and benefits of regulatory alternatives that do not necessarily exempt very small farms. In addition, calculating what the proposed rule would cost very small farms allows us to measure the regulatory relief provided by the exemption for very small farms. Farmers who sell all of their eggs directly to consumers are exempt from all provisions. Sales of eggs directly to consumers include sales of a farmer's own eggs to neighbors, at farmers markets, and at roadside stands. Farms that sell their eggs to another person for distribution or resale are not assumed to be exempt from the listed provisions. We do not anticipate any control measures for farms that sell all of their eggs directly to consumers, so we exclude them from the analysis.

We estimate that approximately 4,100 farm sites with roughly 8,600 poultry houses may be covered by some or all parts of the proposed rule. These figures are calculated as follows:

- We used the NASS 1997 Census of Agriculture to determine the number of farm sites with layers on hand. NASS estimated that there are 69,761 farms with layers over 20 weeks old in their inventory (Ref. 22).
- Next, we adjusted for the fact that a large portion of farms with fewer than 3,000 layers either sell their eggs directly to the consumer or do not sell their eggs at all. We estimated that, of the approximately 64,800 farms with fewer than 3,000 layers,[14] over 33,800 of these farms sell their eggs, but not directly to the consumer.[15]
- NASS data suggested that 82 percent of layers are table egg layers (Ref. 98). For those farms with more than 3,000 layers, we adjusted the estimated number of farms affected by the NASS estimate. The resulting estimated number of farm sites is illustrated in the first column of table 6 of this document.
- The estimated number of houses per farm site is broken down by size

[13] Where economies of scope with regards to SE mitigation occur, we observe that the incremental cost of one provision decreases with the implementation of another provision. For example, if rodent control decreases the chance of SE detection through environmental testing, we would expect the amount (and the cost) of follow up egg testing to decline.

[14] The NASS Census of Agriculture uses farms with 3,200 birds as its cutoff point for categorization. FDA uses 3,000 birds as its cutoff point for small versus large farms, because this is the measure that is used in other egg and poultry regulations. To adjust the NASS data, FDA assumes that all flocks are uniformly distributed across the 400 to 3,200 bird category. Using this assumption, 7.1 percent (200 + 2,800) of these farms fall in the over 3,000 bird category while the remaining 92.9 percent fall in the small farm category.

[15] Based on assumptions that the expert members of the egg safety action group did not disagree with, we have calculated that approximately 2,860 farms sell eggs via retail channels other than farmers markets, roadside stands, and neighborhood sales (Refs. 95, 96, and 97). Many of the remaining 61,940 very small farms sell their eggs to consumers indirectly at roadside stands or farmers markets (Ref. 97). In the absence of better information, we assume that half of those remaining 61,940 very small farms sell eggs indirectly to consumers.

category in table 6 of this document. We used data from the 1999 Table Egg Layer Management in the U.S. Survey (Refs. 25 and 26) to estimate the number of houses per farm site for those farms with more than 3,000 layers.[16] For those farms with fewer than 3,000 layers, we assumed that there is only one house per farm site.

- We calculate the total number of poultry houses that will be affected by this rule by multiplying the adjusted number of farm sites by the expected number of houses per farm site. As table 6 of this document demonstrates, the majority of the houses are on farm sites with fewer than 3,000 layers.

TABLE 6.—FARMS POTENTIALLY COVERED BY THE PROPOSED RULE

Farm Size (No. of layers)	Adjusted No. of Farm Sites	No. of Houses Per Site	Total No. of Houses
Less than 3,000	33,824	1.0	33,824
3,000 to 19,999	2,337	1.4	3,155
20,000 to 49,999	940	1.4	1,317
50,000 to 99,999	359	2.4	861
100,000 or more	443	7.4	3,279
Total Potential Coverage	37,903	1.1	42,435

D. Summary of Costs and Benefits of Regulatory Options and the Proposed Rule

In this section of this document, we summarize the costs and benefits of the proposed rule and the regulatory options. In section V.E of this document, we provide a detailed analysis of the costs and benefits of all of the SE prevention measures we considered, both those in and those not in the proposal.

We considered a number of regulatory options that may be used to prevent the problem of SE in eggs, including no new regulatory action, classification of SE-positive eggs as restricted or SE-positive, HACCP, the proposed rule, more extensive on-farm prevention measures, less extensive on-farm prevention measures, and retail prevention measures.

1. No New Regulatory Action

One possible alternative to the proposed rule is to rely on current Federal, State, and industry efforts to control SE in shell eggs. These efforts include relying on an FDA final rule for labeling and refrigerating shell eggs, FDA educational programs, and the growth of membership in State and industry quality assurance programs. We believe these methods of control, while valuable, are unable to fully address the problem of SE contamination of shell eggs.

FDA issued a related rule designed to help prevent the growth of SE in eggs by requiring refrigeration of shell eggs at retail and requiring shell egg labeling (65 FR 76092, December 5, 2000). As part of that rule, we set refrigeration temperatures to reduce the potential growth of SE inside shell eggs at the retail level, and required safe handling instructions on all cases and cartons of shell eggs. We expect that the consumption of undercooked and raw eggs will decline as a result of that rule. Nevertheless, labeling and refrigeration standards do not prevent or limit the growth of SE while eggs are in production.

FDA also is pursuing a program designed to inform consumers about microbial hazards in egg preparation. The nationally distributed Fight BAC! program targets children in schools and television audiences with a more general food safety message that likely results in better egg handling practices. Again, this program, while useful, does not prevent the initial contamination of eggs with SE.

Several of the large egg producing States and industry groups have encouraged producers of eggs to follow on-farm practices aimed at mitigating SE in their flocks. One of the first States to implement a structured quality assurance program was Pennsylvania. Though voluntary, the Pennsylvania Egg Quality Assurance Program has been accompanied by a significant decrease in SE-related illnesses in those areas where eggs from Pennsylvania are marketed. Industry groups also have drawn up quality assurance plans as guidelines for their members to follow. The voluntary programs have achieved some success in reducing SE contamination in eggs, and the more comprehensive plans contain many preventive measures similar to those in this proposed rule (Ref. 99). These voluntary programs have now been in operation for many years and are well-known throughout the industry. Although the State and industry programs are potentially effective, many producers choose not to participate. As data from CDC show, SE illnesses continue to be associated with shell eggs even in those areas where voluntary programs are in place. Option 1, relying on current Federal, State, and industry efforts to control SE in shell eggs, will be used as a baseline for the rest of the analysis.

2. Classification of SE-Positive Eggs as Restricted or SE Positive

FDA considered the option of labeling eggs that are diverted to breaker plants (called "breakers") from an SE-positive flock with a label similar to the USDA "restricted" label or with a "SE positive" label. The advantage of requiring a label would be that high-risk eggs would be identified and could not be resold in the table egg market.

The economic loss associated with labeling eggs as either "restricted" or "SE positive" would be very high, as is illustrated in table 7 of this document. It has been estimated that eggs labeled SE positive will be discounted up to $0.08 per dozen at breaker plants. The price received for restricted eggs at the breaker plant is equivalent to the price received for checked eggs.[17] Restricted eggs generally command a price that is

[16] Data from the Layers study are used throughout this document. We acquired the data either directly from the NAHMS Web site or through direct correspondence with Lindsey Garber, Centers for Epidemiology and Animal Health (CEAH), Veterinary Services (VS), APHIS, USDA.

[17] Checked eggs are eggs with minute fissures in their eggshells. These eggs generally command less of a price in the breaker market because they are more likely to break in transit and are more susceptible to contamination.

$0.13 to $0.14 less per dozen than do nest run eggs.

We believe that the pasteurization process used at breaker plants is sufficient to largely eliminate any threat from SE-positive eggs. As long as eggs sent to the breaker plant are subjected to pasteurization, the benefits from requiring eggs from an SE-positive flock to be labeled are insignificant. We rejected the option of labeling eggs from an SE-positive flock because the public health benefits of labeling these eggs likely would be small and the cost of doing so would be very high.

TABLE 7.—EGG PRICES[1]

(PRICE PER DOZEN EGGS)

Region	Regional Weight (in %)	Shell Egg Price to Producer	Breaking Eggs		Cost of Diversion	
			Nest Run	Checks And Undergrades[2]	Nest Run	Checks and Undergrades
North Atlantic	17.0	$0.42	$0.31	$0.17	$0.11	$0.26
North Central	68.4	$0.39	$0.30	$0.17	$0.09	$0.22
South Atlantic	4.3	$0.43	$0.31	$0.17	$0.12	$0.26
South Central	5.1	$0.47	$0.30	$0.17	$0.17	$0.30
West	5.2	$0.55	$0.31	$0.17	$0.25	$0.39
Average Cost of Diverting Eggs[3]					$0.13	$0.24
Additional Discount for SE+ Eggs[4] $0.00 to 0.08						$0.00
Total Cost of Diverting Eggs $0.13 to 0.21						$0.24

[1] See section V.F.2 of this document for a full description of the derivation of this table.
[2] Data on the price received for checks and undergrades is from the Poultry Yearbook (Ref. 100).
[3] The average cost of diverting eggs is weighted by regional production (Ref. 98).
[4] SE-positive eggs are intrinsically less valuable than other eggs because they are limited in how they may be used.

3. HACCP

We could require that a HACCP system be implemented on layer farms. Although the general sanitation and hazard control measures in the proposed rule contain some HACCP-like features, the agency has not defined and is not ready to mandate HACCP on farms. HACCP requires the science-driven identification of critical control points throughout production. The technological knowledge needed to identify critical control points for eliminating SE from shell eggs, however, is incomplete. In addition, HACCP is most appropriate in situations where there are many chemical, physical, and microbiological hazards to control. In this proposal, we are concentrating only on the microbiological hazard of transovarian SE, a subset of the hazards that might be covered under HACCP.

4. The Proposed Rule

The proposed rule (as described in the previous paragraph) includes the following requirements for farms with more than 3000 layers that do not have all of their eggs treated or sell all of their eggs directly to consumers: Rodent and pest control, biosecurity, cleaning and disinfecting, use of SE-monitored chicks and pullets, testing and diversion, records of testing and diversion, and refrigeration.

The benefits from the SE prevention measures in the proposed rule would take time to be fully realized, but the costs would be more immediately incurred. Table 8 of this document shows the initial costs and illnesses averted and the eventual costs and illnesses averted of the proposed rule.[18] Following are the detailed calculations underlying table 8 of this document, in section V.E of this document.

TABLE 8.—ANNUAL COSTS AND ILLNESSES AVERTED OF THE PROPOSED RULE

	Costs	Illnesses Averted	Cost per Illness Averted
Initially			
Interest Rate = 7%	$84,000,000	22,132	$3,795
Interest Rate = 3%	$79,000,000	22,132	$3,569
Eventually			
Interest Rate = 7%	$82,000,000	33,452	$2,451
Interest Rate = 3%	$77,000,000	33,452	$2,302

[18] The interest rate is used here to annualize the costs of refrigeration equipment, plan designs, and training. For simplicity, subsequent summary tables will only include figures reflecting the interest rate of 7 percent. Those interested in the total cost number reflecting a 3-percent interest rate should subtract roughly $5 million from the calculations performed with a 7-percent interest rate. The exact difference is shown in section E.1.i of this document, describing the costs and benefits of the refrigeration option, and section E.2, describing the costs of administrative measures.

5. More Extensive On-Farm SE Prevention Measures

FDA could issue a proposed rule that provides the following information: (1) Does not exempt farms with fewer than 3,000 layers from any provisions and (2) includes more on-farm provisions than those in the proposed rule. Additional on-farm provisions include requiring training, the use of SE-negative feed, and vaccinating flocks against SE. We could also require record keeping for all provisions, rather than only for sampling, testing, and diversion.

The option of more extensive controls leads to total eventual costs of $243 million and eventual expected number of illnesses averted of 33,604 (the cost-effectiveness of each additional provision is calculated separately and presented in table 33 of this document and in the analysis of on-farm prevention measures in section V.E of this document). This approach increases costs by over $160 million, while only increasing the number of illnesses averted by about 150 cases, for a marginal cost-effectiveness of more than $1 million per additional illness averted. The main reason for the small increase in benefits relative to costs is that much of the increase in costs comes from adding farms with fewer than 3,000 layers. The large number of such farms (over 33,000, as shown in table 5 of this document) means that requiring them to comply with all provisions of the proposed rule would greatly increase costs. These farms, however, account for less than 1 percent of egg production, so requiring them to comply with all of the SE prevention measures would have a small effect on the volume of shell eggs that could be contaminated with SE. In addition, including these very small farms likely would result in the cessation of egg production at a large number of farms. For these reasons, FDA has decided not to pursue this option.

6. Less Extensive On-Farm SE Prevention Measures

We could also require fewer controls than the proposed rule. Several provisions could be combined to provide a less extensive set of controls than in the proposed rule. Many of the prevention measures could be put forth as stand-alone regulations. We have not presented each of these prevention measures as a separate option, but the reader can see the individual effects of the various on-farm prevention measures in table 28 (see section V.E of this document). As documented in table 28 of this document, the various individual measures would, by themselves, generate lower net benefits than the integrated program outlined in the proposed rule.

7. Retail SE Prevention Measures

FDA examined the possibility of including a retail component in the proposed rule. In particular, we have qualitatively examined the costs and benefits of applying certain SE prevention measures to establishments that specifically serve highly susceptible populations. Those measures include using only eggs that are clean, sound, contain no more restricted eggs than the proportion allowed in U.S. Consumer Grade B, and have been transported at an ambient temperature of 45 °F or below. Other measures that could apply to establishments serving highly susceptible populations, but for which we lack data, include thoroughly cooking raw eggs and raw egg-containing foods, and substituting pasteurized eggs or egg products for raw eggs in the preparation of foods where eggs are combined or served undercooked.

At present, we do not have adequate information to accurately estimate the total costs and benefits of all the retail measures. Nevertheless, we have estimated that more than 130,000 retail establishments would be affected by the retail provisions we examined. We ask for comment regarding the costs and benefits of retail prevention measures.

E. Benefits and Costs of Potential SE Prevention Measures: Detailed Analysis

In this section, we describe the SE prevention measures we considered, including provisions that were not included as proposed requirements or that were only required for certain producers in the proposed rule. For example, we calculated costs and benefits for SE prevention measures, such as rodent control and biosecurity, for producers with fewer than 3,000 layers, but these measures would not be required of such producers in the proposed rule. In addition, FDA looked at a number of administrative requirements designed to support the direct SE prevention measures. Finally, we calculated the total costs and benefits for the provisions in the proposed rule.

We examined a number of on-farm measures, which includes the following measures:

- Rodent and pest control,
- Biosecurity measures,
- Cleaning and disinfecting of layer houses between flocks,
- The use of SE monitored chicks or pullets,
- The use of SE negative feed,
- Vaccinating flocks against SE,
- Refrigeration of eggs,
- Layer house environmental testing,
- Followup egg testing, and
- The diversion of SE positive eggs.

For each of the on-farm measures previously discussed, we estimated the costs of the following administrative measures: registration, training, plan design, and recordkeeping.

Finally, FDA considered retail provisions to help prevent illness from SE positive eggs. The retail provisions would cover retail establishments that specifically serve highly susceptible populations.

1. On-Farm SE Prevention Measures

a. *Interdependence of on-farm measures.* Rodent control, pest control, biosecurity and cleaning and disinfecting all have a role in eliminating SE in the poultry house. Although the actions taken under each heading may be distinct, the effects of each action are related. For example, a biosecurity plan may include provisions to limit standing water and high grass in areas adjacent to the poultry house. Although categorized as biosecurity measures, these practices also help control both rodents and pests. Similarly, cleaning and disinfecting removes not only SE, but also rodents and pests.

This interdependence means that the efficacy of on-farm controls cannot be determined by adding the effects of each provision (as determined by studies that focus on each provision separately). The measurement difficulty arises for two reasons. First, as mentioned earlier, when two practices substitute or complement one another, the efficacy of the first practice is affected by the introduction of a second. Second, a simple comparison of farms that use a given practice with farms that do not use that practice is insufficient in measuring the effectiveness of the practice in question. The use of one good practice tends to be positively correlated with the use of other good practices and therefore a simple comparison between farms will overstate the effectiveness of the practice. For example, those houses that use the best rodent control practices are also likely to be using other SE controls as well, so a measure of rodent control effectiveness is likely to pick up the effects of good biosecurity, pest control, and cleaning and disinfecting practices. On the other hand, a simple farm to farm comparison of practices that are correlated with prevalence may understate the effectiveness of the practice. For example, a group of farms may have practices in place because

they are part of a voluntary SE plan, which in turn may have been put in place in areas with higher than average prevalence. In this case the practices would appear to be correlated with higher than average prevalence.

b. *Organization of economic analysis of potential provisions.* FDA has considered a number of on-farm SE prevention measures. The provisions that we considered are examined below. We have included some, but not all, of these provisions in the proposed rule. The costs and benefits of the provisions included in the proposed rule are summarized in table 35 in section V.F of this document.

c. *Control of rodents and other pests.*

i. *Rodent and pest control provisions.* One potential rodent and pest control provision is a requirement that each layer house be under a rodent and pest control program. Such a program could include the use of traps or poisons to reduce rodents and other pests. A provision also might require that each farm have a written rodent and pest control plan and that rodent and pest control records be kept to verify that the program is accomplishing its goals.

ii. *Current industry practices—rodent and pest control.* Most farms currently address rodent and pest control problems to some extent. However, if SE-positive eggs are required to be diverted, there will be a financial incentive to find ways to prevent SE in poultry houses. As a result, the effectiveness of rodent and pest control in eliminating SE in the poultry house will lead many farms to institute rodent and pest control programs that are more stringent than those currently in place.

Currently, 99.2 percent of all commercial farms with more than 30,000 layers use some form of rodent control, but not all methods of rodent control are compatible with the goal of eliminating SE in poultry houses. In particular, we believe that biological predators such as cats should not be used as a method of rodent control because cats can be vectors for SE contamination.

Table 9 of this document illustrates, by farm size, the number of programs of rodent control that would satisfy the provisions in the proposed rule. Farms that do not use rodent controls as specified in this provision (e.g., many farms primarily use cats as a rodent control measure) are counted as having unacceptable rodent control programs. Based on data from the Layers study (Refs. 25 and 26), we estimate that the number of farms with inadequate rodent control programs will range from 1.8 percent for farms with over 100,000 layers to 21.0 percent for farms with 20,000 to 49,999 layers.[19] Furthermore, we believe that the potential costs of diversion of SE-positive eggs will encourage farmers currently using a level of rodent control that would satisfy the proposed provision to increase their rodent control efforts.[20] Without better information about the number of farms that would increase rodent control efforts, we assume the true number will lie between 0 percent and 100 percent of those currently using an acceptable level of rodent control.

TABLE 9.—RODENT CONTROL

Farm Size (No. of layers)	Unacceptable Rodent Control (in %)	No. of Farms With Unacceptable Rodent Control	No. of Farms Increasing effort
Less than 3,000	50.0%	16,912	8,456
3,000 to 19,999	18.8%	439	949
20,000 to 49,999	21.0%	197	371
50,000 to 99,999	3.8%	14	172
100,000 or more	1.8%	8	218
All Farms		17,570	10,166

We assume that between 25 percent and 75 percent of very small farms (those with fewer than 3,000 layers) are using an acceptable level of rodent control.

Pests, other than rodents, commonly found in poultry houses include flies, mites, beetles, and ants (Ref. 101). For the purposes of this provision, however, we chiefly are interested in the presence of flies and fly control because they have been implicated in the transmission of *Salmonella* (Ref. 102).

The survey used to develop the Layers study asked questions about on-farm fly control practices (Refs. 25 and 26). Using these data, we estimate that over 90 percent of those farms with over 3,000 layers use some form of fly control. Some of these methods, however, should not be used. In particular, we do not suggest the use of biological predators, such as wild birds, for fly control since these predators may themselves be vectors for SE transmission (Ref. 102).

[19] Our primary source for on-farm practices related to SE prevention measures is the Layers study (Refs. 25 and 26). As the only major current survey of the industry, this study has provided us with data that has allowed us to characterize the industry. The study, however, does not fully represent the industry. A total of 526 farm sites responded to the first part of the survey and 252 responded to the second part of the survey. Furthermore, only operations with more than 30,000 layers were included in the survey. Consequently, we had to approximate the practices of smaller farms based on a limited amount of information. Nonetheless, the Layers study has added greatly to our understanding of the industry and its practices.

[20] This conclusion assumes that there will also be a testing and diversion component to the proposed rule. If the proposed rule does not include a testing and diversion component, it is unlikely that farms with an acceptable testing and diversion program would increase rodent control efforts beyond what is required, because the incentive to avoid diversion would not be present.

TABLE 10.—FLY CONTROL

Farm Size (No. of layers)	Unacceptable Fly Control (in %)	No. of Farms With Unacceptable Fly Control	No. of Farms Increasing effort
Less than 3,000	50.0%	16,912	8,456
3,000 to 19,999	26.9%	629	854
20,000 to 49,999	17.5%	165	388
50,000 to 99,999	11.8%	42	158
100,000 or more	21.7%	96	173
All Farms		17,844	10,030

Table 10 of this document shows the number of farms with unacceptable (not sufficient to satisfy the proposed rule) programs of fly control. We assume that farms that do not use fly control or that use biological predators, such as birds, as their primary method of fly control are not using acceptable methods. We estimate that a total of 17,844 farms are using unacceptable methods of fly control.

The actual number of farms that are using unacceptable methods of fly control is likely to be higher than the estimates in table 12 of this document would suggest. The mere fact that a particular method is used does not automatically guarantee that it is used at its optimal level. As with rodent control, even farmers in compliance with the proposed provision would be likely to increase their use of fly controls. We assume that between 0 and 100 percent of farms using acceptable fly control methods will increase their fly control efforts. Consequently, an additional 10,030 farms will increase their fly control efforts.

iii. *Costs of rodent and pest control.*[21] We estimate the cost of rodent and pest control to farms in table 11 of this document. We assume that a farm with an adequate rodent and pest control program will be using a number of control measures.

Included in the cost of rodent control are the cost of setting up and maintaining bait stations and the cost of rodent indexing. The annual cost of rodent control ranges from $30 for the average farm with less than 3,000 layers to $4,970 for the typical farm with over 100,000 layers. The costs of limiting rodents' access to feed and patching holes in the walls of poultry houses are not included in our estimates.

Pest control measures include the cost of sprays, baits, fly monitoring, and manure pit fans. We expect the annual cost of pest control to range from $110 for farms with less than 3,000 layers to $63,500 for farms with more than 100,000 layers.

TABLE 11.—COST OF RODENT AND PEST CONTROL
(IN THOUSANDS)

Farm Size (number of layers)	Rodent Control		Pest Control		Total
	Unacceptable Controls	Increased Effort	Unacceptable Controls	Increased Effort	
Less than 3,000	$501	$125	$1,905	$476	$3,008
3,000 to 19,999	$241	$260	$2,355	$1,600	$4,456
20,000 to 49,999	$133	$125	$1,125	$1,326	$2,709
50,000 to 99,999	$15	$93	$544	$1,016	$1,667,
100,000 or more	$40	$541	$6,102	$5,507	$12,187
All Farms	$929	$1,144	$12,031	$9,922	$24,027

The total cost of rodent and pest control, as expressed in table 11 of this document, is found by multiplying the cost per farm by the number of farms affected, as illustrated in tables 9 and 10 of this document. For those farms that are already using acceptable rodent and pest control methods, but that will increase their rodent and pest control efforts, we estimate that the cost of rodent and pest control will be approximately half of the cost of farms with unacceptable controls. This provision would result in costs of $3.0 million for farms with less than 3,000 layers and costs of $21.0 million for farms with over 3,000 layers.

iv. *Benefits of rodent control.* Rodent control appears to be effective in controlling SE. As a critical vector, rodents may spread SE throughout a given poultry house and between houses. Rodents spread the disease through their droppings, which often are consumed by layers. In this section of this document, we merge

[21] All cost estimates in this section are from data supplied to the FDA through a contract with Research Triangle Institute. Derivations of estimates are described more fully in a memorandum to the record (Ref. 103).

epidemiological data with estimates of the current level of rodent infestation on farms to assess the benefits from increased rodent control.

We used the Layers study (Refs. 25 and 26) to determine the magnitude of the rodent problem on farms. The first four rows of table 12 of this document show the percentages of farms in four size categories with four severities of mouse or rat infestation.[22] Table 12 shows that larger farms are generally more likely to experience moderate or severe rodent problems. The greater prevalence in the larger houses means that, while only 17 percent of houses have moderate or severe rodent problems, 33 percent of all layers are currently in houses with moderate or severe problems.[23]

TABLE 12.—SEVERITY OF RODENT PROBLEM

	Severity in %				No. of Houses in Category
	Severe	Moderate	Slight	None	
Farm Size (No. of Layers)					
<20,000	0.0	14.8	81.7	3.5	36,979
20,000 to 49,999	9.1	13.2	70.1	7.6	1,317
50,000 to 99,999	1.2	28.4	52.3	18.1	861
100,000 or more	1.5	32.1	60.1	6.3	3,279
Percent of Houses Affected	0.5	16.9	78.7	3.8	.....
Percent of Layers Affected	2.9	31.4	60.2	5.5	.....
Risk Ratio	4.2	3.1	2.1	1.0	Total
Percent of Layers in Houses with Positive Environments	19.2	14.3	9.5	4.6	11
Maximum Expected SE Reduction from Increased Rodent Control[1]	38.1	34.0	25.8	0.0	27.3

[1] These values are calculated using the following equations:
Severe: [(19.2 - 4.6) ÷ 2] + 19.2 = 38.1%.
Moderate: [(14.3 - 4.6) ÷ 2] + 14.3 = 34.0%.
Slight: [(9.5 - 4.6) ÷ 2] + 9.5 = 25.8%.
None: [(4.6 - 4.6) ÷ 2] + 4.6 = 0.0%.

Henzler examined the link between rodents and SE, and found that environmental tests of manure in houses with large rodent populations were 4.2 times more likely to be positive for SE than similar tests in houses with small rodent populations.[24] We assume that the risk ratio for SE can be linearly extrapolated between 1 for those farms with no rodent problem and 4.2 for those farms with a severe rodent control problem. This extrapolation is presented in table 11 of this document along with the estimated level of rodent infestation for farms of different sizes.

The third section of the Layers 99 study (Ref. 27)[25] supports the Henzler study. The Layers study finds that farms with a rodent index of at least 20 mice have an SE prevalence rate of 10.1 percent, while farms with a rodent index of less than 20 mice have a prevalence of SE of only 2.0 percent.[26] This difference is statistically significant.

Using data from the Henzler study, we estimated the base level of environmental SE prevalence for houses without rodent problems to be 4.6 percent when the overall prevalence of SE-positive houses is 11 percent. We calculated the base as Base = Overall + [(prevention$_{SEV}$ x Birds$_{SEV}$) + (prevention$_{MOD}$ x Birds$_{MOD}$) + (prevention$_{SLT}$ x Birds$_{SLT}$) + (prevention$_{NON}$ x Birds$_{NON}$)]; where Base is the base level of prevalence for a rodent free house; "Overall" is the total prevalence for all houses; "prevention" is the risk ratio for each level of rodent infestation; and "Birds" is the percentage of layers in houses with a given rodent problem. The subscripts SEV, MOD, SLT, and NON refer to the cases of severe, moderate, slight, and no rodent problems. The percentage of layers in houses with environments positive for SE is found by multiplying the SE risk ratio times the base level of risk. Again, houses with severe rodent control problems are 4.2 times more likely to be positive for SE than houses with no problems (19.2 percent versus 4.6 percent).

In the last row of table 12 of this document, we estimate the expected reduction in SE due to increased rodent control. If rodent control were wholly effective, we would assume that it would result in a drop in SE from current levels to 4.6 percent, the level associated with no rodent problem. For a severe rodent infestation, rodent control would therefore result in a 76.2 percent decline in SE, but such a large decline is not likely for most farms. Those farms with a rodent control problem probably have a problem partly because of factors not experienced by those farms without a problem. House design (open walls, dirt floors, and other

[22] Severity level is self-assessed by respondents to the survey.

[23] To determine the percent of houses affected, the percent of farms with a given rodent problem was weighted using the number of houses in each size category. The number of birds affected was determined by weighting the percent of farms with a given rodent problem in each size category by the number of birds in each size category.

[24] A total of 84 flocks were examined in Pennsylvania (Ref. 48).

[25] The third part of the Layers study (Ref. 27) provides estimates for the prevalence of SE on 200 farm sites with different management practices. For many of the variables analyzed, however, the sample size was too small for statistically significant differences to be measured.

[26] The standardized rodent index is calculated as (number of rodents trapped) x (7 ÷ number of days) x (12 ÷ number of functional traps).

The index standardizes the number of rodents trapped to the equivalent of having 12 traps function for 7 days (Ref. 27).

features), unfavorable location (near other rodent-infested entities, climate, and so on), and lack of knowledge regarding proper rodent control techniques are likely to diminish the effectiveness of rodent control. Consequently, we assume that the effectiveness of rodent control for a particular farm will be uniformly distributed between no reduction and reduction to an SE risk of 4.6 percent. Overall, this leads to an estimated average 27.3 percent reduction in SE, as shown in table 12 of this document.

Based on information from the egg industry, we believe that rodent control may take up to 4 years to be fully effective. During the 4-year transition period, we assume that the effectiveness of rodent control will average 13.7 percent, half of the eventual effectiveness.

We use the base line number of SE cases due to eggs and the value of a typical case of salmonellosis to estimate the value of rodent and pest control benefits. For farms with fewer than 3,000 layers a rodent and pest control program would result in benefits of 71 illnesses averted initially and 142 cases averted eventually at a cost of $58,450 per case averted. For farms with more than 3,000 laying hens, the benefit from rodent and pest control increases from an expected 12,853 illnesses averted initially to 25,701 illnesses averted eventually at a cost of $1,390 per illness averted.

The narrow definition of rodent control is limited to direct methods of catching, killing, and blocking rodents from entering a poultry house. Measures such as pest control, biosecurity, and cleaning and disinfecting also affect rodent control. Cleaning and disinfecting a house, when done properly, removes rodents and their nests from an infested house. Similarly, biosecurity makes rodent penetration of a house more difficult. As a result, the benefits estimated for rodent control are partly due to the adoption of other measures that may be required. We therefore believe that the expected effect of rodent control by itself (assuming no other control measures) would be smaller than our estimates suggest.

v. *Benefits of pest control.* Pests other than rodents also have been shown to be vectors in the spread of SE. In particular, Davies and Wray showed that the ingestion of SE-contaminated maggots by a chicken protects *Salmonella* from the stomach acids of the chicken and aids in the establishment of SE in the chicken's gut (Ref. 102).[27] Beetles and wild birds have also been implicated in the transmission of SE (Ref. 102). Wild birds currently have access to layer feed troughs on 23.5 percent and flies on 91.3 percent of farms (Refs. 25 and 26).

Despite the high prevalence of pests other than rodents on farms, most farms do attempt to limit their presence. Approximately 82 percent of farms currently use fly control methods other than the use of biological predators (Refs. 25 and 26).[28] As with rodents, the effectiveness of fly control is limited by the characteristics of the farm. Farms that operate in damp climates and that are not able to seal their facilities against pests (many houses have dirt floors and open walls) are likely to have more difficulty reducing infestation of all pests.

The third section of the Layers study (Ref. 27) illustrates the effect of pest control. On those farms in which pests have access to feed storage sites, the prevalence of SE is estimated to be 9.6 percent. For farms on which pests do not have access to feed in storage, the prevalence of SE is only 5.8 percent.

vi. *Other benefits of rodent and pest control.* The rodent control provisions are expected to decrease the rodent population in poultry houses. Since rodents consume large amounts of feed, this reduction will benefit producers by lowering their feed costs.

The Cooperative Extension Service of Oklahoma State University estimates that each rat in a poultry house consumes $2.18 worth of feed annually (Ref. 104). Since mice eat 5 to 10 percent as much as rats (Ref. 101), the expected annual loss of feed for each mouse in a house is estimated to cost $0.11 to $0.22.

The upper bound of the savings from increased rodent control due to this provision is the cost of implementing the rodent control measures. In the absence of mandated rodent control, an informed producer will use a level of control that maximizes profits. Any increased rodent control that leads to feed savings in excess of the cost of the control program already will have been implemented before the implementation of a quality assurance program.

We estimate that an infested house may have over 1,000 mice (Ref. 48). This infestation will cost a farmer approximately $165 for that house (1,000 ' $.165). A house infested with rats may have as many as 700 rats (Ref. 105). In this case, the infestation costs the farmer $1,526 (700 ' $2.18).

TABLE 13.—FEED SAVINGS FROM RODENT CONTROL

Problem	Rodents in a House	Feed Savings Per House	% of Houses[1]	Houses in Classification[2]	Cost to Houses in Classification
Mice					
Severe	1,000	$165.00	2.4	114	$18,800
Moderate	500	$82.50	25.5	1,212	$100,000
Slight	250	$41.25	62.4	2,966	$122,300
None	0	$0	9.7	461	$0
Rats					
Severe	700	$1,526.00	1.6	76	$116,000
Moderate	350	$763.00	6.9	328	$250,200
Slight	175	$381.50	43.7	2,077	$792,300

[27] See also Olsen (2000) (Ref. 49).

[28] Use of biological predators is not seen as an effective pest control technique because the predators may themselves become a vector for SE transmission.

TABLE 13.—FEED SAVINGS FROM RODENT CONTROL—Continued

Problem	Rodents in a House	Feed Savings Per House	% of Houses[1]	Houses in Classification[2]	Cost to Houses in Classification
None	0	$0	47.8	2,272	$0
Total Cost of Rodents					$1,399,700
Expected Savings from Control (Assumes 50% reduction)					$699,850

[1] The percentages are from the Layers study (Refs. 25 and 26).
[2] Because rodent populations are estimated for large houses only (over 54,000 layers), we estimate the number of houses to be the number of large house equivalents. This implies that two 27,000-bird houses are counted as one house in this analysis.

The total feed savings from rodent control are illustrated in table 13 of this document. If rodent control leads to just half of all rodents being eliminated, the savings in lost feed from rodent control are estimated to be almost $700,000 annually.

d. *Biosecurity.* i. *Biosecurity provisions.* We have examined the effects of several potential biosecurity provisions. These include the following effects: (1) Limiting visitor access; (2) avoiding the movement of contaminated equipment between poultry houses; (3) ensuring that employees are hygienic; (4) keeping stray poultry, birds, and other animals away from the layer houses; and (5) prohibiting employees from keeping poultry at home.

The first biosecurity measure we examine is the limitation of visitors' access on poultry farms. Limiting a visitor's access may include prohibiting a visitor from entering a house on one farm if that person has already entered a house on another farm. Also, visitors may be banned from entering poultry houses altogether.

Contaminated equipment can also spread SE on a farm. One way to mitigate this problem is to ensure that equipment that is used in multiple houses (such as forklifts and manure removing equipment) is kept clean.

The hygiene of persons moving between houses affects the likelihood of cross-contamination. To protect against cross-contamination, farms may require that employees and visitors use footbaths, change their clothing, or use protective clothing when on the farm. Farms also may choose to require that their employees work on only one farm site on a given day.

Stray poultry, birds, and other animals must also be kept away from the farm's grounds and facilities. This may be done keeping grass and weeds cut, minimizing the existence of standing pools of water near the house, and fencing off the farm site.

Finally, biosecurity precludes employees of the farm from keeping poultry at home.

ii. *Current industry practices; biosecurity.* Most farms already practice some form of biosecurity.[29] According to the Layers study, 68.1 percent of farms do not allow non-business visitors and 22.1 percent do not allow business visitors into layer houses. Of those that do allow visitors to enter, 65.6 percent have biosecurity rules for non-business visitors and 69.5 percent have biosecurity rules for business visitors.

Farms use different methods to keep employee, contract crew, and visitor hygiene at an acceptable level. The Layers study estimates that 24.5 to 24.6 percent use footbaths, 3.9 to 4.8 percent require showers to be taken, and 17.6 to 32.0 percent require persons to change clothes or wear coveralls.

Many farms use biosecurity measures aimed at keeping stray poultry, birds, and other animals away from the layer houses. While data on the number of farms that trim grass and discourage standing pools of water are not available, the Layers study did estimate that fencing is currently used at 26.7 percent of farms.

Finally, 75.7 percent of farms do not allow employees to keep their own layers at home.

iii. *Costs of biosecurity.* It is difficult to quantify many of the costs of biosecurity. This is especially true because the biosecurity measures may be implemented in different ways, allowing each farm to adapt the measures to their operation, as appropriate. However, a few of the costs can be quantified.

First, the cost of limiting visitors can be estimated as the cost of monitoring and providing protective clothing to visitors who are allowed on the farm. The cost of monitoring visitors includes the cost of posting signs asking visitors to check in, the cost of having visitors sign in, and the cost of accompanying visitors around the farm. Protective clothing costs $78.75 for a box of 25 disposable coveralls and $105.38 for a box of 200 plastic shoe covers (Ref. 106). Because farms will choose to implement this part of biosecurity in different ways, it is impossible to determine what the actual cost will be.

The cost of cleaning contaminated equipment is uncertain because we do not know how individual farmers will choose to do this. In our analysis, we assume that the amount of equipment that needs to be kept clean increases linearly with the number of houses on a farm. In particular, we assume that a farm with two houses requires 1 hour of cleaning per week, a farm with three houses requires 2 hours, and so on. Using data from the Layers study, we find that the average farm with more than 3,000 layers will devote 69 labor hours annually to cleaning equipment. At a labor rate of $8.84 per hour, doubled to include overhead costs, the total expected labor cost of this provision is $1,210 per farm, or $5.0 million for all farms with more than 3,000 layers. We expect that there will be little or no cost for farms with fewer than 3,000 layers because the vast majority of these farms have only one layer house.

The cost of chlorine footbaths also can be estimated. We calculate the cost of a footbath as the sum of the cost of the plastic vessel, the cost of bleach, and the cost of the labor needed to fill footbaths. We estimate the total cost per house on farms with more than 3,000 layers to be $420 per year.[30] Houses with fewer than 3,000 layers generally are very small and will need only one footbath. As a result, the cost per house for farms with fewer than 3,000 layers would be $210. Because only 24.6 percent of houses currently use footbaths, the total annual cost of footbaths is estimated to be (100 - 24.6 percent) x 8,612 houses x $420 per house = $2.7 million. We assume

[29] All data in this section are from the Layers study (Refs. 25 and 26).

[30] This estimate is based on the following assumptions: (1) The plastic vessel costs $5 and is replaced annually; (2) bleach costs $1 a gallon, a gallon is used per footbath, and it is changed once a week; (3) there are two footbaths per house; (4) labor costs $8.84 an hour (Ref. 107) and is doubled to include costs of overhead; and (5) changing the bleach-water mixture takes 10 minutes. The estimate in the text is calculated as 2 x ($5 + $1 x 1 x 52 + $17.86 x 0.67 x 52) = $420 per year.

that an insignificant number of farms with fewer than 3,000 layers use footbaths. Therefore, the cost to these very small farms is $7.1 million (33,824 houses x $210 per house).

Employee biosecurity also includes the cost of using protective clothing when moving between houses. As noted above, the cost of plastic coveralls is $78.75 per box of 25, and the cost of plastic shoe covers is $105.38 per box of 200. Because employees will only wear these garments under certain conditions, it is impossible to precisely estimate the annual cost to a farm. We assume that the cost of protective clothing increases linearly with the number of houses on a farm. In particular, we assume that a farm with two houses will use one coverall and two shoe covers per day, a farm with three houses will use 2 coveralls and 4 shoe covers, and so on. If only one coverall and two shoe covers are used per day because of this provision, the annual cost would be $1,534 per farm (365 x ($78.75 ÷ 25 + $105.38 ÷ 100)). The average cost for a farm with more than 3,000 layers would be $2,027. We estimate that the total cost of protective clothing would be $8,268,400 for farms with more than 3,000 layers. We do not foresee that employees on very small farms will use protective clothing because cross-contamination of SE-positive flocks with SE-negative flocks is unlikely (most small farms have one flock), and the cost of protective clothing is relatively high for these producers.

Finally, the cost of keeping stray poultry, birds, and other animals away from poultry houses already is accounted for under rodent and pest control costs. The estimated cost for a complete rodent and pest control program includes all biosecurity measures that contribute to rodent and pest control.

There are potentially significant costs that we have not included here. These include the cost of creating barriers (such as fences) to keep stray poultry and wildlife from entering a layer house.

The total measured costs of biosecurity provisions are $16.0 million for farms with 3,000 or more layers and $7.1 million for farms with fewer than 3,000 layers.

iv. *Benefits of biosecurity.* The importance of biosecurity in the reduction of disease transmission is well established.[31] For example, the Layers study (Ref. 27) estimates that farms allowing non-business visitors onsite are five times more likely to test positive for SE than farms that ban such visitors. Farms allowing non-business visitors have a prevalence of SE of 17.0 percent while farms that do not only have an SE prevalence of 3.6 percent. We include the benefits from biosecurity with those of rodent control, because the effects cannot be estimated separately.

e. *Cleaning and disinfecting.* i. *Cleaning and disinfecting provisions.* Specific cleaning and disinfecting provisions include the removal of all visible manure, a dry clean followed by a wet clean of the house, and disinfecting of the house.

ii. *Current industry practices; cleaning and disinfecting.* To a large extent the layer industry already performs adequate cleaning and disinfecting procedures. For larger houses, the Layers study (Refs. 25 and 26) estimates that, at some point, manure is removed from 100 percent of houses, 80.5 percent of houses are dry cleaned, 53.6 percent of houses are wet cleaned, and 65.1 percent of houses are disinfected. The prevalence of these practices on large farms is illustrated in table 14 of this document.

TABLE 14.—CURRENT CLEANING AND DISINFECTING PRACTICES FOR LARGE FARMS

	Manure Removal (%)	Dry Clean (%)	Wet Clean (%)	Disinfect (%)
Between each flock (cleaned annually)	96.6	79.4	30.6	44.5
After two or more flocks (cleaned occasionally)	3.4	1.1	23.0	20.6
Never	0	19.5	46.4	34.9

We assume that smaller farms are likely to remove manure and dry clean at the same rate as larger farms. The likely economies of scale for wet cleaning and disinfecting houses, however, imply that the cost per square foot wet cleaned or disinfected would be higher for small farms than for larger farms. The cost of hiring someone to complete the job includes the cost of travel time, overhead, and the cost of setting up equipment. Farmers may find it economical to rent or buy equipment. When this occurs, the farmer's labor hours expended on cleaning and disinfecting are likely to be higher than that of trained professionals.

iii. *Costs of cleaning and disinfecting.* The cost of cleaning and disinfecting houses with more than 3,000 layers is illustrated in table 15 of this document. For each component of cleaning and disinfecting, we estimate the annual cost as the number of houses that this provision will affect each year times the cost per house. We calculate the number of houses affected as the product of the percent of houses not using a practice (100 minus the percent using the practice in table 15 of this document), the probability of a positive flock, and the number of houses with 3,000 or more layers (8,612, calculated from data in table 6 of this document).

TABLE 15.—COST OF CLEANING AND DISINFECTING HOUSES WITH 3,000 OR MORE LAYERS

	Houses Using Practice (%)	Probability of a Positive Env. Test (%)	No. of Houses Affected	Cost Per House	Cost to Industry
Dry Clean	79.8	8.4	146	$1,054	$154,090

[31] A number of State extension services have written extensively about the importance of biosecurity (Refs. 108, 109, and 110).

TABLE 15.—COST OF CLEANING AND DISINFECTING HOUSES WITH 3,000 OR MORE LAYERS—Continued

	Houses Using Practice (%)	Probability of a Positive Env. Test (%)	No. of Houses Affected	Cost Per House	Cost to Industry
Wet Clean	38.3	8.4	446	$5,750	$2,564,834
Disinfect	51.4	8.4	351	$513	$180,094
Total Cost					$2,899,018

The percentages of houses engaged in the different cleaning and disinfecting practices (the first column of numbers in table 15 of this document) is based on the first two rows of table 14 of this document. In table 15 we calculate the percent as CA + (CO x PC), where CA is the percent of farms that are cleaned and disinfected annually, CO is the percent of farms that are cleaned and disinfected occasionally, and PC is the probability that a farm that is cleaned occasionally would have been cleaned in a year that it had a positive environmental test. We assume that PC is distributed uniformly between 0 and 0.667, with a mean value of 0.333. CA and CO are taken directly from table 14 of this document.

The per-house cost for each component is taken from Morales and McDowell (Ref. 111). We assume that the true cost of each component is distributed uniformly between the low and the high estimates given.

We show the cost of cleaning and disinfecting separately for farms with fewer than 3,000 layers in table 16 of this document. For the reasons stated above, we assume that it will be more economical for small farmers to do their own cleaning and disinfecting, as opposed to hiring professionals.

TABLE 16.—CLEANING AND DISINFECTING COSTS FOR FARMS WITH FEWER THAN 3,000 LAYERS

	Dry Clean	Wet Clean	Disinfect
Equipment Cost	$10	$90	$0
Chemical Costs	$0	$30	$100
Labor	$141	$283	$71
Cost per House	$151	$403	$171
Percent of Houses Affected	1.7%	6.8%	6.2%
No. of Houses Affected	574	2295	2109
Total Cost	$86,674	$924,885	$360,639

For each category of cleaning and disinfecting we have estimated the equipment, chemical, and labor costs of performing the task. We value labor at the average hourly wage for livestock and poultry workers, $8.84, doubled to include overhead costs (Ref. 107).

Dry cleaning is a necessary precursor to wet cleaning. In this stage of the process, loose dirt, cobwebs, rodent nests, organic matter, litter, and feed are removed from the house. Equipment needs include brooms, shovels, wheelbarrows, and other implements. We assume that farms already will have these types of equipment but may need to pay for protective clothing and masks. We estimate that it will take a day of labor to dry clean a small house.

Wet cleaning is more complicated than dry cleaning. The first step of wet cleaning is to cover all sensitive equipment in the house (such as lighting and any other electrical appliances) with plastic. Next, a pressure washer (in conjunction with an acceptable detergent) is used to thoroughly clean the cages and walls of the house. We assume the pressure washer will be rented for 3 days. Finally, standing pools of water are expelled from the house and the house is left to dry. We assume that 2 days worth of labor will be required to complete a wet clean on a small house.

In the final stage, a disinfectant is sprayed throughout the dried house (or the house may be professionally fumigated). We assume that this will take only a half of a day worth of labor for a small farm.

We assume that the probability of a positive flock is the same for all size farms (8.4 percent). We also assume that the percent of houses that would be affected by the drying cleaning provisions would be the same for farms with fewer than 3,000 layers as for farms with 3,000 or more layers: The percent not dry cleaning multiplied by the probability of a positive flock ((1 - 0.798) x 0.084). Small farms are less likely to wet clean and disinfect; we assume that the percentage of farms with fewer than 3,000 layers not using those practices is uniformly distributed between the percentage of farms with 3,000 or more layers not using those practices and 100 percent. We therefore estimate that 81 percent of farms with fewer than 3,000 layers do not wet clean and 74 percent do not disinfect houses. We multiply these estimates by the probability of a positive flock to estimate the percentage of small farms affected by the wet cleaning and disinfecting provisions.

To estimate the number of farms with fewer than 3,000 layers that would be affected by dry cleaning, wet cleaning, and disinfecting provisions, we multiply the percentage affected by each provision by the number of such farms (33,824). For each practice, dry cleaning, wet cleaning, disinfecting, we multiply the costs per house by the number of houses affected. We then sum the results to estimate the total costs of

cleaning and disinfecting houses on farms with fewer than 3,000 layers. The total increased cost of cleaning and disinfecting on these very small farms would be about $1.4 million.

iv. *Benefits of Cleaning and Disinfecting.* Cleaning and disinfecting is another tool that may decrease or eliminate SE in an infected house. Schlosser et al. estimate that cleaning and disinfecting a house reduces, by 50 percent, the probability that a previously infected house will test positive (Ref. 39). Because cross-contamination is not addressed in this study, the 50 percent reduction is likely to be an overestimate of the actual efficacy of cleaning and disinfecting. Furthermore, the same study estimates that 28 percent of negative houses tested positive after cleaning and disinfecting.

The Layers Report (Ref. 27) finds that farms that are cleaned and disinfected are less likely to be contaminated with SE. No surveyed farms that performed wet washes of houses between flocks were found to be positive. By contrast, houses that neither wash nor fumigate between flocks had SE prevalence rates of 12.2 percent. These results suggest that cleaning and disinfecting a layer house is negatively correlated with SE prevalence.

f. *SE-Monitored chicks and pullets.* i. *Chick and pullet provisions.* We also considered the provision that farmers obtain their chicks or pullets from an SE monitored breeder flock.[32]

ii. *Current industry practices—SE-monitored chicks and pullets.* According to the Layers study (Refs. 25 and 26), 94.6 percent of farm sites representing 94.5 percent of layers received their chicks from flocks that were bred under the NPIP program. Furthermore, NPIP has successfully integrated all of these layers into the NPIP U.S. *Salmonella* Enteritidis monitored program (Ref. 112).

NASS estimates that a total of 138,292,380 pullets and chicks were sold in 1997 (Ref. 22). If 94.5 percent of these birds were purchased from breeder facilities that are NPIP SE monitored, then 5.5 percent (7,606,080) of chicks and pullets are not currently monitored for SE.

iii. *Costs of SE-monitored chicks and pullets.* We do not have data for the cost of monitoring chicks for SE. However, Morales and McDowell (Ref. 111) estimated that pullets monitored for SE cost approximately $0.003 to $0.02 more per pullet. If we assume the cost difference is the same for chicks, the total increased annual cost of requiring SE-monitored chicks is estimated to be $22,820 to $152,120 with a mean expected value of $87,470.[33] If we assume that all farms would be proportionally affected by this provision, the approximate annual cost to farms with fewer than 3,000 layers would be $500, and the annual cost to farms with 3,000 or more layers would be $87,000.

iv. *Benefits of SE-monitored chicks and pullets.* The prevalence of SE in breeder flocks is relatively low.[34] Between 1994 and 1996 only 9 out of 847 breeder flocks (1.1 percent) had environments that tested positive for SE. Furthermore, over the same period only two breeder flocks (0.2 percent) had layers that tested positive for SE.[35] For our estimate of benefits, we used the 0.2 percent figure because breeders under the NPIP program must destroy their flocks when layers test positive, not when the environment tests positive.

The 0.2 percent estimate understates the probability that a farm not currently using NPIP SE-monitored layers will test positive. To the extent that farmers obtain their chicks from multiple sources,[36] we would expect the probability that a farm obtains SE-positive chicks to be greater than the underlying prevalence of SE in hatchery flocks.[37]

We calculated the expected benefit of this provision using the percentage of farms affected by the provision multiplied by the probability of a positive test. Because only 5.5 percent of farms receive birds from breeder flocks that are not SE monitored, the expected effect of this provision on SE contamination on the farm and, hence, human illness, is projected to be slightly greater than 0.01 percent (5.5 percent x 0.2 percent). This percent translates into an expected benefit of less than one case of SE per year averted at farms with fewer than 3,000 layers, and 10 illnesses averted for farms with 3,000 or more layers. The cost per illness averted is $8,960 for farms with fewer than 3,000 layers and $8,410 for farms with more than 3,000 layers.

This provision attempts to bar the introduction of SE onto the farm. SE can be difficult to control once it has been introduced onto a farm, but if SE is never introduced, it is impossible for it to spread. For this reason, effective SE control in chick populations has been cited as critical.

g. *SE-Negative feed.* i. *Feed provisions.* We considered proposing to require the use of feed that meets the standards for SE-negative feed, as defined by FDA's Center for Veterinary Medicine (CVM). CVM defines SE-negative as 10 subsamples that are negative for SE (measured using the Bacteriological Analytical Manual method) collected for a lot of feed (60 FR 50098, September 28, 1995). Composite samples may be used to reduce testing costs. We received comments that SE-negative feed is not currently available commercially.

ii. *Current industry practices—SE monitoring of feed.* The layer industry obtains feed from both independent feed mills and from egg farmers that produce feed in their own mills. The Economic Research Service (ERS) report on the feed manufacturing industry estimates that egg producers operated a total of 144 feed mills in 1984 (Ref. 114). In the absence of more recent data, we assume that they operated the same number in 2002. To isolate the number of independent feed mills operating in the United States, we used the July 2000 version of Dun's Market Identifiers (Ref. 115). Using this database, we were able to isolate 210 mills that primarily produce poultry and chicken feeds. We consider this figure to be the lower bound of the number of independent feed mills producing layer feed. For the upper bound, we assume that all 2,459 establishments that Dun's Market Identifiers reports as producers of animal feeds produce layer feed.[38] This estimate is similar to the 1984 Economic Research Service estimate of 2,432 primary feed manufacturers. Assuming that the true number of feed mills producing layer feed is uniformly distributed between the upper and lower bounds, we estimate that approximately 1,300 feed mills produce layer feed.

iii. *Costs of monitoring feed for SE.* The cost of this provision to a feed mill would be the sum of the labor, laboratory, and shipping costs for testing, multiplied by the number of lots

[32] NPIP certified or the equivalent.

[33] If monitoring costs $0.003 per layer, the total cost is 7,606,080 layers x $0.003 = $22,820. If monitoring costs $0.02 per layer, the total cost is 7,606,080 layers x $0.02 = $152,120. The average of these two figures is $87,470.

[34] The data for this paragraph is drawn from Rhorer (Ref. 113).

[35] Under the NPIP program a flock only loses its certification as a NPIP SE-monitored flock if birds test positive.

[36] The Layers study estimates that 38.2 percent of farms obtain pullets from multiple sites (Refs. 25 and 26).

[37] The following example illustrates this point. If a farmer obtains pullets from two different flocks, each of which has a 0.2 percent chance of having SE positive birds, the probability that the farm will obtain SE positive birds is 0.2 percent + 0.2 percent - 0.04 percent = 0.36 percent.

[38] The lower bound estimate is likely to underreport the number of mills producing layer feed because most firms did not report,to Dun's Market Identifiers what kinds of feeds they produced.

tested. In addition, SE-positive feed would have to be treated or destroyed.

The laboratory cost per test has been estimated to be approximately $49.75 per sample.[39] In addition, we estimate that the collection and preparation of each subsample will take approximately 10 minutes. Given an hourly wage of $14.65 for production inspectors at grain and feed mills (Ref. 117), doubled to include overhead costs, we estimate the cost of labor to be $48.84 ($29.30 x 1.667 hours) for each full sample. The cost of shipping each sample to a lab is estimated to be $22.[40] The total cost per composite sample is $121.47 ($49.75 + $48.84 + $22.88).

Samples must be taken for each lot of feed. We expect that, because of limited storage space for finished feed, a lot of feed will not exceed 3 days worth of production for most large mills. For some small mills, however, a lot may be a week's worth of production; for some large mills a lot may be a day's worth of production. Given these parameters, we assume that the frequency of feed testing will be distributed uniformly between once a week and five times a week with a mean frequency of 3 times a week. Consequently, the expected annual cost of testing for a typical feed mill is calculated to be approximately $18,950 ($121.47 per sample x 52 weeks x 3 times a week). The cost of testing all of the approximately 1,450 entities that produce feed is estimated to be $27.5 million. If these costs are passed on to farmers at a rate proportional to the number of layers on the farm, the total cost to farms with fewer than 3,000 layers would be $137,500 and the cost to farms with more than 3,000 layers would be $27,362,500.

In the event of a positive feed test, feed mills would have to treat or destroy the suspect feed. It is also likely that the mill would take action to address the problem at its source. Furthermore, any feed that the mill has shipped would be considered adulterated. The mill would have to recall this feed and treat or dispose of it, which could be very costly. If, however, an SE positive lot were identified through testing, this provision would result in increased benefits.

iv. *Benefits of monitoring feed for SE.* Feed contaminated with SE is theoretically also a vehicle for the introduction of SE on the farm. In 1997, SE was found in 0.3 percent of finished feed samples that were serotyped in the United Kingdom (Ref. 119). In the United States, however, testing for SE in finished layer feed at the mill has almost never yielded positive results.[41] Nonetheless, the fact that SE has been isolated from finished feed at mills in the United Kingdom and from feed ingredients suggests that SE contamination is a potential problem (Ref. 102).

If feed is contaminated with SE, the consequences for human health are potentially large. A feed mill that does not test feed for SE and becomes contaminated with SE could deliver a large number of shipments of contaminated feed before the problem is uncovered. The potential financial consequences to the farms using the feed include costs due to increased cleaning and disinfecting, egg testing, and diversion of eggs. Also, there likely would be adverse health effects from the consumption of SE-positive eggs.

h. *Vaccination of flocks.* i. *Vaccination provision.* Inoculating layers with vaccines is another potential way of preventing the growth of SE in layers. FDA could mandate that all layers be inoculated against SE.

ii. *Current industry practices; vaccination of flocks.* The Layers study (Refs. 25 and 26) estimates that at least 14.6 percent of all layers on farms with 3,000 or more layers are vaccinated against SE. We assume that an insignificant number of layers on farms with fewer than 3,000 layers are vaccinated against SE.

iii. *Cost of vaccinating flocks.* Vaccination costs approximately $0.135 per layer for an inoculation[42] (Ref. 121). Given 255.5 million layers on larger farms and 1.4 million layers on smaller farms, we expect that this provision would result in 218.0 million new vaccinations on larger farms and 1.4 million new vaccinations on smaller farms. Consequently, the cost of vaccination on farms with at least 3,000 layers would be $29.3 million. The total cost for farms with fewer than 3,000 layers would be $0.2 million.

iv. *Benefits of vaccinating flocks.* The evidence regarding the efficacy of vaccines in reducing SE in laying hens is mixed. Gast et al. showed in an experimental setting that vaccines do partially reduce the shed of SE from laying hens (Ref. 122). By contrast, Davison et al. used a field experiment to show that vaccines are relatively ineffective in stopping the spread of SE on farms (Ref. 123).

v. *Refrigeration.* i. *Refrigeration provisions.* We considered a refrigeration provision that all eggs held for more than 36 hours after lay be refrigerated at a maximum ambient temperature of 45 °F.

ii. *Current industry practices; refrigeration.* Because eggs packed on the farm do not have to be transported to a packing plant, we assume that eggs on these farms are packed for sale within 36 hours of lay. Accordingly, we assume that this provision would impose additional costs only on those farms that do not pack their eggs for the ultimate consumer, are currently storing their eggs for longer than 36 hours, and currently do not refrigerate their eggs at an ambient temperature at or below 45 °F. We use data from the Layers study (Refs. 25 and 26), shown in table 17, to determine the percentage of farms affected by the on-farm storage temperature requirements.

TABLE 17.—FARMS AFFECTED BY ON-FARM EGG STORAGE TEMPERATURE REQUIREMENTS

Farm Size (No. of Layers)	Packed Off-Farm (%)	Stored Longer Than 36 Hours (%)	Temp >45 Degrees F (%)	Percent of Farms Affected	No. of Farms Affected
Less than 3,000	100.0	100.0	81.2	81.2	27,465
3,000 to 19,999	98.3	98.2	78.1	75.4	1,762

[39] This is the cost of an Association of Official Analytical Chemists test for *Salmonella* genus and a serotype test at Silliker Laboratories (Ref. 116). One option that mills have is to initially test for the genus of *Salmonella* ($19.75) and then, if the test is positive, follow through with a test for the serotype enteritidis ($30). We assume that mills will not choose this option because *Salmonella* positive feed is considered adulterated and firms will not want to test to see if their feed is adulterated unless mandated to do so by FDA.

[40] The cost of shipping a 2-pound package overnight in the United States ranges from $18.00 to $27.75. These figures include a $3 pick-up charge. The average charge is estimated to be $22.88 (Ref. 118).

[41] SE has been isolated in ingredients at feed mills in the United States (Ref 120).

[42] This is based on a per layer cost of $0.035 for vaccine plus $0.10 for labor (Ref. 121).

TABLE 17.—FARMS AFFECTED BY ON-FARM EGG STORAGE TEMPERATURE REQUIREMENTS—Continued

Farm Size (No. of Layers)	Packed Off-Farm (%)	Stored Longer Than 36 Hours (%)	Temp >45 Degrees F (%)	Percent of Farms Affected	No. of Farms Affected
20,000 to 49,999	96.3	100.0	75.8	73.0	686
50,000 to 99,999	83.1	83.4	92.1	63.8	229
100,000 or more	65.6	75.0	72.6	35.7	158
Total	81.2	87.3	81.2	57.6	30,300

The first three columns of table 17 of this document are taken directly from data collected for the Layers study. The percentage of farms affected (fourth column) is the product of multiplying the first three columns. The number of farms affected (final column) is estimated by multiplying the percent of farms affected by this provision by the total number of farms covered by the provision.

It is clear from the percentages of farms affected (fourth column) that temperature requirements are more likely to affect smaller farms than larger farms. For those farms with fewer than 3,000 layers, we assume that all eggs are packed off the farm,[43] all are stored for more than 36 hours, and 81.2 percent (the average for all other categories) are stored at a temperature higher than what is required for the provision.[44]

iii. *Cost of refrigeration.*[45] The refrigeration provision will cause producers to choose to perform the following tasks: (1) Turn down the thermostats in their coolers, (2) install new refrigeration, or (3) renegotiate their shipping contracts to require more frequent pickup of unpacked eggs.

In table 17 of this document, we estimate that a total of 30,300 farms do not meet the standards set by the refrigeration provision. Of these farms, some are currently using refrigeration, albeit at higher temperatures than the proposed provision would permit. Others do not have any refrigeration installed on their farms. We assume that those farms that report storing their eggs between 45 and 60 °F already have refrigeration installed. For these farms, the cost of complying with the refrigeration provision is simply the cost of increasing electricity usage to further cool their eggs. For farms that store their eggs at a temperature greater than or equal to 60 °F, we assume that no refrigeration is currently installed. The cost to these farms includes the cost of installing an insulated egg room with refrigeration units.

In table 18, we use data from the Layers study to determine how many covered farms will have to install refrigeration and how many will only have to reduce the temperatures in their egg rooms. The majority of smaller farms lack refrigeration facilities, while larger farms are more likely to use refrigeration at an inadequate level.

The cost of this provision to farms that are using refrigeration at an inadequate level is assumed to be the cost of increased energy usage.[46] If temperatures in egg rooms on these farms are uniformly distributed between 45 and 60 °F, the average needed temperature reduction is 7.5 °F. If the electricity rate is $0.09 per kilowatt-hour, farms will spend between $23 for farms with fewer than 100 layers to over $2,200 for farms with more than 100,000 layers. These estimates are based on the assumption that refrigeration must be run 18 hours a day to achieve the 45 °F mark, while it must be run 15 hours a day to achieve the 60 °F mark. We estimate that the average farm with 20,000 to 50,000 layers would need to run one 5-horsepower refrigeration unit and one 1-horsepower unit to sufficiently cool its egg room. A 5-horsepower unit uses 4.83-kilowatt hours per hour of operation, while a 1-horsepower unit only uses 1.73-kilowatt hours. Therefore, the cost of cooling to 60 °F is (4.83 + 1.73) kilowatt hours used per hour x 15 hours of operation x $0.09 per kilowatt hour used x 30 days ≈ $265 per month, or about $3,190 per year. The cost of cooling to 45 °F is (4.83 + 1.73) kilowatt hours used per hour x 18 hours of operation per day x $0.09 per kilowatt hour x 30 days ≈ $319 per month, or about $3,830 per year. The resulting cost of decreasing the ambient temperature in the egg cooler by 15 °F is approximately $640. Assuming a linear relationship between refrigeration and cost gives us an estimate of approximately $320 for a 7.5 °F reduction.

[43] Although there are some small farms that pack their eggs on the farm, we assume that most small farms that pack their own eggs sell all of their eggs directly to consumers, and therefore are not covered by the proposed rule. We have no information regarding how many farms that are covered by this rule pack their eggs. We request comment on the prevalence of this practice.

[44] The assumptions that all eggs from farms with fewer than 3,000 layers are packed off of the farm and are stored for longer than 1 day are based on an extrapolation of the trends by farm size that are apparent in table 17 of this document. Because there is no obvious trend for compliance with temperature requirements, we use the mean value for all farms as our assumption for farms with fewer than 3,000 layers.

[45] All cost estimates in this section are from data supplied to FDA through a contract with the Research Triangle Institute. Derivation of estimates is more fully described in a memorandum to the record (Ref. 124).

[46] We recognize that some of these farms may require additional refrigeration units to achieve the 45 °F threshold. However, because we do not currently have information that allows us to estimate how many farms fall into this category, we assume that the only cost facing farms that use an inadequate level of refrigeration will be the cost of increased energy usage.

TABLE 18.—ANNUAL COST OF REFRIGERATING AFFECTED FARMS

Farm Size (no. of Layers)	No Refrigeration			Inadequate Refrigeration		Total Cost (in thousands)	
	Number	Cost per Farm (7% discount rate)	Cost per Farm (3% discount rate)	Number	Cost per Farm	7% interest rate	3% interest rate
Fewer than 100	13,950	$325	$312	11,565	$23	$4,800	$4,618
100 to 3,000	1,066	$833	$733	884	$42	$925	$819
3,000 to 19,999	963	$7,763	$5,882	799	$201	$7,636	$5,825
20,000 to 49,999	205	$15,026	$11,052	482	$319	$3,234	$2,419
50,000 to 99,999	94	$28,510	$20,716	135	$553	$2,755	$2,022
100,000 or more	35	$121,329	$87,497	123	$2,219	$4,519	$3,335

The fixed cost of new refrigeration for larger farms includes the cost of constructing an egg room, insulating that room, and installing refrigeration units. Storage rooms and their insulation are assumed to last 30 years. Refrigeration units last from 10 to 20 years. Using these values, along with a 7-percent interest rate, we estimate that the annualized cost of installing new refrigeration would be from $330 for a farm with 300 layers to $94,700 for a farm with 400,000 layers. With an interest rate of 3 percent, we estimate that the annualized cost of installing new refrigeration would be from $230 for a farm with 300 layers to $60,870 for a farm with 400,000 layers.

The cost of constructing an egg room equals the number of square feet required times the construction cost per square foot. The number of square feet required is estimated as the number of square feet required per 1,000 dozen eggs times the number of eggs produced in a 24-hour period (1,000 dozens) times the number of days the eggs are expected to be stored. The cost of construction per square foot has been estimated to be between $50 and $75. Therefore, for the average farm with 20,000 to 50,000 layers the cost of construction is 294 square feet per thousand dozen eggs x 1.7 thousand dozen eggs x $62.50 per square foot x 3.9 days worth of storage = $125,000. The amortized cost over 30 years at 7 percent is approximately $10,050.

The cost of insulating an egg room equals the number of square feet to be covered times the insulation cost per square foot. Insulation costs $11.80 for a 32 square foot sheet. For a farm with 20,000 to 50,000 layers the expected cost of insulation is therefore 3,670 square feet x $0.37 per square foot = $1,350. The annualized cost of insulation (amortized over 30 years at 7 percent) is $110.

The fixed cost of refrigeration for an egg room is the cost of buying and installing refrigeration units. We assume that installation costs are approximately 5 percent of the purchase price of the unit. For a farm with 20,000 to 50,000 layers, the cost of refrigeration is the purchase price for needed refrigeration units ($9,100) plus the cost of installation ($9,100 x 5 percent) = $9,100 + $455 = $9,555. Amortizing this cost over 15 years at 7 percent yields an annual cost of $1,050.

The total annualized cost of installing a refrigerated egg room on a farm with 20,000 to 50,000 layers is estimated to be approximately $11,200. This figure does not include the cost of energy. Including the cost of energy increases the total cost to $15,026.

The smallest farms (those with fewer than 100 layers) will not have to install egg rooms. We believe that farms with fewer than 100 layers will be able to store their eggs in a household refrigerator without a freezer. We estimate the cost of a 16.7 cubic foot frost-free stand-alone refrigerator (without a built-in freezer) to be $500. Amortized at 7 percent over 15 years brings the annualized cost of this purchase to $55. Amortized at 3 percent over 15 years brings the annualized cost of this purchase to $42.

For all types of refrigeration, there also will be a cost associated with the use of electricity to run the cooling units. Given that electricity costs $0.09 per kilowatt-hour, we estimate that farms will spend an additional $270 to $26,600 annually for power.[47]

The cost of this provision to a farm without any refrigeration in place is estimated to range from about $325 for farms with fewer than 100 layers to over $121,300 for farms with more than 100,000 layers. The total cost of the refrigeration provision is approximately $23.9 million ($5.7 million of which is incurred by farms with fewer than 3,000 layers) using a 7-percent interest rate and approximately $19 million ($5.4 million of which is incurred by farms with fewer than 3,000 layers) using a 3-percent interest rate. However, some farms will choose to increase the frequency of egg pickups instead of installing additional refrigeration to remain in compliance with the provision. If more frequent egg pick-ups are a lower cost alternative to refrigeration installation, the previously mentioned figures may overstate the actual cost of increased refrigeration.

iv. *Impact of refrigeration on egg processors.* Eggs washed at a temperature more than 40 degrees over their internal temperature are more likely to suffer thermal checks. These minute cracks increase the chance of egg breakage and egg contamination with pathogens from outside of the egg. Because of this problem, egg processors will not want to wash eggs that have an internal temperature of less than 50 degrees.

We are considering a refrigeration provision requiring that eggs be kept at an ambient temperature of 45 degrees, if they are held by the producer for more than 36 hours.

Whether high wash water temperatures will damage refrigerated eggs depends on whether the internal temperature of the eggs is less than 50 degrees. As a result, the cooling rate of refrigerated eggs becomes an important question. We ask for comment on this question and on the costs to processors.

v. *Benefits of refrigeration.* The probability that an individual will become ill from an SE-contaminated egg

[47] As noted previously, for a farm with 20,000 to 50,000 layers the annualized cost of cooling an egg room to 45 °F is (4.83 + 1.73) kilowatt hours used per hour x 18 hours of operation per day x $0.09 per kilowatt hour x 30 days = $319 per month, or about $3,830 per year.

depends, among other things, on the number of bacteria within the infected egg. Refrigeration of eggs at 45 °F significantly slows the reproduction of the SE bacteria (Ref. 15). This provision would require that eggs that are stored for more than 36 hours after laying be refrigerated at 45 °F while on the farm. In this section, we calculate the effectiveness of potential storage and refrigeration requirements using the USDA SE risk assessment model (Ref. 15). This model is designed to estimate the effects of preventive measures on SE illness.

In the following cost model, we estimate that 35.7 percent (farms with fewer than 3,000 layers) to 81.2 percent (farms with more than 100,000 layers) of farms currently meet the refrigeration standards of the proposed provision. Taking a weighted average, we estimate that 46.6 percent of eggs are produced on farms that do not currently meet the standards set forth in the provision.[48] We programmed the SE risk assessment to estimate the effects on SE if all farms meet the refrigeration requirement. A storage and refrigeration provision is expected to incrementally reduce illnesses by 2.3 percent. In the absence of other provisions this percentage reduction translates into a benefit of 10 illness averted annually for farms with less than 3,000 layers and more than 2,160 illnesses averted for farms with more than 3,000 layers. The cost per illness averted on farms with less than 3,000 layers is $563,206 when we use a 7 percent interest rate ($534,829 when we use a 3 percent interest rate). The cost per illness averted on farms with more than 3,000 layers is $8,380 when we use a 7 percent interest rate ($6,282 when we use a 3 percent interest rate).

j. *Routine environmental testing.* Environmental testing does not serve directly as an SE prevention measure. Testing serves primarily as an indicator of the effectiveness of the SE prevention measures.

i. *Environmental testing provision.* This potential provision would require every farm to routinely test the environment of their layers for SE. For flocks that do not undergo a molt, this requirement would be limited to a test for SE in the environment when each group of layers in the flock is 40 to 45 weeks of age. For those flocks that do undergo a molt, testing would be required when each group of layers is 40 to 45 weeks of age and 20 weeks after molting for each group is completed.

Testing would be accomplished by a method such as swabbing manure piles in the poultry house and then culturing those swabs using a primary enrichment testing method. We are considering variants of sampling protocols that are currently in use. California currently uses a sampling plan that relies on randomly swabbing 30-foot sections of the poultry house (Ref. 125). To obtain a 95 percent probability of catching a house that is 10 percent infected, we estimate that 32 samples would have to be taken. Many other States, including Pennsylvania, require the span of each row of the layer house to be swabbed with one swab, regardless of row length (Ref. 39).

ii. *Current industry molting practices.* Molted flocks face additional testing under this provision, so current industry molting practices are an important element in determining the cost of this provision. Overall, 62.1 percent of all large flocks are molted once and 12.1 percent are molted twice before depopulation (Refs. 25 and 26). Industry molting practices, however, vary by region and by farm size.

Farms in the Central and Great Lakes regions are least likely to molt their flocks while farms in the Southeast and West are most likely to use molting as a practice. (See table 19 of this document.)

TABLE 19.—REGIONAL MOLTING PRACTICES[1]

Region	Times Molted (percent)		
	0	1	2
Great Lakes	30.0	65.2	4.8
Southeast	7.3	80.2	12.5
Central	48.8	51.2	0.0
West	17.9	50.0	32.1

[1] Layers study data provided by Animal and Plant Health Inspection Service.

The implication of the regional disparities in molting practices is that any rule that treats molted and non-molted flocks differently will also affect regions differently.

Molting practices also vary by farm size. As table 20 of this document illustrates, smaller farms are less likely to molt their layers than are larger farms. While almost 85 percent of all farms with 50,000 or more layers molt their layers, only 27.8 percent of farms with fewer than 20,000 layers molt their flocks. This disparity plays a significant role in the determination of the expected cost of testing and diversion.

TABLE 20.—MOLTING PRACTICES BY FARM SIZE[1]

Farm Size (No. of layers)	Times Molted (in %)		
	0	1	2
Fewer than 20,000	72.2	27.8	0.0

[48] The weighted average number of eggs affected by this proposed rule is calculated using the following formula. Percent of eggs affected = the sum of (farms affected, x percent of birds in size category,), where i is an index for farm size. This formula yields: Percent of eggs affected = (78.8 percent x 0.23 percent) + (71.8 percent x 10.55 percent) + (63.7 percent x 10.51 percent) + (56.1 percent x 9.67 percent) + (27.5 percent x 69.04 percent) = 38.9 percent.

TABLE 20.—MOLTING PRACTICES BY FARM SIZE[1]—Continued

Farm Size (No. of layers)	Times Molted (in %)		
	0	1	2
20,000–49,999	35.3	54.0	10.7
50,000–99,999	13.6	68.4	18.0
100,000 or more	15.7	72.3	12.0

[1] Layers study data provided by Animal and Plant Health Inspection Services.

iii. *Current environmental testing practices.* According to the Layers study, approximately 52 percent of all farms with more than 30,000 layers currently conduct some routine environmental tests for SE (Refs. 25 and 26). The vast majority of these producers are also members of formal quality assurance programs. Because very few small farmers are members of these programs, we assume that no farmers with fewer than 3,000 layers currently engage in routine testing of the environment for *Salmonella*. This assumption is likely to lead to an overestimation of testing costs. However, we also assume that all houses contain only one group of layers. Because there are some multi-age houses that are considered to have multiple groups for the purposes of testing, assuming that each house has only one group is likely to lead to an underestimation of costs.

iv. *Environmental testing costs.* The cost of routine environmental testing depends on how many samples are tested, the labor cost of collecting the samples, the cost of shipping the samples to a laboratory, and the laboratory cost per sample tested.

We assume that it will take approximately 15 minutes to collect and pack each sample. Since the wage for a typical livestock and poultry worker is approximately $8.84 per hour (Ref. 107), doubled to reflect overhead costs, the cost of labor is assumed to be (15 ÷ 60) x $17.68 = $4.42 per sample collected.

The cost of shipping samples will vary by the weight of the shipment. We assume that a swab, with its packing material, weighs approximately one pound. To calculate the cost of shipping, we estimate the average number of swabs sent per shipment and use rate tables (Ref. 118) to determine the cost of shipment.

We estimate the laboratory cost of testing for SE that has been collected from the environment to be approximately $37.50 per sample.[49]

The average cost of routine testing for SE in a given house is determined by multiplying the number of tests required for that house by the expected cost per test. For any plan that is used, the per house cost of testing is estimated to be Cost = SWABS x (LABOR + MAIL + LAB), where SWABS is the number of required swabs, LABOR is the cost of labor per test, MAIL is the cost of shipping samples to a lab, and LAB is the laboratory costs of testing for SE.

To determine the testing cost of the row-based plan, we multiply the cost per test by the estimated number of rows that will have to be swabbed. We assume that all farms that are currently conducting routine testing (52 percent) (Refs. 25 and 26) are in compliance with the row-based plan.

The number of rows that will have to be swabbed in larger houses is estimated in table 21 of this document. Information for the first three columns is drawn from the Layers study (Refs. 25 and 26). We estimate the number of houses affected by the provision (the fourth column) by multiplying the number of large houses (8,560) by the percent of houses affected by the provision (48 percent), and then multiplying the product by the percent of houses in the given category. We estimate the number of rows that will have to be swabbed because of the provision as the number of rows per house times the number of houses affected by the provision. A total of 24,960 rows would have to be swabbed due to this provision.

TABLE 21.—NO. OF ROWS TO BE SWABBED
(HOUSES WITH 3,000 OR MORE LAYERS)

No. of Rows or Batteries of Cages	Average No. of Rows[1]	Percent of Houses	No. of Houses Affected	No. of Rows Affected
1	1.0	1.9	80	80
2 to 3	2.5	12.5	520	1,290
4 to 5	4.5	50.8	2,100	9,450
6 or more	10.0	34.2	1,410	14,140
Total	6.1	.....	4,110	24,960

[1] The average number of rows per house is estimated as the midpoint of the range estimated by Layers study. For the "6 or more" category we assume that these houses have an average of 10 rows each. We ask for comment on the validity of this assumption.

Because each row has two sides, each of which will have to be swabbed, the total number of swabs required is estimated to be approximately 49,910. On average, 12.1 swabs will be used for each house with more than 3000 layers.

[49] This is the average of in-State and out-of-State pricing in the California Animal Health & Food Safety Laboratory System (Ref. 126).

The total cost of testing the average large house is $541 (12.1 swabs x ($4.42 labor + $2.77 shipping[50] + $37.50 lab culture)) when two swabs are used per row.

We assume that no houses with fewer than 3,000 layers currently conduct these tests. Furthermore, we assume that these smaller houses have from one to two rows of cages. Thus, the estimated average number of swabs used per small farm is three. The total cost of one round of testing for each very small farm is $148 (3 swabs x [$4.42 labor + $7.42 shipping[51] + $37.50 lab culture]) when two swabs are used per row.

The random swabbing plan requires that 32 samples be taken per house. Although 52 percent of houses are in compliance with the row-based plan, far fewer are likely to be in compliance with the random swabbing plan. In the absence of better information, we assume that between 0 and 52 percent (uniformly distributed) of large houses that are currently testing use random swabbing plans.[52] The cost per swab under the random swabbing sampling plan is $43.65 ($4.42 labor + $1.73 shipping[53] + $37.50 lab culture). The total cost of one round of testing under the random swabbing plan is calculated to be $47.2 million for farms with fewer than 3,000 layers (33,820 houses not in compliance x 32 swabs per house x $43.65 cost per swab) and $12.0 million for farms with more than 3,000 layers (8,610 houses not in compliance x 32 swabs per house x $43.65 cost per swab).

k. *Followup egg testing.* i. *Egg testing provisions.* Followup egg testing would occur if an environmental test is positive for SE. If egg testing is triggered, the following protocol must be followed. First, the farmer must submit 1,000 eggs to a recognized lab initially, and subsequently every 2 weeks, for a total of 4,000 eggs. Consistent with the method described by Valentin-Bon et al (Ref. 62), the eggs that are submitted for testing may be pooled in samples of 10 to 20 eggs each. If pooled into samples of 20 eggs each, a total of 200 egg tests are conducted. If any of these egg tests are positive, the farm will be required to divert its eggs until four consecutive rounds of egg tests are found to be negative. Furthermore, a farm that has had a positive egg test must continue to test 1,000 eggs each month for the life of the flock.

If the cost of egg testing is high enough, however, the farmer may simply choose to forego egg testing and divert all eggs for the life of the flock.

ii. *Current industry practices; Followup egg testing.* We assume that those farms currently under a recognized quality assurance plan that mandates egg testing following a positive environmental test are currently in partial compliance with this provision. Of the major plans, only the Pennsylvania and Maryland plans have followup testing provisions that are largely the same as this provision (Ref. 99). According to "Chicken and Eggs" (Ref. 98), egg production in Maryland and Pennsylvania accounted for 9.7 percent of the U.S. total. Only 85 percent of the eggs in these States fall under the State quality assurance programs. We therefore estimate that 8.2 percent (9.7 percent x 85 percent) of all eggs are currently in partial compliance. Because farms with fewer than 3,000 layers are not currently in these quality assurance programs, we assume that no farms with fewer than 3,000 layers conduct followup egg tests.

Even farms in compliance with the Pennsylvania and Maryland plans are not currently in full compliance with the provision described in this section. This provision would require that batches of 1,000 eggs be tested, while the Pennsylvania and Maryland plans only require 480 eggs to be tested in each batch. Farms on either the Pennsylvania or the Maryland plans are only 48 percent (480 ÷ 1000) in compliance with the provision.

These numbers suggest that the current net level of compliance with the provision is 0 percent for farms with fewer than 3,000 layers and 3.9 percent (8.2 percent x 48 percent) for farms with more than 3,000 layers.

iii. *Egg testing costs.* The cost of followup egg testing is composed of the following: (1) The labor cost of collecting the eggs, (2) the value of the eggs being tested, (3) the cost of shipping the eggs to a qualified laboratory, and (4) the lab costs of testing the eggs.

The cost of collecting the eggs is the hourly cost of labor times the number of hours spent collecting the eggs. We assume that it will take the typical farmhand approximately one-half minute per egg to randomly select eggs for testing, so the labor cost of egg testing is $146.74 per 1,000 eggs tested (50 samples x 20 eggs per sample x 0.0083 hours per egg x $17.68 dollars per hour) (Ref. 107).

The lost value of the eggs used for testing is the number of eggs tested times the value of an unpacked egg. To avoid the double counting of the cost of diversion (for those eggs being tested), we modify this value to account for the fact that as many as 26 percent of eggs being tested may be under required diversion at the time of testing. The price that the typical producer receives for table eggs is about $0.43 per dozen, while the price a producer receives for diverted eggs is about $0.26 per dozen eggs (See table 23). The expected value of a diverted egg is the weighted average of the value of a table egg and a diverted egg, or about $0.03 per egg.[54] The value of the eggs tested is the value per egg times the number of eggs tested. The value of every 1,000 eggs tested is $32.47.

Eggs that are collected will have to be shipped to a laboratory for analysis. The cost of shipping these eggs depends on the weight of the eggs being shipped. We estimate that 1,000 large eggs weigh approximately 111 pounds. The cost of shipping these eggs in two 60-pound packages (including packing) to the laboratory is approximately $179.50.[55]

The largest cost of egg testing is the laboratory; we estimate the lab cost for 1 batch of 20 eggs to be $30 (Ref. 111). Hence, for 50 tests the laboratory cost of eggs testing is $1,500 per 1,000 eggs tested (50 batches x $30 per test).

The total cost of egg testing is the sum of each of the previously stated costs. Therefore, the cost of egg testing is $1,859 per 1,000 eggs tested ($146.74 collection costs + $32.47 lost income from egg sales + $179.50 shipping costs + $1,500 lab costs).

l. *Diversion.* i. *Diversion provisions.* Under this provision, farms that test positive for SE in their eggs would be required to divert their eggs to breaker plants until they are able to show via testing that SE is not present in the eggs produced in the infected house. Both the expected level of diversion and the expected cost of diversion will vary by each operation's location and size.

ii. *Regional differences in the cost of diversion.* Regional differences in the

[50] The cost of shipping 12 swabs (12 pounds) overnight is estimated to be between $26.25 and $40.25, including pickup charges (Ref. 118). We divide the average cost of shipping by 12 to obtain the cost per swab ($2.77).

[51] The cost of shipping 3 swabs (3 pounds) overnight is estimated to be between $19.25 and $25.25, including pickup charges (Ref. 118). We divide the average cost of shipping by 3 to obtain the cost per swab ($7.42).

[52] We assume that no small houses are testing using random swabbing plans.

[53] The cost of shipping 32 swabs (32 pounds) overnight is estimated to be between $40.50 and $70.50, including pickup charges (Ref. 118). We divide the average cost of shipping ($55.50) by 32 to obtain the cost per swab ($1.73).

[54] The following calculation is used to reach this figure. [(74 percent of farms not under diversion x $0.46 per dozen table eggs) + (26 percent of eggs under diversion x $0.26 per dozen diverted eggs)] + 12 eggs in a dozen = $0.03 per egg.

[55] The cost of shipping a 60-pound package overnight is between $64.50 and $115.00, including pickup charges (Ref. 118). We multiply the average cost of shipping ($89.75) by 2 to obtain the total cost of $179.50.

cost of production have led to the centralization of the breaker industry in the North Atlantic and North Central regions of the United States. As table 22 of this document shows, these regions are responsible for only 52 percent of overall egg production, but over 86 percent of breaker eggs.[56] The centralization of the breaker industry is even more cogently illustrated in the fourth column of table 22 of this document. While 36 to 44 percent of eggs make it to breaker plants in the northern regions, the corresponding figures for the west and south are only 10 percent and 6 to 7 percent. The primary purpose of breaker plants outside of the North appears to be as an outlet for eggs not suitable for retail sale as table eggs.

TABLE 22.—PRODUCTION AND BREAKING OF EGGS

Region	Eggs Produced		Eggs Broken		Percent of Eggs Produced That Are Broken
	Millions of Eggs[1]	Percent	Thousands of Dozens[2]	Percent	
North Atlantic	10,106	12.31	300,406	17.12	35.67
North Central	32,869	40.03	1,212,758	69.12	44.28
South Atlantic	13,979	17.03	69,774	3.98	5.99
South Central	14,512	17.68	84,071	4.79	6.95
West	10,636	12.95	87,662	5.00	9.89
Total	82,102	100	1,754,671	100.00	25.65

[1] National Agricultural Statistical Services (NASS) (Ref. 98).
[2] NASS (Ref. 127).

To predict how the industry will respond to a provision mandating diversion, it is important to know the following reasons: (1) Why the breaker egg industry is regionally concentrated while the shell egg industry is distributed more evenly throughout the United States and (2) why the concentration has occurred in the northern regions of the United States.

There are a couple of reasons why the breaker industry is centralized and the shell egg industry is not. First, it is much more expensive to transport shell eggs than it is to transport egg products. Shell eggs are relatively bulky and are susceptible to breakage in transit. Second, shell eggs are ultimately delivered directly to consumers in their natural state, while egg products are often used as ingredients in large-scale food manufacturing operations. Since processed foods are less costly to transport than are their ingredients, it makes sense to locate processed foods facilities in areas where ingredients are locally available. To the extent that these ingredients are available in the northern regions, processed food plants will locate there. Consequently, it makes sense to locate breaker plants in this region as well.

If centralization of breaker plants is going to occur, it will likely occur in the northern regions, for several reasons. The cost of egg production is lowest in the north, partly because feed grains (such as corn and wheat) are locally available at low prices in this region.[57] Also, farms in the north are more likely to be characterized by large in-line houses (up to 250,000 layers). These houses take advantage of economies of scale to produce more eggs more cheaply. Furthermore, since the demand for egg products is higher in the northern regions, breaker plants can avoid the high transportation costs of shipping to food processors by locating closer to their customers.

The implication of the industry structure, as laid out above, is that there are likely to be regional disparities in the cost of diversion. Egg products and, hence, breaker egg prices are not expected to vary regionally by as much as shell egg prices. Where the cost of egg production is high (such as in California), the cost of diversion is likely to be high. Similarly, where the price of egg production is low (such as in Ohio and Pennsylvania), the cost of diversion is likely to be low. Furthermore, there are some remote areas, such as Hawaii, where the absence of breaker plants makes local diversion infeasible. Because it is not economical to ship these eggs to breaker plants in the continental United States, the cost of diversion is simply the lost value of a clean table egg.

FDA met with industry representatives in each of the above regions and was given estimates of diversion costs that are consistent with the above reasoning. The diversion cost per dozen eggs in PA was estimated to be insignificant while the diversion cost in CA was estimated to be $0.21 to $0.42 per dozen.

iii. *Effect of operation size on diversion costs.* Operation size can have a significant effect on average diversion costs for a given producer. A large producer is less likely to be affected by an individual house that tests positive, because the risk is generally spread across many houses and farm sites. Furthermore, in areas where it is economically feasible to produce eggs that are dedicated to breaker plants, large operations are less likely to have contract problems because they can simply substitute SE-positive eggs for the eggs that originally were contracted to go to the breaker plant. By contrast, the economic losses from a positive house may be devastating to a small farm with one house.

iv. *Effect of SE-positive status on diversion costs.* It has been suggested that eggs from an SE-positive flock will command a lower price at the breaker than will other eggs. Indeed, some concern has been raised over whether, because of liability concerns, breakers will be willing to accept these eggs. The

[56] In table 22 of this document, the number of eggs produced includes hatching eggs as well as table eggs. Because most hatching eggs are produced in the South and hatching eggs do not go to breaker plants, the percentages of eggs going to breaker plants are biased downward for the southern regions.

[57] Shipping grains from the Midwest to the West Coast by rail can cost over $1 per bushel (Ref. 128).

pasteurization process for breaker eggs is designed to achieve at least a 5-log reduction in any SE that may be in eggs. Furthermore, eggs from an SE-positive flock are not explicitly labeled as such under this provision. However, because these eggs are limited in how they may be used, SE-positive eggs are intrinsically less valuable than SE-negative eggs.

Contracts for both table and breaker eggs are generally in place before a specific flock is tested for SE. Producers with SE-positive flocks may therefore have to break existing contracts for table eggs and make new contracts for breaker eggs. This new contracting not only will be costly in its own right, but also may send a signal to packers that the eggs that are being supplied under these new contracts are more likely to be from an SE-positive flock. To some extent, the packer will take this possibility into account and purchase these eggs at a discount.

v. *Cost of a diverted egg.* Given all of the factors stated in the previous paragraphs, we estimate that, on average, breaker eggs from an SE-positive flock will command a price below that received for shell eggs. Table 23 illustrates the prices that producers receive for shell and breaker eggs by region. As expected, the North Central region, with its proximity to inexpensive feed and a large food processing industry, has the highest level of production, the lowest prices for eggs, and the lowest cost for diversion. The West, with its higher feed costs and smaller layer houses, has the highest prices for eggs and the highest cost of diversion. We find the weighted average cost of diversion to be approximately $0.13 per dozen eggs. If there is an additional discount for those eggs with SE, the total cost could rise as high as $0.21 per dozen eggs.

TABLE 23.—TOTAL COST OF DIVERTING EGGS

Region	Regional Weight (in %)	Shell Egg Price to Producer[1]	Breaking Eggs(Nest Run)[2]	Cost of Diversion (Nest Run)
North Atlantic	12.3	$0.42	$0.31	$0.11
North Central	40.0	$0.39	$0.30	$0.09
South Atlantic	17.0	$0.43	$0.31	$0.12
South Central	17.7	$0.47	$0.30	$0.17
West	13.0	$0.53	$0.31	$0.22
Average Cost of Diverting Eggs[3]				$0.13
Additional Discount for SE+ Eggs (Ref. 111)				$0.00 - 0.08
Total Cost of Diverting Eggs				$0.13 - 0.21

[1] The shell egg price paid to producers for the North Central Region was estimated as equivalent to the prices Agricultural Marketing Service (AMS) reported as paid in Iowa, Minnesota, and Wisconsin. For regions other than the North Central Region, the shell egg price to the producer was calculated by discounting the price to retailer by a percentage equal to the percent difference between the price to the producer and the price to retailer in the North Central Region. All figures were taken from AMS data accessed through The Institute of Food and Agricultural Services at the University of Florida (Ref. 129).

[2] All figures are from AMS data accessed through the North Carolina Department of Agriculture (Ref. 130).

[3] The average cost of diverting eggs is weighted by regional production (Ref. 98).

vi. *Expected cost of diversion.* The expected cost of diversion is determined by the cost of diverting an egg, the number of eggs in commerce affected by the provision, and the probability that a given egg will be diverted.

m. *A model of testing and diversion costs.* i. *The model.* We use a dynamic model for estimating testing and diversion costs. We model these costs as depending on the probability of SE detection, farm size, molting practices, and the farmer's choice between conducting followup egg tests and diverting until depopulation.

In the first stage of the model, we estimate the probabilities associated with environmental and egg tests. For environmental tests, we estimate that 9.7 percent of all flocks currently test positive. We then adjust this estimate downwards to 8.4 percent initially and 7.1 percent eventually to account for the expected reduction of SE on the farm due to adoption of other provisions to reduce SE. In the experience of Pennsylvania, a flock with at least one environmental positive is likely to have at least one egg test positive 26 percent of the time (Ref. 131). We do not know if the experience of Pennsylvania is representative of the nation as a whole. In the absence of better information, we used the Pennsylvania figure.

In the next stage of the dynamic model, the expected cost of testing and diversion is calculated for farms in each of the five size categories used throughout this analysis. There are two reasons why this is a necessary step. First, the estimation of cost for different size categories allows for the explicit representation of the fact that both the number of tests required and the cost of diversion are directly related to the number of layers on the farm. Second, using different size categories facilitates an algebraic model design that uses logical operators to allow farmers (in the model) to make the low cost choice between egg testing and diversion.

Molting practices are accounted for in the next stage. The different testing protocols for molted and non-molted layers makes it necessary to look at the cost of testing and diversion separately for each of these types of flocks. At this stage of the model, we set out the possible scenarios for testing and diversion, derive the expected cost of each scenario, and calculate the statistical probability that each scenario will occur. The mathematical model for this stage is contained in appendices A and B of this document.

In the final stage of the testing cost model, we insert logical operators into the model in such a way that farmers are given the choice of diverting rather than testing eggs when it is cost-efficient to do so. Failure of the model to give the farmer this choice may lead to estimated costs that are up to double the actual expected costs.[58]

[58] A further refinement of the model would be to include the option of depopulating the flock and

ii. *The costs of testing and diversion.* The model described in the previous paragraph produces estimates of the annual expected cost of testing and diversion for layer houses. Estimates are obtained for each of the size categories by molting practice.

As tables 24 and 25 in this document illustrate, the expected costs of testing and diversion for a poultry house range from $150 to $3,760 depending on house size, environmental testing protocol, and molting practices.[59] The low figures in the environmental testing and total cost columns represent costs given the row-based sampling scheme, while the high estimates represent the random swab sampling method. The costs for molted houses are annualized for the purpose of comparison.

TABLE 24.—COST PER HOUSE (NON-MOLTED FLOCKS)

Farm Size (No. of layers)	Environmental Testing	Egg Testing	Diversion	Dynamic Total Cost	Static Total Cost
Fewer than 3,000	$150 to $1,400	$0	$4	$154 to $1,404	$1,010 to $2,260
3,000 to 19,999	$540 to $1,400	$0	$750	$1,290 to $2,150	$1,520 to $2,380
20,000 to 49,999	$540 to $1,400	$620	$470	$1,630 to $2,490	$1,690 to $2,550
50,000 to 99,999	$540 to $1,400	$860	$410	$1,810 to $2,670	$1,810 to $2,670
Over 100,000	$540 to $1,400	$860	$760	$2,160 to $3,020	$2,170 to $3,020

TABLE 25.—COST PER HOUSE (MOLTED FLOCKS)

Farm Size (No. of layers)	Environmental Testing	Egg Testing	Diversion	Dynamic Total Cost	Static Total Cost
3,000 to 19,999	$540 to $1,400	$610	$640	$1,800 to $2,650	$1,920 to $2,780
20,000 to 49,999	$540 to $1,400	$900	$690	$2,130 to $2,990	$2,180 to $3,040
50,000 to 99,999	$540 to $1,400	$920	$700	$2,170 to $3,030	$2,360 to $3,210
Over 100,000	$540 to $1,400	$1,050	$940	$2,530 to $3,370	$2,900 to $3,760

The inclusion of a choice to opt out of egg testing also results in egg testing costs increasing with farm size. The choice to opt out of egg testing significantly increases diversion costs for smaller farms while having a limited effect on larger farms.[60] This difference is apparent in the comparison between dynamic total costs and static total costs. If the incentive to switch from egg testing into diversion were removed, the costs incurred would be the static total costs. Nonetheless, diversion costs also generally rise with farm size.

Whether or not a farmer chooses to molt the flock also has an effect on cost. The annual cost of testing and diversion for a molted flock is greater than that for a non-molted flock, largely because a molted flock forced to divert for the life of the flock is expected to experience diversion for a longer time. In the dynamic model, where the farmer can opt out of testing, molting has a secondary effect of increasing egg-testing costs due to the high expected cost of opting out.

For comparison with dynamic costs, the static cost of testing and diversion is included in the final column of tables 24 and 25 of this document. As expected, when the producer is given the choice of opting out of egg testing the total cost of testing and diversion falls. The savings to the farmer are greatest on the smallest farms, where expected costs may fall by over 75 percent.[61] On the largest farms, it is less economical to divert, and thus the cost savings can be insignificant.

To obtain the total cost of testing and diversion for all houses on all farms we multiplied the cost per house in each category by the number of houses in each category and the percentage of houses that would be affected by the provision. These costs are summarized in tables 26 and 27 of this document.

TABLE 26.—TOTAL COST OF TESTING AND DIVERSION: ROW-BASED SAMPLING (THOUSANDS OF DOLLARS)

Farm Size (No. of layers)	No. of Houses	Percent Molted	Environmental Testing	Egg Testing	Diversion	Total Cost
Fewer than 3,000	33,824	0	$5,006	$0	$122	$5,129
3,000 to 19,999	3,155	28	$1,268	$513	$2,088	$3,869
20,000 to 49,999	1,317	65	$529	$1,017	$736	$2,282
50,000 to 99,999	861	86	$346	$756	$523	$1,625

starting over with a new flock. There is a large degree of uncertainty over whether this is feasible given that the growing cycle of chicks and pullets must be coordinated with the laying cycle of flocks. Therefore, we did not include this option in our analysis. For the final rule we invite comment on the feasibility of this option.

[59] Tables 24 and 25 of this document present the cost estimates for houses based on the current estimated prevalence of SE. In the total cost tables (26 and 27 of this document), we also present an estimate that reflects the expected prevalence following the full implementation of this rule.

[60] It is never in the interest of the smallest farms to test eggs because the expected cost of testing exceeds the revenue loss from simply diverting all eggs for the life of the flock.

[61] This conclusion assumes that the farmer will be paying all of the costs of testing and diversion.

TABLE 26.—TOTAL COST OF TESTING AND DIVERSION: ROW-BASED SAMPLING (THOUSANDS OF DOLLARS)—Continued

Farm Size (No. of layers)	No. of Houses	Percent Molted	Environmental Testing	Egg Testing	Diversion	Total Cost
Over 100,000	3,279	84	$1,317	$3,200	$2,747	$7,264
All Farms, Initially			$8,466	$5,487	$6,216	$20,169
All Farms Eventually			$8,466	$4,608	$5,236	$18,310

TABLE 27.—TOTAL COST OF TESTING AND DIVERSION: RANDOM SWAB SAMPLING (THOUSANDS OF DOLLARS)

Farm Size (No. of layers)	No. of Houses	Percent Molted	Environmental Testing	Egg Testing	Diversion	Total Cost
Fewer than 3,000	33,824	0	$47,353	$0	$122	$47,475
3,000 to 19,999	3,155	28	$3,269	$513	$2,088	$5,870
20,000 to 49,999	1,317	65	$1,364	$1,017	$736	$3,117
50,000 to 99,999	861	86	$892	$756	$523	$2,171
Over 100,000	3,279	84	$3,397	$3,200	$2,747	$9,344
All Farms, Initially			$56,275	$5,487	$6,216	$68,978
All Farms, Eventually			$56,275	$4,608	$5,236	$66,119

As shown in table 26 of this document, the estimated total cost of testing and diversion is approximately $20.2 million when row-based sampling is used. When we assume that a random swab method of environmental sampling is used, as in table 27, the estimated costs increase to $69.0 million. There also will be a cost associated with reviewing and updating the SE prevention measures when a poultry house tests positive.[62] We assume that the review and updating would take approximately 20 hours of supervisory labor for the typical house. We assume that, as with plan design and implementation (see following), farms with fewer than 3,000 layers that are subject to SE prevention measures would not be equally burdened. We therefore assume that the review and updating of the measures for these smaller houses would take 10 hours of supervisory labor. We estimate the total initial cost of review and updating to be $524,900 for farms with at least 3,000 layers (20 hours x $36.28 an hour x 8,612 larger houses x 8.4 percent of houses testing positive) and $1,030,800 for smaller farms (10 hours x $36.28 an hour x 33,824 smaller houses x 8.4 percent of houses testing positive). The decline of positive houses from 8.4 percent to 7.1 percent over 4 years will be met with a corresponding decline in the cost of prevention measure review. In particular, the total cost to larger farms will fall to $443,700, while the total cost to very small farms will fall to $871,300.

n. *Benefits of testing and diversion.* While the primary purpose of testing is to obtain an indication of the effectiveness of the farm's SE prevention measures, the testing and diversion program would also directly reduce SE infection by preventing SE-positive eggs from reaching consumers. To the extent that SE-positive eggs are diverted to pasteurization, the number of these eggs that reach the consumer in an untreated form would decline. We estimate the benefits from diversion using the experience of the States.

The first key measure to be determined is the probability that the environment of a flock will test positive. We use two sources to estimate the current prevalence of SE-positive houses. Our first source is the Layers study (Ref. 27), which recruited 200 farm sites to be tested across the United States. We also use estimates based on the experience of testing under quality assurance plans.

The Layers study estimates that 7.1 percent of all houses are positive for SE. Regionally, SE prevalence ranges from a low of 0 percent in the Southeast to a high of 17.2 percent in the Great Lakes region. Nonetheless, because only 200 of an original sample of 526 farm sites chose to participate in this phase of the study, we are hesitant to rely solely on this figure for SE prevalence.

Regional quality assurance programs have also collected data on SE prevalence on the farm. As an upper bound, Pennsylvania experienced a prevalence of 40 percent in the early 1990's (Ref. 132). As a lower bound, we use 1 to 3 percent, which is the current prevalence of houses with SE-positive environments in Maine (Ref. 133). We believe that Pennsylvania's current prevalence of 7 to 9 percent (Ref. 131) is a likely prevalence for the nation as a whole.[63] When we put this data into a Beta-Pert probability distribution using a uniform distribution over 1 to 3 percent as the lower bound, 40 percent as the upper bound, and a uniform distribution over 7 to 9 percent as the mode, or most likely value, we estimate a national prevalence rate of 12.3 percent.

We assume that the Layers study and quality assurance program estimates are equally likely to be valid. Therefore, we put these values in a uniform distribution (7 to 12.3 percent) to estimate that 9.7 percent of farms would currently test SE-positive. Based on the experience of Pennsylvania, we estimate that 26 percent of houses that are environmentally positive also will have eggs that test positive (Ref. 131).

These figures imply that 502 million eggs from farms with more than 3,000 layers and 10 million eggs from farms

[62] All estimates related to plan design, review, and recordkeeping are based on estimates used to calculate the cost of HACCP for juice producers (63 FR 24253 at 24275 to 24285, May 1, 1998).

[63] This assumption is based on the fact that the number of outbreaks in the Northeast (where Pennsylvania is located) has fallen to a level equivalent with the rest of the nation (Ref. 7).

with less than 3,000 layers,[64] a combined 0.7 percent of all shell eggs,[65] would be diverted each year following the initial effective date. Of these eggs, we expect eggs to be positive at a rate of 2.75 per 10,000 (Ref 39). Consequently, within the pool of all diverted eggs, we estimate that an average of 138,000 SE positive eggs from farms with more than 3,000 layers and 2,800 SE-positive eggs from farms with fewer than 3,000 layers would be diverted annually. Given a total estimated number of positive eggs of 1.5 million, we can estimate that diversion would decrease the number of SE-related illnesses by 9.4 percent. This translates to potentially 46 cases of SE per year prevented by farms with fewer than 3,000 layers and 8,883 illnesses prevented by farms with more than 3,000 layers. For farms with 3,000 or fewer layers the cost is $571,800 per SE case prevented. For farms with more than 3,000 layers the cost is $2,000 per SE case prevented.

o. *Summary of costs and benefits potential on-farm SE prevention measures.* Table 28 summarizes the costs and benefits of the potential on-farm SE prevention measures. Some features of these summary estimates are worth addressing here. First, because the effectiveness of rodent and pest control is strongly linked to biosecurity and cleaning and disinfecting practices, we estimated the benefits of these provisions jointly. Second, we derive benefits without taking into account the interdependence of all proposed provisions. Therefore, table 28 reflects the incremental effects of each provision starting from a baseline of no new regulation. For example, the benefits of testing and diversion alone for large farms is 8,883 illnesses avoided annually at a cost of $1,800 per SE case avoided. As shown in table 4, a typical case of SE costs society roughly $17,700, assuming the VSL=$5 million, QALY=$300 thousand, and a 7 percent discount rate. Therefore, net benefits of testing and diversion alone are $141 million annually (8,883 cases avoided* ($17,700 - $1,800)). The benefits reported for the provisions in table 28 can be added together, mixed and matched, to achieve a rough upper bound estimate of the effectiveness of different combinations of provisions. Because there is some substitutability in benefits between some of the provisions, particularly between diversion and rodent and pest control, the actual benefits of combinations of provisions, as well as the proposed rule, will be somewhat smaller than what is reflected in table 28. A rough lower bound estimate of the incremental effect of each provision when combined with another is shown in table 33. Third, we estimate costs and benefits separately for farms with fewer than 3,000 layers and for farms with more than 3,000 layers.

TABLE 28.—ANNUAL COSTS, ILLNESSES AVERTED, AND COST PER ILLNESS AVERTED OF POTENTIAL ON-FARM MEASURES, BY FARM SIZE

	Farm Size	
	<3,000 Layers	>3,000 Layers
Costs (thousands of dollars)		
Rodent and Pest Control	$3,008	$21,019
Biosecurity	$7,100	$15,954
Cleaning and Disinfecting	$1,372	$2,441
SE Monitored Chicks and Pullets	$0.5	$87
SE Negative Feed	$138	$27,363
Vaccination	$188	$29,261
Refrigeration	$5,718	$18,120
Environmental Tests (Row Based Sampling)	$5,006	$3,460
Environmental Tests (Random Sampling)	$47,353	$8,922
Egg Tests	$0	$4,608
Diversion	$103	$5,133
Review of SE Prevention Measures	$871	$444
Cases of SE Averted (eventual)		
Rodent and Pest Control	142	25,701
Biosecurity	Included in Rodent Control	
Cleaning and Disinfecting	Included in Rodent Control	
SE Monitored Chicks and Pullets	< 1	10

[64] The total cost of diversion is divided by the cost of diversion per egg to obtain the number of eggs diverted.

[65] The percent of shell eggs that is diverted is determined by dividing the number of eggs diverted by the total number of shell eggs produced (69,771 million) as published in the USDA's Chicken and Eggs report (Ref. 98).

TABLE 28.—ANNUAL COSTS, ILLNESSES AVERTED, AND COST PER ILLNESS AVERTED OF POTENTIAL ON-FARM MEASURES, BY FARM SIZE—Continued

	Farm Size	
	<3,000 Layers	>3,000 Layers
SE Negative Feed	Theoretical	
Vaccination	Uncertain	
Refrigeration	10	2,162
Testing and Diversion	46	8,883
Other Benefits		
Rodent Control (Feed Savings - thousands of dollars)	$3.8	$696
Cost per Case of SE Averted (eventual - thousands of dollars)		
Rodent and Pest Control	$80.8	$1.5
Biosecurity	Included in Rodent Control	
Cleaning and Disinfecting	Included in Rodent Control	
SE Monitored Chicks and Pullets	$0.9	$8.7
SE Negative Feed	Theoretical	
Vaccination	Uncertain	
Refrigeration	$571.8	$8.4
Testing and Diversion	$559.4	$1.8

2. Administrative Measures

FDA has considered a number of administrative requirements that could be applied to farms. The provisions that we considered are examined below. Some, but not all, of the provisions are in the proposed rule. The costs and benefits of the provisions that are in the proposed rule are summarized in section V.F.

a. *Plan design and recordkeeping.* i. *Plan design and recordkeeping provisions.* We consider a provision that each farm site that sells raw eggs to the table egg market, other than directly to the consumer, design and monitor an SE prevention plan. If required, this prevention plan would include all measures the farm is taking to prevent SE in its flock. The following information includes potential components of the plan: (1) Chicks and pullets, (2) biosecurity, (3) rodent and other pest control, (4) cleaning and disinfecting, (5) feed, and (6) refrigeration. Recordkeeping may also be a provision of the plan. Records could be required for each of the provisions included in the plan, as well as for testing results. Farms may be required to have a trained or experienced supervisor that would be responsible for overseeing the plan.

ii. *Current industry practices—plan design and recordkeeping.* We assume that those farms that are currently operating according to recognized industry or State quality assurance plans are already largely in compliance with the plan design and recordkeeping provisions discussed in this section, and therefore would not experience additional costs to comply with record keeping provisions. Using data from the Layers study (Refs. 25 and 26), we find that 59 percent of farms with more than 50,000 layers are currently members of State or industry quality assurance plans. Fewer than 8 percent of farms with fewer than 50,000 layers are currently members of quality assurance plans.[66] The estimated number of farms and houses affected by plan design and recordkeeping provisions is shown in table 29 of this document.

TABLE 29.—FARMS AFFECTED BY PLAN DESIGN AND RECORDKEEPING PROVISIONS

Farm Size (No. of layers)	No. of Farms	Houses Per Farm	Percent of Farms on a QA Program	Farms Affected by the Proposal	Houses Affected by the Proposal
Fewer than 3,000	33,824	1.0	0.0	33,824	33,824
3,000 to 19,999	2,337	1.4	4.9	2,223	3,000
20,000 to 49,999	940	1.4	27.7	680	952
50,000 to 99,999	359	2.4	58.0	151	361

[66] We do not have data on participation by farms with fewer than 3,000 layers. We assume that none of these farms are currently members of recognized quality assurance programs.

TABLE 29.—FARMS AFFECTED BY PLAN DESIGN AND RECORDKEEPING PROVISIONS—Continued

Farm Size (No. of layers)	No. of Farms	Houses Per Farm	Percent of Farms on a QA Program	Farms Affected by the Proposal	Houses Affected by the Proposal
100,000 or more	443	7.4	59.7	179	1,322
All Farms	37,903	1.1	97.8	37,055	39,459

As table 29 of this document shows, we expect that a total of 37,055 farm sites with 39,459 poultry houses would be affected by plan design and recordkeeping provisions, if required.

iii. *Plan design costs.* In table 30 of this document we estimate the cost of designing a prevention plan and the corresponding cost of keeping records of plan performance. Because information on the costs of designing the QA plan for eggs is not available, we base these costs on assumptions used to analyze the design of HACCP programs (63 FR 24253 at 24275 to 24285, May 1, 1998). In particular, we assume that each farm measure will take approximately 20 hours to design. Farms with fewer than 3,000 layers are generally less complex. For these farms, we assume that it will take only 10 hours to design each component of the plan. We assume that the labor used to design the plan costs $18.14 an hour (Ref. 134). We double this figure to account for overhead. The cost of designing a plan with one component for a farm with less than 3,000 layers is expected to be $363, while the cost to larger farms is expected to be $726. Amortized over 10 years at 7 percent, the total cost of plan design to small farms is expected to be $1,747,100 per required provision, while the cost to larger farms will be $333,900 per provision. Amortized over 10 years at 3 percent, the total cost of plan design to small farms is expected to be $1,438,600 per required provision, while the cost to larger farms will be $274,900 per provision.

TABLE 30.—COST OF PLAN DESIGN PER PROVISION

Farm Size (No. of layers)	Farms Affected by the Proposal	Cost Per Farm	Total Costs
Fewer than 3,000	33,824	$363	$12,271,200
3,000 to 19,999	2,223	$726	$1,612,700
20,000 to 49,999	680	$726	$493,400
50,000 to 99,999	151	$726	$109,300
100,000 or more	179	$726	$129,585
All Farms	37,055		$14,616,100
Amortized Over 10 Years at 7%			$2,081,000

The total cost of plan design will depend on the number of on-farm provisions that are ultimately required by the proposed rule.

iv. *Recordkeeping costs.* In table 31 of this document, we estimate the cost of keeping records for one proposed provision for all poultry houses.

TABLE 31.—COST OF RECORDKEEPING FOR ONE PROVISION

Farm Size (No. of layers)	Houses Affected by the Proposal	Annual Cost Per House	Recordkeeping Costs
Fewer than 3,000	33,824	$472	$15,952,600
3,000 to 19,999	3,000	$943	$2,830,200
20,000 to 49,999	952	$943	$897,900
50,000 to 99,999	361	$943	$341,100
100,000 or more	1,322	$943	$1,246,600
All Farms	39,459		$21,268,400

We assume that the time required for recordkeeping is equivalent to the time necessary to monitor and document the provisions of a HACCP plan (63 FR 24253 at 24275 to 24286). Because the HACCP time estimate upon which we are basing our estimate involves multiple controls points and monitoring, this assumption tends to overstate the cost of recordkeeping for a provision of this proposal. In particular, we expect that, for each house affected,

recordkeeping will take one half an hour per week per required provision. At $18.14 an hour, doubled to reflect overhead costs, the cost of recordkeeping would be $943 ($18.14 x 52). We estimate that farms with fewer than 3,000 layers will have costs that are approximately half of those of larger farms. Our reasoning is further explained in section V.F.3 of this document.

b. *Training.* We are considering a provision that the person responsible for overseeing the SE prevention measures be trained or have equivalent job experience. A training course would last 2 to 3 days. The cost of taking a course consists of tuition, the cost of the supervisor's labor while in class, and any travel related expenditures that may be incurred.

The cost of a recent 3-day HACCP training course for egg processors was advertised to be $450 to $550 (Ref. 135). The cost of the supervisor's labor is estimated to be $1,161 (32 hours[67] x $36.28 an hour).

Travel expenditures consist of transportation, hotel, and miscellaneous expenses. These costs range from insignificant (reimbursement for minimal mileage) to $1,000 ($400 airfare + $400 hotel expenses + $200 expenses). We believe that most training will be relatively close to where producers are located. In addition, training is likely to take place in rural areas where lodging is relatively inexpensive. Therefore, we estimate that the most likely travel expense will be roughly $200 to $300. We use a Beta-Pert distribution to estimate that the expected cost of travel is $330.

The average cost of attending a training class is estimated to be $1,991 ($500 tuition + $1,161 labor + $330). Not all producers will have to send a supervisor to a class. The 12 percent of large farms already on quality assurance programs will have a trained supervisor already running the program. Of the remaining farms, some have experienced personnel who do not need formal training. Without better information, we assume that the true number of establishments that will need to formally train a supervisor will be uniformly distributed between 0 and 100 percent for all sizes of farms. Therefore, we expect 16,910 farms with fewer than 3,000 layers and 1,620 farms with 3,000 or more layers to incur training expenses. This cost will have to be incurred only at the outset of the program, and then again when a farm loses a trained supervisor. The total cost for all farms training a supervisor every 10 years, amortized at 7 percent, is estimated to be $4.8 million for very small farms and $0.5 million for larger farms. Amortized at 3 percent, the total cost is estimated to be $4.0 million for farms with less than 3000 layers and $0.4 million for larger farms.

c. *Registration.* Under this potential provision, all farms covered by any part of the proposed rule would be required to register with FDA. We estimate that approximately 33,820 farms with fewer than 3,000 layers and 4,080 farms with 3,000 or more layers would be covered by a registration provision. The cost of registration is composed of the labor cost of learning about, obtaining, filling out, and sending the registration form to FDA. We assume that the typical producer would spend a total of 30 minutes registering and that the value of labor is $18.14 per hour, doubled for overhead costs, for a total cost of $18.14 per producer. The total cost to the industry is $687,600 ($18.14 x 37,903). Amortized at 7 percent, the annual cost of registration is expected to be $97,900. The cost to farms with fewer than 3,000 layers would be $87,400, while the cost to farms with more than 3,000 layers would be $10,500. Amortized at 3 percent, the annual cost of registration is expected to be $80,600. The cost to farms with fewer than 3,000 layers would be $71,900, while the cost to farms with more than 3,000 layers would be $8,700.

d. *Summary of costs and benefits of administrative provisions.* The costs of administrative provisions are summarized in table 32 of this document. These provisions do not have independently quantifiable benefits. The provisions would be likely to generate benefits because administrative provisions help farmers verify whether SE prevention measures are being implemented appropriately. Early intervention on a plan that is not being implemented appropriately could result in corrective action to prevent SE that might otherwise occur. Furthermore, early troubleshooting in the event that SE is found on their farms would help farmers reduce any additional exposure from SE.

TABLE 32.—COSTS OF POTENTIAL ON-FARM ADMINISTRATIVE PROVISIONS (THOUSANDS OF DOLLARS)

	Farm Size	
	<3,000 Layers	>3,000 Layers
Costs (eventual)		
Plan Design	$1,747 per Provision	$334 per Provision
Recordkeeping	$15,953 per record kept	$5,316 per record kept
Training	$4,800	$459
Registration	$87	$11

3. Summary of On-Farm SE Prevention and Administrative Measures

Table 33 of this document shows the estimated costs and benefits for all of the on-farm SE prevention measures that we have considered. These totals include covering farms with fewer than 3,000 layers. The total costs and benefits of all of these prevention measures represent the costs and benefits of the regulatory option (described previously) of more extensive on-farm controls. Table 33 can also be used to illustrate the costs and lower bound incremental benefits of individual provisions or combinations of provisions. Because table 33 shows the effects of each provision when all are enacted, and the interdependence of rodent and pest control, biosecurity, cleaning and disinfecting, and testing and diversion is accounted for, these estimates can be added together, mixed and matched, to

[67] The number of hours is estimated as 24 hours of class time plus 8 hours of travel time.

achieve a rough estimate of the lower bound effects of different combinations of provisions. Between table 28 and table 33, a bounded estimate of the incremental effect of each provision is achieved. For example, testing and diversion will cost farms with more than 3,000 layers an incremental amount between $1,800 and $2,600 per illness avoided.

TABLE 33.—SUMMARY OF ANNUAL COSTS AND BENEFITS OF ON-FARM SE PREVENTION MEASURES (THOUSANDS OF DOLLARS)

	Farm Size	
	<3,000	>3,000
On-Farm Measures		
Costs (thousands of dollars)		
Rodent and Pest Control	$3,008	$21,019
Biosecurity	$7,100	$15,954
Cleaning and Disinfecting	$1,372	$2,441
SE Monitored Chicks and Pullets	$0.5	$87
SE Negative Feed	$138	$27,363
Vaccination	$188	$29,261
Refrigeration	$5,718	$18,200
Environmental Tests (Row Based Sampling)	$5,006	$3,460
Environmental Tests (Random Sampling)	$47,353	$8,922
Egg Tests	$0	$4,608
Diversion	$103	$5,133
Review of SE Prevention Plan	$871	$444
Cases of SE Averted (eventual)		
Rodent and Pest Control	142	25,701
Biosecurity		
Cleaning and Disinfecting		
SE Monitored Chicks and Pullets	<1	10
SE Negative Feed	Theoretical	Theoretical
Vaccination	Uncertain	Uncertain
Refrigeration	7	1,427
Testing and Diversion	33	6,296
Other Benefits		
Rodent Control (Feed Savings—thousands of dollars)	3.8	696
Cost per Case of SE Averted (eventual—thousands of dollars)		
Rodent and Pest Control	$80.8	$1.5
Biosecurity	Included in Rodent Control	Included in Rodent Control
Cleaning and Disinfecting	Included in Rodent Control	Included in Rodent Control
SE Monitored Chicks and Pullets	1	8.7
SE Negative Feed	Theoretical	Theoretical
Vaccination	Uncertain	Uncertain
Refrigeration	816.9	12.8

TABLE 33.—SUMMARY OF ANNUAL COSTS AND BENEFITS OF ON-FARM SE PREVENTION MEASURES (THOUSANDS OF DOLLARS)—Continued

	Farm Size	
	<3,000	>3,000
Testing and Diversion[1]	822.8	2.6
Administrative Measures		
Plan Design (Assumes 11 Provisions)	$19,217	$3,674
Recordkeeping (Assumes 7 Records Kept)	$111,671	$37,212
Training	$4,800	$459
Registration	$87	$11

[1] Assumes the average cost for environmental testing between random and row based sampling, assuming either type of test is equally likely.

4. Retail Provisions

a. *Coverage.* We considered whether Federal SE prevention measures should cover retail establishments that specifically serve highly susceptible populations. Establishments possibly covered would include nursing homes, child and adult day care centers, senior centers, and hospitals. The 2001 Model Food Code recommends additional safeguards for these establishments.

b. *SE prevention measures at retail.* i. *Provisions.* Under the measures we considered, establishments that specifically serve consumers from highly susceptible populations would be required to comply with certain provisions in the Food Code that we describe in section IV.D of this document. Those provisions for which we have adequate information to estimate costs and benefits would require that the previously mentioned establishments:

- Use only eggs that are clean, sound, contain no more restricted eggs than the proportion allowed in U.S. Consumer Grade B, and have been transported at an ambient temperature of 45 °F or below;
- Use pasteurized eggs or egg products in dishes that will be undercooked; and
- Substitute pasteurized eggs or egg products for raw shell eggs in dishes in which two or more eggs are broken and combined, unless the eggs are broken, combined, thoroughly cooked, and served immediately or are broken, combined, and used immediately as an ingredient in products (such as cookies or muffins) that will be thoroughly cooked.

ii. *Current state and industry practices—institutions serving highly susceptible populations.* These potential provisions are currently contained in the 2001 FDA Food Code (Refs. 136, 137, and 138). To date, 41 of 56 states and territories have adopted some version (1993 or later) of the FDA Food Code. Actual coverage is complicated, because the states and territories that have adopted the FDA Food Code do not necessarily follow all of the provisions, and states that have not adopted the FDA Food Code may have other regulations that have provisions that provide the same level of protection for highly susceptible populations.

iii. *Costs of retail SE prevention measures.* Two costs would occur if the retail SE prevention measures applicable to establishments that specifically serve highly susceptible populations were included in a final rule. First, covered retail establishments would incur increased costs from using pasteurized eggs and egg products in place of raw shell eggs. Second, covered retail establishments would incur costs from training employees to hold, prepare, and cook raw eggs properly.

If retail establishments used pasteurized shell eggs in place of unpasteurized shell eggs, they would pay more for their eggs ($0.35 per dozen) (Ref. 139). We do not know how many establishments would choose to do so. Alternatively, retail establishments could choose to use pasteurized egg products in place of unpasteurized shell eggs. If this option were chosen, the cost of this provision would be the cost differential between shell eggs and pasteurized egg products. We ask for comments regarding what these costs would be.

While there are no provisions that specifically require the training of food service industry employees, we believe that employers would choose to train their employees to hold, prepare, and cook raw eggs in accordance with these provisions. We also ask for comments regarding what these costs would be.

iv. *Benefits of retail SE prevention measures.* If all establishments serving highly susceptible populations were to implement these SE prevention measures through either Food Code adoption by states and territories (or other governments) or Federal regulations, we would expect to largely eliminate SE illnesses due to eggs and egg dishes served at these establishments. The USDA *Salmonella* Enteritidis Risk Assessment estimated that 24.7 percent of egg-related SE illness occurs from eggs consumed in institutions (Ref. 15). We assume this proportion to hold for highly susceptible and other consumers. The SE risk assessment also calculates that 50.4 percent of the population that becomes ill from SE comes from the highly susceptible population.[68] We therefore expect that a total of 12.4 percent (24.7 percent x 50.4 percent) of SE illnesses fall into the category of highly susceptible consumers who ate contaminated egg dishes at institutions. We do not know where highly susceptible consumers eat the eggs that make them ill. If we assume that half of these illnesses occur in institutions that specifically serve highly susceptible populations, these retail provisions would reduce illness due to SE contaminated eggs by 6.2 percent. We do not have robust estimates of the costs and benefits associated with those provisions.

F. Summary of Benefits and Costs of the Proposed Rule

In the previous section of this document, we described and estimated the benefits and costs of all of the SE

[68] The *Salmonella* Enteritidis Risk Assessment's "susceptible" populations and the Food Code's "highly susceptible" populations served by institutions are roughly equivalent. The SE risk assessment defines susceptible populations to include pregnant women, infants, the elderly, and immunocompromised persons. Children, the elderly, and immunocompromised persons could all be in institutions serving highly susceptible populations.

prevention measures we have considered. Here, we summarize and estimate the benefits and costs of the proposed rule.

1. Coverage

The proposed rule would only apply to farms with at least 3,000 layers that do not have all of their eggs treated, do not sell all of their eggs directly to consumers, and produce shell eggs for the table market. Farms in this category would be required to comply with all parts of the proposed rule. No retail establishments are directly affected by the proposed rule, because no retail establishments would be covered by the proposed rule.

2. Provisions in the Proposed Rule

a. *On-Farm preventive controls.* Many of the on-farm preventive controls examined above are included in this proposed rule. Provisions included in the proposed rule are rodent and pest control, biosecurity, cleaning and disinfecting, and procurement of chicks and pullets from SE-monitored breeders.

b. *On-Farm SE prevention measures.* The proposed rule also contains most of the on-farm SE prevention measures described above. In particular, the refrigeration, sampling, testing, and diversion provisions are included in the proposed rule.

c. *Administrative provisions.* Some of the administrative provisions we considered are also required by the proposed rule. In particular, records for all environmental and egg sampling and testing must be kept. Furthermore, farms must keep records indicating compliance with diversion requirements.

Farms are required to use SE prevention measures but are not required to have a formal written SE prevention plan. We believe that many farms will choose to implement a written plan. Each farm is required to have a trained or otherwise qualified individual to administer the prevention measures required by the proposed rule.

3. Summary of Costs and Benefits

In table 34 of this document, we summarize the costs and illnesses averted of this proposed rule and its provisions. After the on-farm adjustment phase (up to 4 years), we expect costs to fall and illnesses averted to increase. Eventually, the proposed rule will prevent approximately 33,430 cases of SE per year at a cost of $2,200 per illness averted. This value is less than the most conservative estimate (one that does not account for the pain and suffering of arthritis) of the expected value of an SE related illness, shown in table 5 of this document. Furthermore, though not listed in table 34, we also calculated the cost per estimated QALY saved. Assuming a 7-percent discount rate, we estimate the proposed rule will save approximately 1,870 QALYs annually. Assuming a 3-percent discount rate the estimated number QALYs saved annually is 3,410. This translates to $39,400 per QALY saved using a 7 percent discount rate and $21,600 per QALY saved using a 3 percent discount rate.[69] Either estimate falls well below our most conservative estimate of $100,000 for the value of a quality adjusted statistical life year.

TABLE 34.—SUMMARY OF ANNUAL COSTS AND ILLNESSES AVERTED OF THE PROPOSED RULE (THOUSANDS OF DOLLARS)

Provision	Costs		Illnesses Averted		Cost per Illness Averted	
	Initial	Eventual	Initial	Eventual	Initial	Eventual
On-Farm Measures						
Procurement of SE-Monitored Chicks and Pullets	$87	$87	10	10	$8.7	$8.7
Rodent and Pest Control	$21,019	$21,019	12,851	25,703	$3.1	$1.5
Biosecurity	$15,594	$15,594	—[1]	—[1]		
Cleaning and Disinfecting	$2,899	$2,441	—[1]	—[1]		
Refrigeration	$18,200	$18,200	1,693	1,426	$10.8	$12.8
Environmental Testing (Average)	$5,861	$5,861	—[2,3]	—[2,3]		
Egg Testing	$5,487	$4,608	—[2]	—[2]		
Review of Program	$525	$444	—[2]	—[2]		
Diversion	$6,094	$5,133	7,559	6,294	$2.4	$2.5
Administrative Measures						
Program Management	$2,672	$2,672	—	—		
Recordkeeping	$5,316	$5,316	—	—		
Training	$459	$459	—	—		
Total	$84,213	$81,834	22,113	33,433	$3.8	$2.4

[1] Estimated rodent control benefits also include benefits from biosecurity and cleaning and disinfecting.
[2] The benefits from all elements of the testing and diversion program are reported jointly under diversion.
[3] The environmental testing cost number reported is the average of the costs of the random swab and row based sampling methods.

[69] QALD's were converted back to QALYs for each possible outcome by dividing by 365. Annual QALYs lost for a case chronic arthritis (0.14) and death (1.0) were summed and subsequently discounted (at 3 percent and 7 percent) over 50 years.

The mean estimated dollar values of the benefits, the complete range and discussion of which is presented in section V.E.4 of this document and shown in table 37 of this document, range from $82 million to $1.65 billion, depending on the assumptions made about VSL, QALY, and the discount rate. Although the lowest mean estimated benefits are close to the mean estimated costs, these estimated benefits do not capture the health effects of chronic reactive arthritis sufferers. The most plausible estimated benefits values lie between $250 million and $1 billion, well above expected costs. The mean of all of the estimates is $580 million and most closely corresponds to the assumption set with VSL = $5 million, VSLY = $300 thousand, and the discount rate = 7 percent. Thus, at the mean, net benefits are roughly $500 million annually. Considering the plausible range of benefits and costs, net benefits of the proposed rule could be as low as $130 million annually and as high as $950 million annually.

As noted previously, the benefits of some provisions in the proposed rule are slightly lower in table 34 of this document than are the benefits listed in the analysis of potential provisions. This difference arises from the fact that each provision in the proposed rule reduces the base line number of illnesses that is used to estimate the benefits of the next provision in the list. In the benefits estimates for potential provisions, by contrast, the base line number of illnesses due to SE in shell eggs is fixed at the total number of illnesses estimated for 2001.

Table 34 of this document illustrates that we have not explicitly determined the benefits for the administrative provisions. The administrative provisions enhance the effectiveness of the SE prevention measures mandated by the rule, and the benefits are therefore embedded in the benefits estimates for each control measure.

In table 34 of this document, we include a cost for program management, because we assume that some management will be necessary to plan and carry out the provisions of the proposed rule. We assume that program management costs will be roughly equal to the cost of the potential plan design with eight provisions. We ask for comment on this assumption.

The recordkeeping costs in table 34 of this document are based on the requirement to keep testing, sampling, and diversion records. The cost of this requirement is assumed to be equal to the cost of one record, as presented in table 31 of this document. As discussed in section V.E.2.a.iv of this document, this estimated cost is likely to overestimate the true cost of keeping testing and diversion records. The recordkeeping costs calculated above are estimated for the typical record that a farm might keep. A typical record is assumed to reflect routine monitoring of a facet of an SE prevention program. Sampling, testing, and diversion records are only collected at the time that testing or diversion is taking place. We ask for comment regarding the actual burden of keeping records associated with the testing and diversion provisions of the proposed rule.

4. Analysis of Uncertainty

In table 34 of this document and elsewhere we present the expected effects of the proposed rule as point estimates. While this is a convenient way to summarize the effects of individual provisions and alternative regulatory options, the use of point estimates neglects the large degree of uncertainty intrinsic to the underlying analysis. In table 35 of this document, we present the results of a Monte Carlo simulation of uncertainty for the eventual annual costs of the proposed rule. Results are reported for the 5th and 95th percentiles, as well as for the mean value. Because many uncertainties could not be measured, this table should not be seen as a complete characterization of the uncertainty underlying the analysis. Nonetheless, table 35 of this document is a good illustration of the effect of the uncertainties we know to exist. Based on the data for which we have been able to characterize uncertainty, we believe that the eventual annual cost of the proposed rule will lie between $50 million and $1.12 billion. We outline descriptions of the distributions used to measure the uncertainties accruing to each provision in appendix C of this document.

TABLE 35.—COSTS OF THE PROPOSED RULE: ANALYSIS OF UNCERTAINTY (THOUSANDS OF DOLLARS)

	5th Percentile	Mean	95th Percentile
On-Farm Measures			
SE Monitoring of Chicks and Pullets	$23	$87	$176
Rodent and Pest Control	$11,389	$21,019	$32,916
Biosecurity	$15,290	$15,594	$15,894
Cleaning and Disinfecting	$1,190	$2,441	$5,567
Refrigeration	$11,850	$18,120	$24,844
Environmental Testing	$2,361	$5,861	$10,794
Egg Testing	$3,407	$4,608	$9,186
Review of Program	$330	$444	$875
Diversion	$3,811	$5,133	$10,071
Administrative Measures			
Program Management	$2.672	$2,672	$2,672
Recordkeeping	$4,481	$5,316	$6,833
Training	$44	$459	$912

TABLE 35.—COSTS OF THE PROPOSED RULE: ANALYSIS OF UNCERTAINTY (THOUSANDS OF DOLLARS)—Continued

	5th Percentile	Mean	95th Percentile
Total	$54,924	$81,754	$123,407

In tables 36 and 37 of this document, we characterize the uncertainties associated with the benefits of the proposed rule. A description of the distributions underlying the estimates in tables 36 and 37 can be found in appendix C. The expected annual benefits in terms of illness averted from the proposed rule range from nearly 21,300 SE illnesses averted to more than 49,500 cases of SE illnesses averted.

TABLE 36.—ILLNESSES AVERTED BY THE PROPOSED RULE: ANALYSIS OF UNCERTAINTY

Provision	5th Percentile	Mean	95th Percentile
On-Farm Measures			
SE Monitoring of Chicks and Pullets	7	10	15
Rodent and Pest Control	16,329	25,703	38,082
Biosecurity	Included in Rodent Control		
Cleaning and Disinfecting	Included in Rodent Control		
Refrigeration	914	1,426	2,125
Testing and Diversion	4,020	6,294	9,281
Total	21,270	33,433	49,503

Table 37 of this document shows that the estimated annual benefits in constant 2001 dollars range from $52.4 million to $2.45 billion. The large range is due in great part to the uncertainties underlying the economic assumptions. Although the lower bound estimate of expected benefits overlaps the upper bound of expected costs, it is safe to say that nearly all of the estimated distributions of benefits exceed the expected costs. Under very reasonable economic assumptions, the expected benefits of the proposed rule exceed the expected costs.

TABLE 37.—ESTIMATED VALUE OF ALL ILLNESSES AVERTED, GIVEN DIFFERENT ECONOMIC ASSUMPTIONS (THOUSANDS OF DOLLARS)

	Discount Rate = 3%					
	VSL = $5 million			VSL = $6.5 million		
	5th percentile	Mean	95th percentile	5th prcentile	Mean	95th percentile
VSLY = $0	$56,276	$88,457	$130,975	$69,950	$109,950	$162,799
VSLY = $100 thousand	$252,790	$397,344	$588,333	—	—	—
VSLY = $300 thousand	$645,816	$1,015,119	$1,503,048	$659,490	$1,036,611	$1,534,872
VSLY = $500 thousand	—	—	—	$1,052,516	$1,654,385	$2,449,587

	Discount Rate = 7%					
	VSL = $5 million			VSL = $6.5 million		
	5th percentile	Mean	95th percentile	5th prcentile	Mean	95th percentile
VSLY = $0	$52,406	$82,373	$121,967	$66,079	$103,866	$153,791
VSLY = $100 thousand	$161,703	$254,170	$376,341	—	—	—
VSLY = $300 thousand	$380,296	$597,764	$885,087	$393,970	$619,257	$916,911
VSLY = $500 thousand	—	—	—	$612,564	$962,851	$1,425,657

[1] VSL means value of a statistical life.
[2] VSLY value of a statistical life year.

Tables 35 through 37 of this document present the results of Monte Carlo simulations that treat the costs and benefits as distributions rather that as point estimates. The tables show that the range of potential costs is much narrower than the range of potential benefits. One additional component of costs not captured in the simulation involves enforcement costs. If FDA or States devote additional resources to inspections as a result of this rule, then the costs of those increased resources must be included in the total costs of the rule. FDA estimates that the potential social cost of increased inspections carried out by FDA or by States in cooperation with FDA, including costs of inspections, re-inspections, egg testing, training, education, assistance, additional staff, and operating costs, is $8 million per year. The egg safety program costs increase the expected annual costs of the proposed rule to $90 million.

The monetary estimates of benefits cover a broad range. The range is largely generated by the different values placed on cases of chronic reactive arthritis that result from SE illness. The higher the value of a statistical life year used to value the health effects of chronic reactive arthritis, the higher the estimated monetary benefits of this proposed rule. If the health effects of reactive arthritis are excluded from the estimated benefits, as in the first 4 rows of table 37 of this document, then the benefits and cost of the proposed rule are of approximately the same magnitude: the distribution of costs and benefits overlap and we cannot definitively conclude that the benefits exceed costs. Once the health effects of preventing chronic reactive arthritis are included, however, even the 5th percentile estimated benefits easily exceed estimated costs.

VI. Initial Regulatory Flexibility Analysis

A. Introduction

FDA has examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a proposed rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the proposed rule on small entities.

B. Economic Effects on Small Entities

1. Number of Small Entities Affected

The Small Business Administration (SBA) defines chicken and egg producers to be small if their total revenues are less than $9 million (65 FR 30836 at 30841, May 15, 2000). A producer that receives $0.45 per dozen eggs and has layers that produce 265 eggs per year would have to have over 900,000 layers in production to earn revenues of over $9 million. While there are a number of producers that fall into this category, the vast majority of the farms affected by this proposed rule are considered to be small by SBA standards.

We estimate that approximately 8 percent of producers that are identified by the standard industrial classification (SIC) codes and the North American Industry Classification System (NAICS) as chicken and egg producers are large by SBA definition.[70] However, because the smallest egg producers are not classified by SIC or NAICS codes, we believe that fewer than 8 percent of egg producers actually fit the SBA definition of "large."

2. Costs to Small Entities

The on-farm portion of the proposed rule will result in significant costs to small businesses. In this PRIA we have estimated costs by farm size. These costs are presented in table 38 of this document. For the industry as a whole, the annual cost of the proposed rule is estimated to be $2,157 per farm site. This translates into a cost of $0.32 per egg layer.

TABLE 38.—DISTRIBUTION OF COST BY FARM SIZE

Farm Size (No. of layers)	Per Farm Cost of Proposed Rule[1]	Per Layer Cost of Proposed Rule
Less than 3,000	$0	$0
3,000 to 19,999	$11,779	$1.01
20,000 to 49,999	$13,364	$0.47
50,000 to 99,999	$24,412	$0.35
100,000 or more	$74,266	$0.19
All Farms	$2,157	$0.32

[1] These figures are drawn from the Preliminary Regulatory Impact Analysis (PRIA). In the PRIA not all costs are explicitly broken out by farm size. In this case, we assume that costs are either: (1) Equal for all farms (training and registration), (2) scaled to the number of houses per farm site (cleaning and disinfecting for flocks with more than 3,000 layers, biosecurity, and plan review in the case of a positive), or (3) scaled to the number of layers per farm site (National Poultry Improvement Plan SE monitored chicks and feed).

C. Regulatory Options

1. Exemption for Small Entities

a. *Exemption for all small entities.* One possible approach to reduce the impact on small entities would be to exempt all small entities from the rule. Although this would significantly reduce costs, it would also significantly reduce benefits. As mentioned above, under the SBA size standards the vast majority of farms affected by this proposed rule are small. Small farms include not only farms with a few hundred layers, but also some larger farms with over 100,000 layers. This exemption would lead to a significant reduction in the benefits estimated for the proposed rule.

The alternative approach implemented in the proposed rule exempts farms with fewer than 3,000 layers.[71] While over 89 percent of the farm sites covered by this rule have fewer than 3,000 layers, less than 1 percent of the eggs produced in the

[70] Data are drawn from Dun and Bradstreet's financial records using the Dialog database (Ref. 140).

[71] An exemption for farms with fewer than 3,000 birds is consistent with the exemption given by the EPIA for egg farms that are also egg processors.

United States are produced on these farms.

FDA has decided to exempt all farms with fewer than 3,000 layers from all provisions of this proposed rule. By exempting these farms, we reduce expected benefits by less than one percent while reducing expected costs by half.

We also exempt from all parts of the proposed rule those farms that sell all of their eggs directly to consumers.

2. Longer Compliance Periods

We recognize that it may be more difficult for some small farms to learn about and implement these SE prevention measures than it will be for other farms. FDA is therefore proposing to give farm sites with 3,000 or more but fewer than 50,000 layers, 2 years (as opposed to 1 year for larger farm sites) to comply with this proposed rule.

D. Description of Recordkeeping and Recording Requirements

The Regulatory Flexibility Act requires a description of the recordkeeping required for compliance with this proposed rule. We require recordkeeping for the sampling, testing, and diversion provisions of the proposed rule. The cost of recordkeeping is exhibited in table 39 of this document. How recordkeeping costs are calculated is detailed in section V.E of this document.

TABLE 39.—COST OF RECORDKEEPING BY FARM SIZE

Farm Size (No. of layers)	Per Farm Cost of Recordkeeping	Per Layer Cost of Recordkeeping
Less than 3,000	$0	$0
3,000 to 19,999	$2,830	$0.11
20,000 to 49,999	$898	$0.05
50,000 to 99,999	$341	$0.03
100,000 or more	$1,247	$0.02
All Farms	$135	$0.02

E. Summary

FDA finds that, under the Regulatory Flexibility Act (5 U.S.C. 605(b)), this proposed rule would have a significant impact on a substantial number of small entities. More than 1,000 small farms would be affected by the proposed rule.

VII. Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4) requires cost-benefit and other analyses for rules that would cost more than $100 million in a single year. The current inflation-adjusted statutory threshold is $115 million. Since the estimated annual cost for this proposed rule is less than $115 million, FDA has determined that this proposed rule, if it becomes a final rule as proposed, would not be a significant rule under UMRA.

VIII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132 on federalism. We have examined the effects of the requirements of this proposal for on-farm SE prevention measures for shell egg production on the relationship between the Federal Government and the States. The agency concludes that preemption of State or local rules that establish requirements for production of shell eggs that would be less stringent than Federal law is consistent with this Executive Order. Section 3(b) of Executive Order 13132 recognizes that Federal action limiting the policymaking discretion of States is appropriate "where there is constitutional and statutory authority for the action and the national activity is appropriate in light of the presence of a problem of national significance." The constitutional basis for FDA's authority to regulate the safety and labeling of foods is well established.

Section 4(a) of Executive Order 13132 expressly contemplates preemption where the exercise of State authority conflicts with the exercise of Federal authority under a Federal statute. Moreover, section 4(b) of Executive Order 13132 authorizes preemption of State law by rulemaking when the exercise of State authority directly conflicts with the exercise of Federal authority under the Federal statute or there is clear evidence to conclude that Congress intended the agency to have the authority to preempt State law.

State and local laws and regulations that would impose less stringent requirements for production of shell eggs would undermine the agency's goal of ensuring that shell eggs are produced using measures that will prevent their contamination with SE and, thus, reduce the risk of foodborne illness. The proposed requirements for production of shell eggs are the minimal prevention measures that we believe are necessary to ensure safety.

The proposed rule would establish national minimum prevention measures with respect to production of shell eggs. However, the egg production requirements of this proposed rule do not preempt State and local laws, regulations, and ordinances that establish more stringent requirements with respect to production requirements. As required by the Executive order, States and local governments will be given, through this notice of proposed rulemaking, an opportunity to participate in the proceedings to preempt State and local laws. In addition, appropriate officials and organizations will be consulted before this proposed action is implemented; the agency plans to have public meetings specifically addressing the issue of implementation of these proposed regulations. The agency consulted with a working group comprised of State officials in developing the provisions of this proposed rule and plans to continue to consult with this group in the development of a final rule. In addition, we sent facsimiles of a **Federal Register** document announcing a public meeting on egg safety and the availability of egg safety "current thinking" documents prepared by FDA and USDA to Governors, State health and agriculture commissioners, State attorneys general, and State food program coordinators.

IX. Environmental Impact

The agency has determined under 21 CFR 25.30(j) that this action is of a type

that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

X. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). A description of these provisions is given in the following paragraphs with an estimate of the annual recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each 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 the agency'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 the use of automated collection techniques, when appropriate, or other forms of information technology.

Title: Control of *Salmonella* Enteritidis in Shell Eggs During Production—Recordkeeping Provisions Under Proposed Part 118.

Description: FDA is proposing to require shell egg producers to implement SE measures to prevent SE from contaminating eggs on the farm. We are only proposing recordkeeping provisions for the sampling, testing and diversion requirements for shell egg producers.

We have tentatively concluded that recordkeeping is necessary for the success of the SE prevention measures. Records of testing and diversion will assist FDA in determining if the farm in question currently has a problem with SE and is making an effort to ameliorate any problem it might have. FDA's statutory authority for these proposed requirements is discussed in section III.L of this document.

Description of Respondents: Businesses or other for profit organizations.

FDA estimates the burden of this collection of information as follows:

TABLE 40.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
118.10	5,635	1	5,635	26	146,510
Total					146,510

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden estimates in table 40 in this document are based on estimates of the total number of layer houses affected by this proposed rule from statistics obtained from the NASS. Individual burdens were obtained by estimating the number of layer houses affected by each portion of the proposed rule and multiplying it by the corresponding number of records required annually and the hours needed to complete the record. These burden estimates are an estimate of the hours needed to complete each record contained in the agency's PRIA prepared for this proposed rule.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), the agency has submitted the information collection provisions of this proposed rule to OMB for review. Interested persons are requested to submit comments regarding information collection to OMB, via facsimile on 202–395–6974, Attn: Desk Officer for FDA.

XI. Comments

Submit written comments regarding this proposal to the Division of Dockets Management (see **ADDRESSES**), unless comments regard information collection. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Submit comments regarding information collection to OMB (see **ADDRESSES**). Submit a single copy of electronic comments or two copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

XII. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Centers for Disease Control and Prevention, "Fact Sheets: *Salmonella*," Office of Communication Media Relations, July 16, 1999.

2. Centers for Disease Control and Prevention Memorandum from Chief, Foodborne Diseases Epidemiology Section, February 8, 1996.

3. Swerdlow, D. L., L. A. Lee, R. V. Tauxe, N. H. Bean, and J. Q. Jarvis, "Reactive Anthropathy Following a Multistate Outbreak of *Salmonella typhimurium* Infections," Abstract 916, Thirtieth Interscience Conference on Antimicrobial Agents and Chemotherapy.

4. Mead, P. S., L. Slutsker, V. Dietz, L. F. McCaig, J. S. Bresee, C. Shapiro, P. M. Griffin, and R. V. Tauxe, "Food-Related Illness and Death in the United States," *Emerging Infectious Diseases* 5:607–625, 1999.

5. Centers for Disease Control and Prevention, *Salmonella Surveillance Annual Tabulation Summary*, 2001.

6. Centers for Disease Control and Prevention, *Salmonella Surveillance Annual Tabulation Summary*, 2000.

7. Centers for Disease Control and Prevention, "Outbreaks of *Salmonella* Serotype Enteritidis Infection Associated with Eating Raw or Undercooked Shell Eggs-United States, 1996–1998", MMWR 2000; 49:73–79.

8. CDC memorandum, Christopher Braden to the Record, September 14, 2004.

9. Centers for Disease Control and Prevention, "Outbreaks of *Salmonella* Serotype Enteritidis Infection Associated with Eating Shell Eggs-United States, 1999–2001", MMWR 2002; 51:1149–1152.

10. U.S. Department of Health and Human Services. *Healthy People 2010: Understanding and Improving Health*. 2nd ed. Washington, DC: U.S. Government Printing Office, November 2000. Accessed online at *www.healthypeople.gov*, February 5, 2004.

11. Mishu, B, J. Koehler, L.A. Lee, D. Kodrigue, F. Hickman Brenner, P. Blake, and R.V. Tauxe, "Outbreaks of *Salmonella*

Enteritidis infections in the United States, 1985–1991," *Journal of Infectious Disease* 169: 547–552, 1994.

12. Keller, L. H., C. E. Benson, K. Krotec, and R. J. Eckroade, "*Salmonella* enteritidis Colonization of the Reproductive Tract and Forming of Freshly Laid Eggs of Chickens," *Infection and Immunity* 7: 2443–2449, 1995.

13. Snoeyenbos, G. H., C. F. Smyser, and H. Van Roekel, "*Salmonella* Infections of the Ovary and Peritoneum of Chickens," *Avian Diseases* 13: 668–670, 1969.

14. Humphrey, T. J. "Contamination of Egg Shell and Contents with *Salmonella* enteritidis: A Review," *International Journal of Food Microbiology* 21: 31–40, 1994.

15. Baker Jr., A. R., E. D. Ebel, R. M. McDowell, R. A. Morales, W. D. Schlosser, and R. Whiting, *Salmonella* Enteritidis Risk Assessment Team, *Salmonella Enteritidis Risk Assessment: Shell Eggs and Egg Products*, Washington, DC: United States Department of Agriculture, June 12, 1998.

16. Council for Agricultural Science and Technology, *Foodborne Pathogens: Risks and Consequences*, Ames, IA: Council for Agricultural Science and Technology, Task Force Report No. 122, Chapter 3, 1994.

17. Hennessey, T. W., C. W. Hedberg, L. Slutsker, K. E. White, J. M. Besser-Wiek, M. E. Moen, J. Feldman, W. W. Colemen, L. M. Edmonson, K. L. MacDonald, and M. T. Osterholm, "A National Outbreak of *Salmonella enteritidis* Infections from Ice Cream," *The New England Journal of Medicine* 334: 1282–1286, 1996.

18. Vought, K. J. and S. R. Tatini, "*Salmonella enteritidis* Contamination of Ice Cream Associated with a 1994 MultiState Outbreak," *Journal of Food Protection* 61: 5–10, 1998.

19. Humphrey, T. J., A. Whitehead, A. H. L. Gawler, A. Henley, and B. Rowe, "Numbers of *Salmonella enteritidis* in the Contents of Naturally Contaminated Hens' Eggs," *Epidemiology and Infection* 106: 489–496, 1991.

20. American Egg Board, "Egg Industry Facts Sheet," February 3, 2000.

21. National Agricultural Statistics Service, United States Department of Agriculture, Layers and Egg Production 1998 Summary, January 1999.

22. National Agricultural Statistics Service, "Table 20. Poultry Inventory and Sales: 1997 and 1992," *1997 Census of Agriculture: United States Summary and State Data*, vol. 1, part 51, U.S. Department of Agriculture, Accessed at *www.usda.gov/nass/*, April 2000.

23. U.S. Department of Agriculture, Food Safety and Inspection Service, "FDA: Consumers Are Changing," *The Food Safety Educator* 3(4):2–3, 1998.

24. Fein, S. B., A. Levy, and A. Lando, "Food Safety Survey: Summary of Major Trends in Food Handling Practices and Consumption of Potentially Risky Foods," U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, Consumer Studies Branch, August 27, 2002.

25. National Animal Health Monitoring System, Animal and Plant Health Inspection Service, United States Department of Agriculture, "Layers'99, Part I: Reference of 1999 Table Egg Layer Management in the U.S." October 1999.

26. National Animal Health Monitoring System, Animal and Plant Health Inspection Service, United States Department of Agriculture, "Layers'99, Part II: Reference of 1999 Table Egg Layer Management in the U.S." January 2000.

27. National Animal Health Monitoring System, Animal and Plant Health Inspection Service, United States Department of Agriculture, "Layers '99: *Salmonella enterica* serotype Enteritidis in Table Egg Layers in the U.S." October 2000.

28. Pennsylvania Poultry Federation, "Pennsylvania Egg Quality Assurance Program," revised April 1997, 500 N. Progress Ave., Harrisburg, PA 17109.

29. California Egg Industry, "California Egg Quality Assurance Program," California Department of Food and Agriculture, 1220 N Street, rm. A–107, Sacramento, CA 95814.

30. New York State, "New York State Egg Quality Assurance Program," 1 Winners Circle, Albany, NY 12235.

31. Maryland Department of Agriculture, "Egg Quality Assurance Program," April 2, 1997, 50 Harry S. Truman Pkwy., Annapolis, MD 21401.

32. Ohio Poultry Association, "Ohio Egg QA Program," 5930 Sharon Woods Blvd., Columbus, OH 43229.

33. United Egg Producers, "UEP 5-Star Total QA Program," 1303 Hightower Trail, suite 200, Atlanta, GA 30350.

34. United States Animal Health Association, "National Standardized *Salmonella Enteritidis* Reduction Program for Eggs," 8100 3 Chopt Rd., suite 203, P.O. Box K227, Richmond, VA 23288.

35. Hogue, A, P. White, J. Guard-Petter, W. Schlosser, R. Gast, E. Ebel, J. Farrar, T. Gomez, J. Madden, M. Madison, A. M. McNamara, R. Morales, D. Parham, P. Sparling, W. Sutherlin, and D. Swerdlow, "Epidemiology and Control of Egg-Associated *Salmonella* Enteritidis in the United States of America," *Revue Scientifique et Technique Office International des Epizooties* 16: 542–553, 1997.

36. White, P. L., W. Schlosser, C. E. Benson, C. Maddox, and A. Hogue, "Environmental Survey by Manure Drag Sampling for *Salmonella enteritidis* in Chicken Layer Houses, "*Journal of Food Protection* 60: 1189–1193, 1997.

37. Holt, P. S., B. W. Mitchell, and R. K. Gast, "Airborne Horizontal Transmission of *Salmonella* enteritidis in Molted Laying Chickens," *Avian Diseases* 42: 45–52, 1998.

38. Leslie, J., "Simulation of the Transmission of *Salmonella enteritidis* Phage Type 4 in a Flock of Laying Hens, "*Veterinary Record* 139: 388–391, 1996.

39. Schlosser, W. D., D. J. Henzler, J. Mason, D. Kradel, L. Shipman, S. Trock, S. H. Hurd, A. T. Hogue, W. Sischo, and E. D. Ebel, "The *Salmonella enterica* Serovar Enteritidis Pilot Project," Chapter 32 in *Salmonella enterica Serovar Enteritidis in Humans and Animals Epidemiology, Pathogenesis, and Control*, Editor A. M. Saeed, Iowa State University Press, Ames, IA, 1999.

40. Cox, N. A., "Incidence and Impact of *Salmonella*e in Broiler Hatcheries," International Symposium on Food-Borne *Salmonella* in Poultry, Baltimore, MD, July 25–26, 1998.

41. Gast, R. K. and P. S. Holt. "Persistence of *Salmonella enteritidis* from One Day of Age Until Maturity in Experimentally Infected Layer Chickens," *Poultry Science* 77: 1759–1762, 1998.

42. Hoop, R. K., "The Swiss Control Programme for *Salmonella* Enteritidis in Laying Hens: Experiences and Problems," *Revue Scientifique et Technique Office International des Epizooties* 16: 885–890, 1997.

43. Guard-Petter, J., D. J. Henzler, M. M. Rahman, and R. W. Carlson, "On-Farm Monitoring of Mouse-Invasive *Salmonella enterica* Serovar Enteritidis and a Model for Its Association with the Production of Contaminated Eggs," *Applied and Environmental Microbiology* 63: 1588–1593, 1997.

44. Henzler, D. J. and H. M. Opitz, "The Role of Mice in the Epizootiology of *Salmonella* enteritidis Infection on Chicken Layer Farms," *Avian Diseases* 36: 625–631, 1992.

45. Kreager, K, "Egg Industry Initiatives to Control *Salmonella*," International Symposium on Food-Borne *Salmonella* in Poultry, Baltimore, MD, July 25–26, 1998.

46. Davison, S. A., P. A. Dunn, D. J. Henzler, S. J. Knabel, P. H. Patterson, and J.H. Schwartz, *Preharvest HACCP in the Table Egg Industry: Hazard Analysis Critical Control Point System for Enhancing Food Safety*, Penn State College of Agricultural Sciences, 1997.

47. Wray, C. and R. H. Davies, "Environmental Problems in Poultry Production: Dust and Pests," International Symposium on Food-Borne *Salmonella* in Poultry, Baltimore, MD, July 25–26, 1998.

48. Henzler, D. J. and H. M. Opitz, "Role of Rodents in the Epidemiology of *Salmonella enterica* Enteritidis and Other *Salmonella* Serovars in Poultry Farms," chapter 30 in *Salmonella enterica Serovar Enteritidis in Humans and Animals Epidemiology, Pathogenesis, and Control*, Editor A. M. Saeed, Iowa State University Press, Ames, IA, 1999.

49. Olsen, A. R. and T. S. Hammack, "Isolation of *Salmonella* spp. from the Housefly, *Musca domestica* L., and the Dump Fly, *Hydrotaea aenescens* (Wiedemann) (Diptera: MU.S.C.idae), at Caged-Layer Houses," *Journal of Food Protection* 63:958–960, 2000.

50. Axtell, R. C., "Integrated Fly-Control Program for Caged-Poultry Houses," *Journal of Economic Entomology* 63:400–405, 1970.

51. Hogsette, J. A., R. D. Jacobs, and R. W. Miller, "The Sticky Card: Device for Studying the Distribution of Adult House Fly (Diptera: Muscidae) Populations in Closed Poultry Houses," *Journal of Economic Entomology* 86: 450–454, 1993.

52. Scott, H. G. and K. S. Littig, "Flies of Public Health Importance and Their Control, Training Guide-Insect Control Series," U.S. Department of Health, Education, and Welfare, Public Health Service, Communicable Disease Center, Atlanta, GA 30333.

53. Stege, H. J. Dahl, J. Christensen, D. L. Baggesen, J. P. Nielsen, and P. Willeberg,

"Subclinical *Salmonella* Infection in Danish Finishing Pig Herds: Risk Factors," in *Proceedings of the Second International Symposium on Epidemiology and Control of Salmonella in Pork*, 148–152, Axelborg, Axeltorv 3, 1609 Copenhagen V, Denmark, 1997.

54. Kim, C. J., D. A. Emery, H. Rinkle, K. V. Nagaraja, and D. A. Halvorson, "Effect of Time and Temperature on Growth of *Salmonella* enteritidis in Experimentally Inoculated Eggs, "*Avian Diseases* 33:735–742, 1989.

55. Humphrey, T. J., "Growth of *Salmonellas* in Intact Shell Eggs: Influence of Storage Temperature," *The Veterinary Record*, 126:292, 1990.

56. Bradshaw, J. G., D. B. Shah, E. Forney, and J. M. Madden, "Growth of *Salmonella enteritidis* in Yolk of Shell Eggs from Normal and Seropositive Hens," *Journal of Food Protection* 53:1033–1036, 1990.

57. Memorandum from Richard Wood, Food Animal Concerns Trust, to Lou Carson, Food and Drug Administration, August 25, 2000.

58. United States Department of Agriculture, Transcript: "Public Meeting on Current Thinking Egg Safety Standards," Washington, DC, July 31, 2000, online at *www.foodsafety.gov*.

59. Mallinson, E. T., C. R. Tate, R. G. Miller, B. Bennett, and E. Russek-Cohen, "Monitoring Poultry Farms for *Salmonella* by Drag-Swab Sampling and Antigen-Capture Immunoassay," *Avian Diseases* 33: 684–690, 1989.

60. Castellan, D., Staff Veterinarian, Production Food Safety Program, Animal Health and Food Safety Services, 1220 N Street, Sacramento, CA 95814, provided "Drag Swab Sampling Study" by Rolfe, D., H. Riemann, and S. Himathonkham.

61. FDA memorandum, Qian Graves to the Record, September 9, 2004.

62. Valentin-Bon, I.E., R.E. Brackett, K.H. Seo, T.S. Hammack and W.H. Andrews, "Preenrichment Versus Direct Selective Agar Plating for the Detection of *Salmonella* Enteritidis in Shell Eggs," *Journal of Food Protection* 66(9): 1670–1674, 2003.

63. Centers for Disease Control and Prevention, "Update: *Salmonella* enteritidis Infections in Grade A Shell Eggs-United States," MMWR 1988; 37:490, 495–496.

64. Centers for Disease Control and Prevention, "Outbreaks of *Salmonella* Serotype Enteritidis Infection Associated with Consumption of Raw Shell Eggs-United States, 1994–1995," MMWR 1996; 45:737–742.

65. FDA memorandum, Marilyn Balmer to the Record, September 6, 2000.

66. FDA memorandum, Marilyn Balmer to the Record, December 18, 1998.

67. FDA memorandum, Robert Brackett to the Record, September 6, 2000.

68. Holt, P. S., "Horizontal Transmission of *Salmonella enteritidis* in molted and unmolted laying chickens," *Avian Diseases* 39: 239–249, 1995.

69. Bailey, J. S., N. A. Cox, and L. C. Blakenship, "Persistence and Spread of External *Salmonella* Contamination During Broiler Production," *Poultry Science* 69S:154, 1990.

70. Seo, K. H., P. S. Holt, R. K. Gast, and C. L. Hofacre, "Combined Effect of Antibiotic and Competitive Exclusion Treatment of *Salmonella* Enteritidis Fecal Shedding in Molted Laying Hens," *Journal of Food Protection* 63:545–548, 2000.

71. United States Department of Agriculture, PA Poultry Producers, PA Poultry Federation, Egg Association of America, PA Department of Agriculture, PA State University, and the University of PA, "*Salmonella* Enteritidis Pilot Project Progress Report," May 22, 1995.

72. FDA memorandum, Record of telephone conversation between Robert Brackett and John Mason, August 31, 2000.

73. Letter from A. Mirande, Biomune Co., to L. Carson, Food and Drug Administration, February 7, 2000.

74. Donahoe, J. P., E. Lovell, B. Glidewell, H. M. Opitz, and D. Henzler, Slide presentation entitled "Vaccination Strategy for *Salmonella* Enteritidis Bacterin," *Foodborne Pathogens in Poultry*, Summit III, February 29 to March 1, 2,000.

75. Klontz, K. C., B. Timbo, S. Fein, and A. Levy, "Prevalence of Selected Food Consumption and Preparation Behaviors Associated With Increased Risks of Food-Borne Disease," *Journal of Food Protection* 58(8):927–930, 1995.

76. Market Research Corp. of America, Consumption of Raw Beef, Raw Fish, Raw Eggs, Menu Census Report to the U.S. Department of Agriculture—ERS, 1995.

77. Lin, C-T. J., R. A. Morales, and K. Ralston, "Raw and Undercooked Eggs: A Danger of Salmonellosis," *Food Review* 20:27–32, 1997.

78. FDA Memorandum, Alan S. Levy, Ph.D. to Kenneth Falci, Ph.D., June 26, 1997.

79. U.S. General Accounting Office, "Food Safety: U.S. Lacks a Consistent Farm-to-Table Approach to Egg Safety," GAO/RCED–99–184, July 1999.

80. Buzby, Jean C., T. Roberts, C. T. Lin, and J. M. MacDonald, *Bacterial Foodborne Disease: Medical Costs & Productivity Losses*, Washington, DC: Economic Research Service, U.S. Department of Agriculture, 1996.

81. Zorn, D. J. and K. Klontz, Appendix: The Value of Consumer Loss to Foodborne Reactive Arthritis (63 FR 24253, May 1, 1998).

82. FoodNet, Foodborne Diseases Active Surveillance Network, *1999 Surveillance Results: Preliminary Report* Centers for Disease Control, March 2000.

83. Cutler, D. M. and E. Richardson, "Measuring the Health of the U.S. Population," Brookings Paper. Microeconomics 1997, pp. 217–271.

84. Scharff, R. L. and A. Jessup, "Valuing Chronic Disease for Heterogeneous Populations: The Case of Arthritis," Working Paper, 2000.

85. Williams, R.M., "The Costs of Visits to Emergency Departments," *The New England Journal of Medicine* 334(10): 642–646, 1996.

86. *Consumer Price Index-All Urban Consumers*, Bureau of Labor Statistics, accessed online November 17, 2003.

87. Healthcare Cost and Utilization Project, *Nation Inpatient Sample (NIS) - 2001*, Washington, D.C., Agency for HealthCare Research and Quality, 2003.

88. Garber, A.M. and C.E. Phelps, "Economic Foundations of Cost-Effectiveness Analysis," *Journal Health Economics*, vol. 16, pp. 1–31, 1997.

89. U.S. Census Bureau, Statistical Abstract of the United States, pp. 413–416 and 436, 2002.

90. Viscusi, W.K. and J.E. Aldy, "The Value of a Statistical Life: A Critical Review of Market Estimates throughout the World," *AEI-Brookings Joint Center for Regulatory Studies*, January 2003.

91. Alberini, A., M. Cropper, A. Krupnick, and N.B. Simon, "Does the Value of a Statistical Life Vary with Age and Health Status? Evidence from the United States and Canada," *Resources for the Future*, Discussion Paper 02–19, April 2002.

92. *Campylobacter FAQ Page*, New Mexico Department of Health, accessed online August 11, 2000.

93. Humphrey, T. J., "Contamination of Eggs and Poultry Meat with *Salmonella* enterica Serovar Enteritidis," in *Salmonella enterica Serovar Enteritidis in Humans and Animals*, Iowa State University Press, Ames, IA, 1999.

94. Stadelman, W. J., "Chapter 4: The Preservation of Quality in Shell Eggs," in *Egg Science and Technology*, Fourth Edition, Food Products Press, NY, 1995.

95. E-mail Correspondence between Robert Scharff, FDA. and Deanna Baldwin, May 31, 2000.

96. E-mail Correspondence between Robert Scharff, FDA, and Michael Opitz, June 1, 2000.

97. E-mail Correspondence between Robert Scharff, FDA, and Phillip Debok, June 1, 2000.

98. National Agricultural Statistics Service, *Chicken and Eggs*, Washington, DC, United States Department of Agriculture, accessed online, February 2, 2000.

99. PA Poultry Federation. "Comparison of PEQAP and Other Programs," 500 N. Progress Ave., Harrisburg, PA 17109.

100. Economic Research Service, "Table 53: Breaking Eggs (Checks and Undergrades)" Poultry Yearbook, U.S. Department of Agriculture, Obtained through e-mail correspondence with Ronald Meekhof, April 27, 2000.

101. Hoelscher, Clifford E., "Poultry Pest Management," Texas Agricultural Extension Service, The Texas A&M University System, 1997.

102. Evans, S. J., R. H. Davies, and C. Wray, "Chapter 28: Epidemiology of *Salmonella* enterica Serovar Enteritidis Infection in British Poultry Flocks" in *Salmonella enterica Serovar Enteritidis in Humans and Animals*, Iowa State University Press, Ames, IA, 1999.

103. FDA Memorandum, Research Triangle Institute to the Record, June 18, 2002.

104. Berry, Joe, "Rodent Control in the Poultry House" Cooperative Extension Program, Division of Agriculture, Oklahoma State University, June 1987.

105. Thornberry, Fred D., "Pest Control," Texas Agricultural Extension Service, The Texas A&M University System.

106. *Leonard Safety Equipment Catalog*, accessed online, July 23, 2000.

107. Bureau of Labor Statistics, *2003 National Occupational Employment and*

Wage Estimates, Washington, D.C., U.S. Department of Labor, accessed online August 31, 2004.

108. "Biosecurity for Poultry," Publication 408–310, Virginia Cooperative Extension Service, 1989.

109. Halvorson, David A., *Good Management Practices for Salmonella Risk Reduction in the Production of Table Eggs*, University of Minnesota Extension Service, 1997.

110. Carey, J. B., J. F. Prochaska, and J. S. Jeffrey, *Poultry Facility Biosecurity*, Texas Agricultural Extension Service, 1997.

111. Morales, R. A. and R. M. McDowell, "Chapter 25: Economics Consequences of *Salmonella* enterica Serovar Enteritidis Infection in Humans and the U.S. Egg Industry" in *Salmonella enterica Serovar Enteritidis in Humans and Animals*, Iowa State University Press, Ames, IA, 1999.

112. E-mail Correspondence between Robert Scharff, FDA, and Andrew Rhorer, August 15, 2000.

113. Rhorer, A. R., "Chapter 27: Control of *Salmonella* enterica Serovar Enteritidis Under the National Poultry Improvement Plan" in *Salmonella enterica Serovar Enteritidis in Humans and Animals*, Iowa State University Press, Ames, IA, 1999.

114. Economic Research Service, *The Formula Feed Manufacturing Industry*, 1984, Washington, DC: U.S. Department of Agriculture, accessed online August 21, 2000.

115. Dun and Bradstreet, Dun's Market Identifiers, The Dialog Corp. Mountain View, CA, August 22, 2000.

116. Memorandum to the record of phone conversation between John Sheehan, FDA, and Silliker Laboratories, August 17, 2000.

117. Bureau of Labor Statistics, *2003 National Occupational Employment and Wage Estimates*, Washington, D.C., U.S. Department of Labor, accessed online August 31, 2004.

118. Federal Express, *FedEx Standard Overnight Per-Pound Rates*, Federal Express, accessed online June 10, 2002.

119. McChesney, D. G. and G. Kaplan, "*Salmonella* Survey of Animal Feed and Protein Products at Feed Mills and On-Farm Mixer," Food and Drug Administration, Center for Veterinary Medicine, Division of Animal Feeds, 7500 Standish Pl., rm. E478, Rockville, MD 20855.

120. McChesney, D. G., G. Kaplan, and P. Gardner, "FDA Survey Determines *Salmonella* Contamination," Feedstuffs 67, February 13, 1995.

121. Wood, Richard, "The Comments of the Food Animal Concerns Trust About the Egg Safety Action Plan," comment 14, Food and Drug Administration Docket No. 00N–0504.

122. Gast, R.K., H.D. Stone, P.S. Holt, "Evaluation of the Efficacy of Oil-Emulsion Bacterins for Reducing Fecal Shedding of *Salmonella* Enteritidis by Laying Hens," *Avian Diseases* 37: 1085–91, 1993.

123. Davison, S., C.E. Benson, D.J. Henzler, R.J. Eckroade, "Field Observations with *Salmonella* Enteritidis Bacterins," *Avian Diseases* 43: 664–9, 1999.

124. FDA Memorandum, Research Triangle Institute to the Record, September 3, 2000.

125. Riemann, H., S. Himathongkham, D. Willoughby, R. Tarbell, and R. Breitmeyer, "A Survey for *Salmonella* by Drag Swabbing Manure Piles in California Egg Ranches," *Avian Diseases*, vol. 42, pp. 67–71, 1998.

126. California, Animal Health & Food Safety Laboratory System, University of California, Davis, School of Veterinary Medicine, accessed online May 31, 2000.

127. National Agricultural Statistics Service, *Egg Products* (issues covering January through December 1999), Washington, DC: U.S. Department of Agriculture, accessed online February 2, 2000.

128. Agricultural Marketing Service. *Grain Transportation Report*, United States Department of Agriculture, January 4, 2000.

129. Agricultural Marketing Service, *USDA AMS, Poultry Market News*, data accessed online through the Institute of Food and Agricultural Sciences, University of Florida, April 24, 2000.

130. Agricultural Marketing Service, *USDA AMS, Poultry Market News*, data accessed online through the North Carolina Department of Agriculture & Consumer Services, Division of Marketing, Market News, April 24, 2000.

131. Memorandum of estimates given by Phillip Debok at the Egg Safety Workshop, January 10–14, 2000.

132. Hogue, Allan, Chairperson, *Salmonella* Enteritidis Review Team, *Salmonella Enteritidis Review Team Report*, Washington, DC: Food Safety Inspection Service, U.S. Department of Agriculture, January 18, 1997.

133. Memorandum of estimate given by Michael Opitz at the Egg Safety Workshop, January 10–14, 2000.

134. Bureau of Labor Statistics, *2003 National Occupational Employment and Wage Estimates*, Washington, D.C., U.S. Department of Labor, accessed on-line August 31, 2004.

135. *U.S. Poultry & Egg Association Educational Programs*, U.S. Poultry and Egg Association, accessed online August 8, 2000.

136. U.S. Public Health Service, "Food Code: 2001, Recommendations of the United States Public Health Service, Food and Drug Administration," Annex 3, Chapter 3, Section 3–801.11.

137. Shah, D. B., J. G. Bradshaw, and J. T. Peeler, "Thermal Resistance of Egg-Associated Epidemic Strains of *Salmonella* enteritidis," *Journal of Food Science*, 56:391–393, 1991.

138. U.S. Public Health Service. "Food Code: 2001, Recommendations of the United States Public Health Service, Food and Drug Administration," Section 3–401.11 and Annex 3, Chapter 3, Section 3–401.11.

139. Severson, Kim, "Pending Pasteurization Policy Could Alter Eggs Forever," *San Francisco Chronicle*, online, April 19, 2000.

140. Dun and Bradstreet, Dun's Market Identifiers, The Dialog Corp. Mountain View, CA, August 21, 2000.

List of Subjects

21 CFR Part 16

Administrative practice and procedure.

21 CFR Part 118

Eggs and egg products, Incorporation by reference, Recordkeeping requirements, Safety.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, and under the authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR chapter I be amended as follows:

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

1. The authority citation for 21 CFR part 16 continues to read as follows:

Authority: 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364.

2. Section 16.5 is amended by adding paragraph (a)(5) to read as follows:

§ 16.5 Inapplicability and limited applicability.

(a) * * *

(5) A hearing on an order for diversion or destruction of shell eggs under section 361 of the Public Health Service Act (42 U.S.C. 264), and § 118.12 of this chapter.

* * * * *

3. Part 118 is added to read as follows:

PART 118—PRODUCTION AND STORAGE OF SHELL EGGS

Sec.

118.1 Shell egg producers covered by the requirements in this part.
118.3 Definitions.
118.4 *Salmonella* Enteritidis (SE) prevention measures.
118.5 Environmental testing for *Salmonella* Enteritidis (SE).
118.6 Egg testing for *Salmonella* Enteritidis (SE).
118.7 Sampling methodology for *Salmonella* Enteritidis (SE).
118.8 Testing methodology for *Salmonella* Enteritidis (SE).
118.9 Administration of the *Salmonella* Enteritidis (SE) prevention measures.
118.10 Recordkeeping requirements for the *Salmonella* Enteritidis (SE) prevention measures.
118.12 Enforcement and compliance.

Authority: 21 U.S.C. 321, 331–334, 342, 371, 381, 393; 42 U.S.C. 243, 264, 271.

§ 118.1 Shell egg producers covered by the requirements in this part.

If you are a shell egg producer with 3,000 or more laying hens at a particular farm that does not sell all of your eggs directly to consumers and that produces shell eggs for the table market, you are covered by some or all of the requirements in this part, as follows:

(a) If any of your eggs that are produced at the particular farm do not

receive a treatment as defined in § 118.3, you must comply with all of the requirements of this part for egg production on that farm.

(b) If all of your eggs that are produced at the particular farm receive a treatment as defined in § 118.3, you must comply only with the refrigeration requirements in § 118.4 for production of eggs on that farm.

§ 118.3 Definitions.

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (the FFDCA) (21 U.S.C. 321) are applicable to such terms when used in this part, except where they are redefined in this part. The following definitions also apply:

Biosecurity means a program, including limiting visitors to poultry houses, keeping small animals out of poultry houses, and requiring personnel to wear protective clothing, to ensure that there is no introduction or transfer of *Salmonella* Enteritidis (SE) onto a farm or among poultry houses.

Farm means all poultry houses and grounds immediately surrounding the poultry houses covered under a single biosecurity program.

Flock means all laying hens within one poultry house.

Group means all laying hens of the same age within one poultry house.

Induced molting means molting that is artificially initiated.

Laying cycle means the period of time that a hen begins to produce eggs until it undergoes induced molting or is permanently taken out of production and the period of time that a hen produces eggs between successive induced molting periods or between induced molting and the time that the hen is permanently taken out of production.

Molting means a life stage during which hens stop laying eggs and shed their feathers.

Pest means any objectionable animals or insects including, but not limited to, birds, rodents, flies, and larvae.

Positive flock means a flock that has had an egg test that was positive for SE and applies until that flock meets the egg testing requirements in § 118.6(b) to return to table egg production.

Positive poultry house means a poultry house from which there has been an environmental test that was positive for SE during any of the laying cycles of a group in the poultry house until that house is cleaned and disinfected according to § 118.4(d).

Poultry house means a building, other structure, or separate section within one structure used to house poultry. For structures comprising more than one section containing poultry, each section is enclosed and separated from the other sections, and each section has a biosecurity program in place to ensure that there is no introduction or transfer of SE from one section to another.

Producer means a person who maintains laying hens for the purpose of producing shell eggs for human consumption.

Shell egg (or egg) means the egg of the domesticated chicken.

Treatment means a technology or process that achieves at least a 5-log destruction of SE for shell eggs, or the processing of egg products in accordance with the Egg Products Inspection Act.

§ 118.4 *Salmonella* Enteritidis (SE) prevention measures.

You must have SE prevention measures that are specific for each farm where you produce eggs and that include, at a minimum, the following:

(a) *Chicks and pullets.* You must procure chicks and pullets that came as chicks from SE-monitored breeder flocks that meet the National Poultry Improvement Plan's standards for "U.S. S. Enteritidis Monitored" status (9 CFR 145.23(d)) or equivalent standards.

(b) *Biosecurity.* You must develop and implement a biosecurity program. The biosecurity program must include the grounds and all facilities at each farm. As part of this program you must:

(1) Limit visitors on the farm and in the poultry houses;

(2) Ensure that equipment that is moved among poultry houses is kept clean and is not a source of SE contamination;

(3) Ensure the proper hygiene of persons that move between poultry houses through use of protective clothing and sanitizing stations, or other appropriate means that will protect against cross contamination;

(4) Prevent stray poultry, wild birds, and other animals from entering grounds and facilities; and

(5) Not allow employees to keep poultry at home.

(c) *Rodents, flies, and other pest control.* You must develop and implement a pest and rodent control program to reduce the rodent, fly and other pest populations in your poultry house(s). As part of this program, you must:

(1) Monitor for rodents by visual inspection and mechanical traps or glueboards or another appropriate monitoring method and, when monitoring indicates unacceptable rodent activity within a poultry house, use appropriate methods to achieve satisfactory rodent control;

(2) Monitor for pests by spot cards, Scudder grills, or sticky traps or another appropriate monitoring method and, when monitoring indicates unacceptable pest activity within a poultry house, use appropriate methods to achieve satisfactory pest control.

(3) Remove debris within a poultry house and vegetation and debris outside a poultry house that may provide harborage for pests.

(d) *Cleaning and disinfection.* You must develop procedures for cleaning and disinfecting a poultry house as outlined in paragraphs (d)(1) through (d)(4) of this section. You must clean and disinfect the poultry house according to these procedures before new laying hens are added to the house, if you have had an environmental test or an egg test that was positive for SE at any point during the life of a flock that was housed in the poultry house prior to depopulation. As part of the cleaning and disinfection procedures, you must:

(1) Remove all visible manure;

(2) Dry clean the positive poultry house to remove dust, feathers, and old feed;

(3) Wet clean the positive poultry house, including washing with detergents. Use detergents according to label instructions, followed by recommended rinsing procedures; and

(4) Following cleaning, disinfect the positive poultry house with spray, aerosol, fumigation, or another appropriate disinfection method.

(e) *Refrigeration.* You must store eggs at or below 45 °F ambient temperature if you hold them for more than 36 hours after laying.

§ 118.5 Environmental testing for *Salmonella* Enteritidis (SE).

(a) *Environmental testing when laying hens are 40 to 45 weeks of age.* As one indicator of the effectiveness of your SE prevention measures, you must perform environmental testing for SE (as described in §§ 118.7 and 118.8) in a poultry house when any group of laying hens constituting the flock within the poultry house is 40 to 45 weeks of age.

(1) If an environmental test at 40 to 45 weeks is negative and your laying hens do not undergo induced molting, then you do not need to perform any additional environmental testing within that poultry house, unless the poultry house contains more than one group of laying hens. If the poultry house contains more than one group of laying hens, then you must perform environmental testing on the poultry house when each group of laying hens is 40 to 45 weeks of age.

(2) If the environmental test at 40 to 45 weeks is positive, then you must:

(i) Review and make any necessary adjustments to your SE prevention measures to ensure that all measures are being properly implemented and

(ii) Begin egg testing (described in § 118.6) within 24 hours of receiving notification of the positive environmental test, unless you divert eggs to treatment as defined in § 118.3 for the life of the flock in that poultry house.

(b) *Environmental testing after an induced molting period.* If you induce a molt in a flock or a group in a flock, you must perform environmental testing for SE in the poultry house approximately 20 weeks after the end of any molting process.

(1) If an environmental test approximately 20 weeks after the end of the molting process is negative and none of your laying hens in that poultry house is molted again, then you do not need to perform any additional environmental testing in that poultry house. Each time a flock or group within the flock is molted, you must perform environmental testing in the poultry house approximately 20 weeks after the end of the molting process.

(2) If the environmental test approximately 20 weeks after the end of a molting process is positive, then you must:

(i) Review and make any necessary adjustments to your SE prevention measures to ensure that all measures are being properly implemented; and

(ii) Begin egg testing (described in § 118.6) within 24 hours of receiving notification of the positive environmental test, unless you divert eggs to treatment as defined in § 118.3 for the life of the flock in that poultry house.

§ 118.6 Egg testing for *Salmonella* Enteritidis (SE).

(a) If you have an SE-positive environmental test at any time during the life of a flock, you must divert eggs to treatment (defined in § 118.3) for the life of the flock in that positive poultry house or conduct egg testing as specified in paragraphs (b) through (e) of this section.

(b) Eggs must be sampled as described in § 118.7 and tested using methodology as described in § 118.8.

(c) You must conduct four egg tests, using sampling and methodology in §§ 118.7 and 118.8, on the flock in the positive poultry house at 2-week intervals. If all four tests are negative for SE, you are not required to do further egg testing.

(d) If any of the four egg tests is positive for SE, you must divert, upon receiving notification of an SE-positive egg test, all eggs from that flock to treatment (defined in § 118.3) until the conditions of paragraph (c) of this section are met.

(e) If you have a positive egg test in a flock and divert eggs from that flock and later meet the negative test result requirements described in paragraph (c) of this section and return to table egg production, you must conduct one egg test per month on that flock, using sampling and methodology in §§ 118.7 and 118.8, for the life of the flock.

(1) If all the monthly egg tests in paragraph (e) of this section are negative for SE, you may continue to supply eggs to the table market.

(2) If any of the monthly egg tests in paragraph (e) of this section is positive for SE, you must divert eggs from the positive flock to treatment for the life of the flock or until the conditions of paragraph (c) of this section are met.

§ 118.7 Sampling methodology for *Salmonella* Enteritidis (SE).

(a) *Environmental sampling.* An environmental test must be done for each poultry house in accordance with § 118.5(a) and (b). Within each poultry house, you must sample the environment using a scientifically valid sampling procedure.

(b) *Egg sampling.* When you conduct an egg test required under § 118.6, you must randomly collect and test the following number of eggs from the positive poultry house.

(1) To meet the egg testing requirements of § 118.6(c), you must randomly collect 1,000 eggs from a day's production. The 1,000-egg sample must be tested according to § 118.8. You must randomly collect and test four 1,000-egg samples at 2-week intervals for a total of 4,000 eggs.

(2) To meet the monthly egg testing requirement of § 118.6(e), you must randomly collect 1,000 eggs from a day's production per month for the life of the flock. Eggs must be tested according to § 118.8.

§ 118.8 Testing methodology for *Salmonella* Enteritidis (SE).

(a) *Testing of environmental samples for SE.* Testing to detect SE in environmental samples must be conducted by the method entitled "Detection of *Salmonella* in Environmental Samples from Poultry Houses" dated January 19, 2001, (proposed for inclusion in FDA's Bacteriological Analytical Manual) or another method that is at least equivalent to the method cited previously in accuracy, precision, and sensitivity in detecting SE. The Director of the **Federal Register** approves the incorporation by reference "Detection of *Salmonella* in Environmental Samples from Poultry Houses" in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from Division of Dairy and Egg Safety (HFS–306), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Parkway, College Park, MD 20740, or you may examine a copy at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Parkway, College Park, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulation/ibr_locations.html.*

(b) *Testing of egg samples for SE.* Testing to detect SE in egg samples must be conducted according to the pre-enrichment method described by Valentin et al., in the *Journal of Food Protection*, or another method that is at least equivalent to the method cited previously in accuracy, precision, and sensitivity in detecting SE. The egg sampling method is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from Division of Dairy and Egg Safety (HFS–306), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Parkway, College Park, MD 20740, or you may examine a copy at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Parkway, College Park, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulation/ibr_locations.html.*

§ 118.9. Administration of the *Salmonella* Enteritidis (SE) prevention measures.

You must have one individual at each farm who is responsible for administration of the SE prevention measures. This individual must have successfully completed training on SE prevention measures for egg production that is at least equivalent to that received under a standardized curriculum recognized by the Food and Drug Administration or must be otherwise qualified through job experience to administer the SE prevention measures. Job experience

will qualify an individual to perform these functions if it has provided knowledge at least equivalent to that provided through the standardized curriculum. This individual is responsible for:

(a) Development and implementation of SE prevention measures that are appropriate for your specific farm and meet the requirements of § 118.4;

(b) Reassessing and modifying the SE prevention measures as necessary to ensure that the requirements in § 118.4 are met; and

(c) Review of records created under § 118.10. The individual does not need to have performed the monitoring or created the records.

§ 118.10 Recordkeeping requirements for the *Salmonella* Enteritidis (SE) prevention measures.

(a) *Records that egg producers are required to maintain.* You must maintain the following records:

(1) Records of environmental and egg sampling performed under § 118.7 and the results of SE testing performed under § 118.8 as required in §§ 118.5 and 118.6.

(2) Records indicating compliance with the diversion requirements in § 118.6.

(3) Records indicating that all of the eggs at a particular farm will be given a treatment as defined in § 118.3, if you are a producer complying with the requirements of this section as described in § 118.1(b).

(b) *General requirements for records maintained by egg producers.* All records required by § 118.10(a) must include:

(1) Your name and the location of your farm,

(2) The date and time of the activity that the record reflects,

(3) The signature or initials of the person performing the operation or creating the record, and

(4) Data and information reflecting compliance activities must be entered on records at the time the activity is performed or observed, and the records must contain the actual values observed, if applicable.

(c) *Length of time records must be retained.* You must retain all records required by this part at your place of business, unless stored offsite under § 118.10(d), for 1 year after the flock to which they pertain has been taken permanently out of production.

(d) *Offsite storage of records.* You may store the records required by this part offsite after 6 months following the date that the monitoring occurred. You must be able to retrieve and provide the records at your place of business within 24 hours of request for official review. Electronic records are considered to be onsite if they are accessible from an onsite location.

(e) *Official review of records.* You must have all records required by this part available for official review and copying at reasonable times.

(f) *Public disclosure of records.* Records required by this part are subject to the disclosure requirements under part 20 of this chapter.

§ 118.12 Enforcement and compliance.

(a) *Authority.* This part is established under authority of the Public Health Service Act (the PHS Act). Under the FFDCA, the Food and Drug Administration (FDA) can enforce the food adulteration provisions under 21 U.S.C. 331 through 334 and 342. Under the PHS Act (42 U.S.C. 264), FDA has the authority to make and enforce regulations for the control of communicable diseases. FDA has established the following administrative enforcement procedures for the diversion or destruction of shell eggs and for informal hearings under the PHS Act:

(1) Upon a finding that any shell eggs have been produced or held in violation of this part, an authorized FDA representative or a State or local representative in accordance with paragraph (c) of this section may order such eggs to be diverted, under the supervision of said representative, for processing in accordance with the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031 *et seq.*) or by a treatment that achieves at least a 5-log destruction of SE or destroyed by or under the supervision of an officer or employee of FDA, or, if applicable, of the State or locality in accordance with the following procedures:

(i) *Order for diversion or destruction under the PHS Act.* Any district office of FDA or any State or locality acting under paragraph (c) of this section, upon finding shell eggs that have been produced or held in violation of this regulation, may serve a written order upon the person in whose possession the eggs are found requiring that the eggs be diverted, under the supervision of an officer or employee of the issuing entity, for processing in accordance with the EPIA (21 U.S.C. 1031 *et seq.*) or by a treatment that achieves at least a 5-log destruction of SE or destroyed by or under the supervision of the issuing entity, within 10-working days from the date of receipt of the order, unless, under paragraph (a)(2)(iii) of this section, a hearing is held, in which case the eggs must be diverted or destroyed consistent with the decision of the Regional Food and Drug Director under paragraph (a)(2)(v) of this section. The order must include the following information:

(A) A statement that the shell eggs identified in the order are subject to diversion for processing in accordance with the EPIA or by a treatment that achieves at least a 5-log destruction of SE or destruction;

(B) A detailed description of the facts that justify the issuance of the order;

(C) The location of the eggs;

(D) A statement that these eggs must not be sold, distributed, or otherwise disposed of or moved except as provided in paragraph (a)(1)(iv) of this section;

(E) Identification or description of the eggs;

(F) The order number;

(G) The date of the order;

(H) The text of this entire section;

(I) A statement that the order may be appealed by written appeal or by requesting an informal hearing;

(J) The name and phone number of the person issuing the order; and

(K) The location and telephone number of the office or agency issuing the order and the name of its Director.

(ii) *Approval of District Director.* An order, before issuance, must be approved by FDA's District Director or the Acting District Director. If prior written approval is not feasible, prior oral approval must be obtained and confirmed by written memorandum as soon as possible.

(iii) *Labeling or marking of shell eggs under order.* An FDA, State, or local representative issuing an order under paragraph (a)(1)(i) of this section must label or mark the shell eggs with official tags that include the following information:

(A) A statement that the shell eggs are detained in accordance with regulations issued under section 361(a) of the PHS Act (42 U.S.C. 264(a)).

(B) A statement that the shell eggs must not be sold, distributed or otherwise disposed of or moved except, after notifying the issuing entity in writing, to:

(*1*) Divert them for processing in accordance with the EPIA or by a treatment that achieves at least a 5-log destruction of SE or destroy them, or

(*2*) Move them to an another location for holding pending appeal.

(C) A statement that the violation of the order or the removal or alteration of the tag is punishable by fine or imprisonment or both (section 368 of the PHS Act (42 U.S.C. 271)).

(D) The order number and the date of the order, and the name of the government representative who issued the order.

(iv) *Sale or other disposition of shell eggs under order.* After service of the order, the person in possession of the shell eggs that are the subject of the order must not sell, distribute, or otherwise dispose of or move any eggs subject to the order unless and until receiving a notice that the order is withdrawn after an appeal except, after notifying FDA's district office or, if applicable, the State or local representative, in writing, to:

(A) Divert or destroy them as specified in paragraph (a)(1)(i) of this section, or

(B) Move them to another location for holding pending appeal.

(2) The person on whom the order for diversion or destruction is served may either comply with the order or appeal the order to the Regional Food and Drug Director in accordance with the following procedures:

(i) *Appeal of a detention order.* Any appeal must be submitted in writing to FDA's District Director in whose district the shell eggs are located within 5 working days of the issuance of the order. If the appeal includes a request for an informal hearing, the hearing must be held within 5 working days after the appeal is filed or, if requested by the appellant, at a later date, which must not be later than 20 calendar days after the issuance of the order. The order may also be appealed within the same period of 5 working days by any other person having an ownership or proprietary interest in such shell eggs. The appellant of an order must state the ownership or proprietary interest the appellant has in the shell eggs.

(ii) *Summary decision.* A request for a hearing may be denied, in whole or in part and at any time after a request for a hearing has been submitted, if the Regional Food and Drug Director or his or her designee determines that no genuine and substantial issue of fact has been raised by the material submitted in connection with the hearing or from matters officially noticed. If the Regional Food and Drug Director determines that a hearing is not justified, written notice of the determination will be given to the parties explaining the reason for denial.

(iii) *Informal hearing.* Appearance by any appellant at the hearing may be by mail or in person, with or without counsel. The informal hearing must be conducted by the Regional Food and Drug Director or his designee, and a written summary of the proceedings must be prepared by the Regional Food and Drug Director.

(A) The Regional Food and Drug Director may direct that the hearing be conducted in any suitable manner permitted by law and by this section. The Regional Food and Drug Director has the power to take such actions and make such rulings as are necessary or appropriate to maintain order and to conduct an informal, fair, expeditious, and impartial hearing, and to enforce the requirements concerning the conduct of hearings.

(B) Employees of FDA will first give a full and complete statement of the action that is the subject of the hearing, together with the information and reasons supporting it, and may present oral or written information relevant to the hearing. The party requesting the hearing may then present oral or written information relevant to the hearing. All parties may conduct reasonable examination of any person (except for the presiding officer and counsel for the parties) who makes any statement on the matter at the hearing.

(C) The hearing shall be informal in nature, and the rules of evidence do not apply. No motions or objections relating to the admissibility of information and views will be made or considered, but any party may comment upon or rebut any information and views presented by another party.

(D) The party requesting the hearing may have the hearing transcribed, at the party's expense, in which case a copy of the transcript is to be furnished to FDA. Any transcript of the hearing will be included with the Regional Food and Drug Director's report of the hearing.

(E) The Regional Food and Drug Director must prepare a written report of the hearing. All written material presented at the hearing will be attached to the report. Whenever time permits, the Regional Food and Drug Director may give the parties the opportunity to review and comment on the report of the hearing.

(F) The Regional Food and Drug Director must include as part of the report of the hearing a finding on the credibility of witnesses (other than expert witnesses) whenever credibility is a material issue, and must include a recommended decision, with a statement of reasons.

(iv) *Written appeal.* If the appellant appeals the detention order but does not request a hearing, the Regional Food and Drug Director must render a decision on the appeal affirming or revoking the detention order within 5 working days after the receipt of the appeal.

(v) *Regional Food and Drug Director decision.* If, based on the evidence presented at the hearing or by the appellant in a written appeal, the Regional Food and Drug Director finds that the shell eggs were produced or held in violation of this section, he must affirm the order that they be diverted, under the supervision of an officer or employee of FDA for processing under the EPIA or by a treatment that achieves at least a 5-log destruction of SE or destroyed by or under the supervision of an officer or employee of FDA; otherwise, the Regional Food and Drug Director must issue a written notice that the prior order is withdrawn. If the Regional Food and Drug Director affirms the order, he must order that the diversion or destruction be accomplished within 10-working days from the date of the issuance of his decision. The Regional Food and Drug Director's decision must be accompanied by a statement of the reasons for the decision. The decision of the Regional Food and Drug Director constitutes final agency action, subject to judicial review.

(vi) *No appeal.* If there is no appeal of the order and the person in possession of the shell eggs that are subject to the order fails to divert or destroy them within 10-working days, or if the demand is affirmed by the Regional Food and Drug Director after an appeal and the person in possession of such eggs fails to divert or destroy them within 10-working days, FDA's district office or, if applicable, the State or local representative may designate an officer or employee to divert or destroy such eggs. It shall be unlawful to prevent or to attempt to prevent such diversion or destruction of the shell eggs by the designated officer or employee.

(b) *Inspection.* Persons engaged in production of shell eggs must permit authorized representatives of FDA to make, at any reasonable time, an inspection of the egg production establishment in which shell eggs are being produced. Such inspection includes the inspection and sampling of shell eggs and the environment, the equipment related to production of shell eggs, the equipment in which shell eggs are held, and examination and copying of any records relating to such equipment or eggs, as may be necessary in the judgment of such representatives to determine compliance with the provisions of this section. Inspections may be made with or without notice and will ordinarily be made during regular business hours.

(c) *State and local cooperation.* Under sections 311 and 361 of the Public Health Service Act, any State or locality that is willing and able to assist the agency in the enforcement of §§ 118.4 through 118.10, and is authorized to inspect or regulate egg production establishments, may, in its own jurisdiction, enforce §§ 118.4 through

118.10 through inspections under paragraph (b) of this section and through administrative enforcement remedies specified in paragraph (a) of this section unless FDA notifies the State or locality in writing that such assistance is no longer needed. When providing assistance under paragraph (a) of this section, a State or locality may follow the hearing procedures set out in paragraphs (a)(2)(iii) through (a)(2)(v) of this section, substituting, where necessary, appropriate State or local officials for designated FDA officials or may utilize comparable State or local hearing procedures if such procedures satisfy due process.

Dated: September 15, 2004.

Lester M. Crawford,

Acting Commissioner of Food and Drugs.

Note: The following appendices will not appear in the Code of Federal Regulations.

Appendix A to the PRIA: Costs of Alternative Testing and Diversion Scenarios

The costs of testing and diversion depend on a number of factors, including the probabilities of SE-positive results for environmental and egg tests, the costs of testing and diversion, and whether the layers are molted. FDA assumes that there are five possible scenarios for non-molted layers and seventeen possible scenarios for molted layers.

Non-molted layers—all scenarios. The environmental testing costs are calculated to be the laboratory cost of environmental testing (C_{NT}) plus the labor cost of collecting one test (C_{NL}) times the number of tests to be collected (N_{NT}), or: $Cost_{NT} = (C_{NT} + C_{NL}) \times N_{NTS}$.

Scenario 1: 40 to 45 week environmental test negative.

- In the first scenario, the 40 to 45 week environmental test is negative. No other tests are taken.
- There are no egg testing or diversion costs in this scenario.
- The first scenario occurs with a probability $PS_1 = (1 - p_{N1})$, where p_{N1} is the probability that the 40 to 45 week environmental test is positive.

Scenario 2: 40 to 45 week environmental test positive. Egg testing negative.

- In scenario two, a positive 40 to 45 week environmental test triggers egg testing. All 4 of the required egg tests come up negative. No other tests are performed.
- This is the first scenario under which eggs will have to be tested. The cost of an egg test is the sum of the laboratory (C_{GT}), labor (C_{GL}), and lost revenue (C_{GG}) costs for a 20-egg test times the number of 20 egg batches to be tested (N_{GT}) times the number of test collections (4). If 1,000 eggs were tested, they would be tested in 50 20-egg tests. The total cost of egg testing is therefore: $Cost_{GT2} = (C_{GT} + C_{GL} + C_{GG}) \times N_{GT} \times 4$.
- There are no diversion costs in this scenario.
- The probability that this scenario will occur is equal to $PS_2 = p_{N1} \times (1 - p_{G1})$, where p_{G1} is the probability that the first egg test is positive.

Scenario 3: 40 to 45 week environmental and first egg test positive. Subsequent egg test negative.

- In this scenario, a positive 40 to 45 week environmental test triggers egg testing. One of the 4 required egg tests is positive, and the farmer must divert. The next 4 egg tests are negative, diversion is stopped, and eggs are tested monthly for the life of the flock without any additional positive results.
- In this case, there will be two sets of egg tests. In addition, the farm will be expected to test monthly for the remaining life of the flock (LF - 1).[1] The total cost of egg testing is therefore: $Cost_{GT3} = (C_{GT} + C_{GL} + C_{GG}) \times N_{GT} \times (8 + LF_3 - 1)$.
- The cost of diversion is the price differential between a table egg and an SE-positive egg (DC) times the number of days diverted times the number of eggs produced per day by a typical bird (0.72) times the number of layers in a typical layer house (HS). We expect that a set of four 1,000-egg tests will occur over a total of 8 weeks including laboratory time. Therefore, the total number of days diverted is equal to 56. This figure assumes that only one egg positive will be found and that diversion will end after eight weeks of testing. The total cost of diversion is: $Cost_{D3} = DC \times 56 \times 0.72 \times HS$.
- The probability that this scenario will occur is equal to $PS_3 = p_{N1} \times p_{G1} \times (1 - p_{G2})$, where p_{G2} is the probability that the second egg test is positive.

Scenario 4: 40 to 45 week environmental and first two egg tests positive. Eventually test off diversion.

- In this scenario, a positive 40 to 45 week environmental test triggers egg testing. One of the first 4 1,000-egg tests comes up positive, and the farmer must divert. After the positive egg test, one of the next 4 egg tests is also positive, and the farmer continues to divert. However, the farmer eventually tests off diversion, and eggs are tested monthly for the life of the flock.
- The cost of egg testing in this scenario builds on the cost of egg testing in scenario 3. In this case the cost is equivalent to that of the last case with the exception that testing continues to occur halfway to the end of lay. Mathematically, this is written as: $Cost_{GT4} = (C_{GT} + C_{GL} + C_{GG}) \times [(8 \times N_{GT}) + 2.17 \times (LF_4 - 1) \times N_{GT5} \div 2 + (LF_4 - 1) \times N_{GT} \div 2]$.
- The cost of diversion equals the cost of diversion in scenario 3 (DC x 56 x 0.72 x HS) plus the cost of diversion for half of the remaining lay period DC x [30 x (LF_4 - 1) ÷ 2] x 0.72 x HS. After like terms are grouped, the total cost under this scenario can be written as: $Cost_{D4} = (DC \times 0.72 \times HS) \times (56 + 30 \times (LF_4 - 1) \div 2)$.
- The probability that this scenario will occur is equal to $PS_4 = p_{N1} \times p_{G1} \times p_{G2} \times (1 - p_{G3})$, where p_{G3} is the probability that the farm never tests out of diversion.

Scenario 5: 40 to 45 week environmental and first two egg tests positive. Farm stays on diversion for the life of the flock.

- In this scenario, a positive 40 to 45 week test triggers egg testing. One of the first 4 egg tests comes up positive, and the farmer must divert. One of the 4 subsequent 1,000-egg tests also comes up positive and the farmer continues to divert. Subsequent tests continue to be positive, and the farmer diverts for the life of the flock.
- The cost of egg testing is equivalent to the cost of testing every two weeks for the life of the flock following the first egg positive, or $Cost_{GT5} = 2 \times (C_{GT} + C_{GL} + C_{GG}) \times [(8 \times N_{GT}) + 2.17 \times (LF_5 - 1) \times N_{GT}$.
- The farm is forced to divert eggs for the life of the flock following the first egg positive, or $Cost_D = (DC \times 0.72 \times HS) \times (56 + 30 \times (LF_5 - 1))$.
- The probability that this scenario will occur is equal to $PS_5 = p_{N1} \times p_{G1} \times p_{G2} \times p_{G3}$.

a. Molted layers. The introduction of molted flocks complicates the analysis of testing costs by introducing new protocols for end of cycle testing. Molting increases the original 6 scenarios to 22. Also, molted flocks have a much longer life expectancy than do non-molted flocks. Any problems resulting from analyzing flocks with different life spans is dealt with in the latter part of this appendix where the costs are annualized. The method used to estimate the cost of testing and diversion for molted flocks is outlined below.

b. All scenarios. Under all scenarios with molted layers, the producer will have to conduct two sets of environmental tests. The costs of

[1] The remaining test life of the flock is LF -1 (LF is the remaining number of months) because the last month of lay generally produces substandard eggs that are sent to the breaker regardless of SE status. Thus, this last month is omitted from our calculations.

environmental testing are: $Cost_{NT} = 2 \times (C_{NT} + C_{NL}) \times N_{NTS}$.

Scenario 1a: 40 to 45 week environmental test negative. Post-molt environmental test negative.

• In the first scenario for molted layers, both the 40 to 45 week and the post-molt environmental tests are negative. No further action is required.

• There are no egg testing or diversion costs in this scenario.

• The first scenario occurs with a probability $PS_{1a} = (1 - p_{N1}) \times (1 - p_{N3A})$, where p_{N1} is the probability that the 40 to 45 week environmental test is positive and p_{N3A} is the probability that the post-molt environmental test is positive.

Scenario 1b: 40 to 45 week environmental test negative. Post-molt environmental test positive. Egg test negative.

• In this scenario, the 40 to 45 week environmental test is negative. However, a positive post-molt test triggers egg testing. Further testing is avoided because all 4 egg tests are negative.

• As with non-molted flocks, the cost of an egg test is the sum of the laboratory (C_{GT}), labor (C_{GL}), and lost revenue (C_{GG}) costs for a 20-egg test times the number of 20-egg batches to be tested (N_{GT}) times the number of test collections (4). The total cost of egg testing is therefore: $Cost_{GT1b} = (C_{GT} + C_{GL} + C_{GG}) \times N_{GT} \times 4$.

• There are no diversion costs in this scenario.

• This scenario occurs with a probability $PS_{1b} = (1 - p_{N1}) \times p_{N3A} \times (1 - p_{G1A})$, where p_{G1A} is the probability that the first set of egg tests, if taken, will be positive.

Scenario 1c: 40 to 45 week environmental test negative. Post-molt environmental test positive. First egg test positive. Second egg test negative.

• In this scenario, the 40 to 45 week environmental test is negative. However, a positive post-molt environmental test triggers egg testing. One of the first 4 post-molt eggs tests is positive, triggering diversion. The 4 post-molt tests are negative and diversion is stopped. Eggs are tested monthly for the life of the flock without any additional positive test results.

• In this case, there will be two sets of egg tests. In addition, the farm will be expected to test monthly for the remaining life of the flock ($LF_{1c} - 1$). The total cost of egg testing is therefore: $Cost_{GT1c} = (C_{GT} + C_{GL} + C_{GG}) \times N_{GT} \times (8 + LF_{1c} - 1)$.

• The cost of diversion is the price differential between a table egg and an SE-positive egg (DC) times the number of days diverted times the number of eggs produced per day by a typical bird (0.72) times the number of layers in a typical poultry house (HS). We expect that a set of four 1,000-egg tests will occur over a total of 8 weeks including laboratory time. Therefore, the total number of days diverted is equal to 56. The total cost of diversion is: $Cost_{D1c} = DC \times 56 \times 0.72 \times HS$.

• This scenario occurs with a probability $PS_{1c} = (1 - p_{N1}) \times p_{N3A} \times p_{G1A} \times (1 - p_{G2A})$, where p_{G2A} is the probability that a second set of egg tests, if taken, will be positive.

Scenario 1d: 40 to 45 week environmental test negative. Post-molt environmental test positive. First two egg tests positive. Farm eventually tests out of diversion.

• In this scenario, the 40 to 45 week environmental test is negative. However, a positive post-molt environmental test triggers egg testing. One of the first 4 egg tests comes up positive, and the farmer must divert. One of the second four egg tests also comes up positive, and the farmer continues to divert. Eventually, however, the farm is able to test off diversion and diversion is stopped. Eggs are tested monthly for the life of the flock without any additional positive test results.

• In this case, there will be eight egg tests (occurring in 2 week intervals), tests every 2 weeks for half of the remaining life of the flock, and monthly tests for the remaining half of the life of the flock. The total cost of egg testing is therefore: $Cost_{GT1d} = (C_{GT} + C_{GL} + C_{GG}) \times N_{GT} \times [8 + 2.17 \times (LF_{1d} - 1) \div 2 + (LF_{1d} - 1) \div 2]$.

• In this case, diversion costs will be borne by the producer for the 8 weeks of the second set of egg tests plus half of the remaining lay period. The total cost of diversion is: $Cost_{D1d} = DC \times 0.72 \times HS \times [56 + 30 \times (LF_{1d} - 1) \div 2]$.

• This scenario occurs with a probability $PS_{1d} = (1 - p_{N1}) \times p_{N3A} \times p_{G1A} \times p_{G2A} \times (1 - p_{G3A})$, where p_{G3A} is the probability that a farm with two positive sets of egg tests will not be able to test off of diversion.

Scenario 1e: 40 to 45 week environmental test negative. Post-molt environmental test positive. First two egg tests positive. Farm diverts to depopulation.

• In this scenario, the 40 to 45 week environmental test is negative. However, a positive post-molt environmental test triggers egg testing. One of the first four egg tests is positive, and the farmer must divert. One of the second four egg tests also comes up positive, and the farmer continues to divert. The farm is never able to test off diversion.

• The cost of egg testing is equivalent to the cost of testing every two weeks for the life of the flock following the first egg positive, or $Cost_{GT1e} = (C_{GT} + C_{GL} + C_{GG}) \times N_{GT} \times [8 + 2.17 \times (LF_{1e} - 1)]$.

• In this case, diversion costs will be borne by the producer for the 8 weeks of the second set of egg tests plus all of the remaining lay period. The total cost of diversion is: $Cost_{D1e} = DC \times 0.72 \times HS \times [56 + 30 \times (LF_{1e} - 1)]$.

• This scenario occurs with a probability $PS_{1e} = (1 - p_{N1}) \times p_{N3A} \times p_{G1A} \times p_{G2A} \times p_{G3A}$.

Scenario 2a: 40 to 45 week environmental test positive. Pre-molt egg test negative. Post-molt environmental test is negative.

• The 40 to 45 week environmental test is positive. The 4 egg tests are negative. No action is taken until the post-molt environmental test, which is negative. Further testing is avoided.

• The 4 egg tests are done pre-molt at a cost of: $Cost_{GT} = (C_{GT} + C_{GL} + C_{GG}) \times N_{GT} \times 4$.

• There are no diversion costs in this scenario.

• This scenario occurs with probability $PS_{2a} = p_{N1} \times p_{N2} \times (1 - p_{G1E}) \times (1 - p_{N3C})$, where p_{G1E} is the probability that a pre-molt egg test will be positive and p_{N3C} is the probability that the end of cycle environmental test will be positive.

Scenario 2b: 40 to 45 week environmental test positive. Pre-molt egg test negative. Post-molt environmental test positive. Egg test negative.

• The 40 to 45 week environmental test is positive. The four egg tests are negative. No action is taken until the post-molt environmental test, which is positive. All four post-molt egg tests are negative.

• In this case two sets of 4 1,000-egg tests are required. The cost of this testing is: $Cost_{GT} = (C_{GT} + C_{GL} + C_{GG}) \times N_{GT} \times 8$.

• There are no diversion costs in this scenario.

• This scenario occurs with a probability $PS_{2b} = p_{N1} \times p_{N2} \times (1 - p_{G1E}) \times p_{N3C} \times (1 - p_{G1c})$, where p_{G1C} is the probability that the first set of post-molt egg tests will be positive.

Scenario 2c: 40 to 45 week environmental test positive. Pre-molt egg test negative. Post-molt environmental test positive. First egg test positive. Second egg test negative.

• The 40 to 45 week environmental test is positive. All four required egg tests are negative. No action is taken. The post-molt environmental test is positive, triggering egg testing. One of the four egg tests is positive, triggering diversion. All four of the second tests

are negative, and diversion is stopped. Eggs are tested monthly for the remaining life of the flock.

• In this case, there will be three sets of egg tests. In addition, the farm will be expected to test monthly for the remaining life of the flock (LF_{2c} - 1). The total cost of egg testing is therefore: $Cost_{GT} = (C_{GT} + C_{GL} + C_{GG}) \times N_{GT} \times (12 + LF_{2c} - 1)$.

• The cost of diversion is the price differential between a table egg and a SE positive egg (DC) times the number of days diverted times the number of eggs produced per day by a typical bird (0.72) times the number of layers in a typical layer house (HS). We expect that a set of four 1,000-egg tests will occur over a total of 8 weeks, including laboratory time. Therefore, the total number of days diverted is equal to 56. The total cost of diversion is: $Cost_D = DC \times 56 \times 0.72 \times HS$.

• This scenario occurs with a probability $PS_{2c} = p_{N1} \times p_{N2} \times (1 - p_{G1E}) \times p_{N3C} \times p_{G1c} \times (1 - p_{G2C})$, where p_{G2C} is the probability that a second set of egg tests, if taken, will be positive.

Scenario 2d: 40 to 45 week environmental test positive. Pre-molt egg test negative. Post-molt environmental test positive. The first two egg tests positive. Farm eventually tests out of diversion.

• The 40 to 45 week environmental test is positive. All four pre-molt egg tests are negative. No action is taken. The post-molt environmental test is positive, triggering egg testing. One of the first four post-molt egg tests comes up positive, and the farmer must divert. One of the second four post-molt egg tests also comes up positive, and the farmer continues to divert. The farm is eventually able to test off of diversion. Eggs are tested monthly for the remaining life of the flock.

• In this case, there will be 12 egg tests (occurring in 2 week intervals), tests every 2 weeks for half of the remaining life of the flock, and monthly tests for the remainder of the life of the flock. The total cost of egg testing is therefore: $Cost_{GT} = (C_{GT} + C_{GL} + C_{GG}) \times N_{GT} \times [12 + 2.17 \times (LF_{2d} - 1) \div 2 + (LF_{2d} - 1) \div 2]$.

• In this case, diversion costs will be borne by the producer for the 8 weeks of the second set of egg tests plus half of the remaining lay period. The total cost of diversion is: $Cost_D = DC \times 0.72 \times HS \times [56 + 30 \times (LF_{2d} - 1) \div 2]$.

• This scenario occurs with a probability $PS_{2d} = p_{N1} \times p_{N2} \times (1 - p_{G1E}) \times p_{N3C} \times p_{G1c} \times p_{G2C} \times (1 - p_{G3C})$, where p_{G3C} is the probability that a farm with two positive sets of egg tests will not be able to test off of diversion.

Scenario 2e: 40 to 45 week environmental test positive. Pre-molt egg test negative. Post-molt environmental test positive. First two egg tests positive. Farm diverts until depopulation.

• The 40 to 45 week environmental test is positive. All four pre-molt egg tests are negative. No action is taken. The post-molt environmental test is positive, triggering egg testing. One of the first four post-molt egg tests comes up positive, and the farmer must divert. One of the second 4 post-molt egg tests also comes up positive, and the farmer continues to divert. The farm is never able to test out of diversion.

• The cost of egg testing is equivalent to the cost of testing every 2 weeks for the life of the flock following the first egg positive, or $Cost_{GT} = (C_{GT} + C_{GL} + C_{GG}) \times N_{GT} \times [12 + 2.17 \times (LF_{2e} - 1)]$.

• In this case, diversion costs will be borne by the producer for the 8 weeks of the second set of egg tests plus all of the remaining lay period. The total cost of diversion is: $Cost_D = DC \times 0.72 \times HS \times [56 + 30 \times (LF_{2e} - 1)]$.

• This scenario occurs with a probability $PS_{2e} = p_{N1} \times p_{N2} \times (1 - p_{G1E}) \times p_{N3C} \times p_{G1c} \times p_{G2C} \times p_{G3C}$.

Scenario 3a: 40 to 45 week environmental test positive. First pre-molt egg test positive. Second pre-molt egg test negative. Post-molt environmental test is negative.

• The 40 to 45 week environmental test is positive. On of the first four pre-molt egg tests is positive, triggering diversion. All four of the second pre-molt tests are negative, ending diversion. No further action is taken until the post-molt environmental test, which is negative. Further testing is avoided.

• Two sets of egg tests are carried out pre-molt. Also, monthly egg tests must be taken for the life of the flock. The cost of egg testing is: $Cost_{GT} = (C_{GT} + C_{GL} + C_{GG}) \times N_{GT} \times (8 + LF_{3a} - 1)$.

• Eggs are diverted between the first and second egg tests. We expect that a set of 4 1,000-egg tests will occur over a total of 8 weeks, including laboratory time. Therefore, the total number of days diverted is equal to 56. The total cost of diversion is: $Cost_D = DC \times 56 \times 0.72 \times HS$.

• This scenario occurs with probability $PS_{3a} = p_{N1} \times p_{N2} \times p_{G1E} \times (1 - p_{G2E}) \times (1 - p_{N4D})$, where p_{G2E} is the probability that the second set of pre-molt egg tests will be positive and p_{N3D} is the probability that the end of cycle environmental test will be positive.

Scenario 3b: 40 to 45 week environmental test positive. First pre-molt egg test positive. Second pre-molt egg test negative. Post-molt environmental test positive. Egg test negative.

• The 40 to 45 week environmental test is positive. One of the first four pre-molt egg tests is positive, triggering diversion. All four of the second pre-molt egg tests are negative, ending diversion. No action is taken until the post-molt environmental test, which is positive. The first four post-molt egg tests are negative.

• In this case, three sets of egg tests are required. Furthermore, monthly egg testing is required for the life of the flock. The cost of this testing is: $Cost_{GT} = (C_{GT} + C_{GL} + C_{GG}) \times N_{GT} \times (12 + LF_{3b} - 1)$.

• Eggs are diverted between the first and second egg tests. We expect that a set of four 1,000-egg tests will occur over a total of 8 weeks, including laboratory time. Therefore, the total number of days diverted is equal to 56. The total cost of diversion is: $Cost_D = DC \times 56 \times 0.72 \times HS$.

• This scenario occurs with a probability $PS_{3b} = p_{N1} \times p_{N2} \times p_{G1E} \times (1 - p_{G2E}) \times p_{N4D} \times (1 - p_{G1D})$, where p_{G1D} is the probability that the first set of post-molt egg tests will be positive.

Scenario 3c: 40 to 45 week environmental test positive. First pre-molt egg test positive. Second pre-molt egg test negative. Post-molt environmental test positive. First egg test positive. Second egg test is negative.

• The 40 to 45 week environmental test is positive. One of the first four pre-molt egg tests is positive, triggering diversion. The second 4 pre-molt egg tests are negative, ending diversion. No action is taken until the post-molt environmental test, which is positive. One of the first four post-molt egg tests is positive, triggering diversion. The second four post-molt egg tests are negative and diversion is stopped. Eggs are tested monthly for the remaining life of the flock.

• In this case, there will be four sets of egg tests. In addition, the farm will be expected to test monthly for the remaining life of the flock (LF_{3c} - 1). The total cost of egg testing is therefore: $Cost_{GT} = (C_{GT} + C_{GL} + C_{GG}) \times N_{GT} \times (16 + LF_{3c} - 1)$.

• Twice in the life of this flock eggs have tested positive in one test and negative in the next. We expect that a set of four 1,000-egg tests will occur over a total of 8 weeks, including laboratory time. Therefore, the total number of days diverted is equal to 56. The total cost of diversion is: $Cost_D = DC \times 112 \times 0.72 \times HS$.

• This scenario occurs with a probability $PS_{3c} = p_{N1} \times p_{N2} \times p_{G1E} \times (1 - p_{G2E}) \times p_{N4D} \times p_{G1D} \times (1 - p_{G2D})$, where

p_{G2D} is the probability that a second set of egg tests, if taken, will be positive.

Scenario 3d: 40 to 45 week environmental test positive. First pre-molt egg test positive. Second pre-molt egg test negative. Post-molt environmental test positive. First two egg tests positive. Farm eventually tests out of diversion.

• The 40 to 45 week environmental test is positive. One of the first four pre-molt egg tests is positive, triggering diversion. The second four pre-molt egg tests are negative, ending diversion. No action is taken until the post-molt environmental test, which is positive. One of the first four post-molt egg tests comes up positive, and the farmer must divert. One of the second four post-molt egg tests also comes up positive, and the farmer continues to divert. The farm is eventually able to test off of diversion. Eggs are tested monthly for the remaining life of the flock.

• In this case, there will be eight egg tests (occurring in 2 week intervals), tests every 2 weeks for half of the remaining life of the flock, and monthly tests for the remainder of the life of the flock. The total cost of egg testing is therefore: $Cost_{GT} = (C_{GT} + C_{GL} + C_{GG}) \times N_{GT} \times [16 + 2.17 \times (LF_{3d} - 1) \div 2 + (LF_{3d} - 1) \div 2]$.

• In this case, diversion costs will be borne by the producer for the 8 weeks of the second set of egg tests plus half of the remaining lay period. The total cost of diversion is: $Cost_D = DC \times 0.72 \times HS \times [112 + 30 \times (LF_{3d} - 1) \div 2]$.

• This scenario occurs with a probability $PS_{3d} = p_{N1} \times p_{N2} \times p_{G1E} \times (1 - p_{G2E}) \times p_{N4D} \times p_{G1D} \times p_{G2D} \times (1 - p_{G3D})$, where p_{G3D} is the probability that a farm with two positive sets of egg tests will not be able to test off of diversion.

Scenario 3e: 40 to 45 week environmental test positive. First pre-molt egg test positive. Second pre-molt egg test negative. Post-molt environmental test positive. First two egg tests positive. Farm diverts until depopulation.

• The 40 to 45 week environmental test is positive. One of the first four eggs tests is positive, triggering diversion. and the second four pre-molt tests are negative, ending diversion. No action is taken until the post-molt environmental test, which is positive. One of the first four post-molt egg tests comes up positive, and the farmer must divert. One of the second four post-molt egg tests also comes up positive, and the farmer continues to divert. The farm is never able to test out of diversion.

• The cost of egg testing is equivalent to the cost of testing every 2 weeks for the life of the flock following the first egg positive, or $Cost_{GT} = (C_{GT} + C_{GL} + C_{GG}) \times N_{GT} \times [16 + 2.17 \times (LF_{3e} - 1)]$.

• In this case diversion costs will be borne by the producer for the 16 weeks following each second set of egg tests plus the remaining lay period. The total cost of diversion is: $Cost_D = DC \times 0.72 \times HS \times [112 + 30 \times (LF_{3e} - 1)]$.

• This scenario occurs with a probability $PS_{3e} = p_{N1} \times p_{N2} \times p_{G1E} \times (1 - p_{G2E}) \times p_{N4D} \times p_{G1D} \times p_{G2D} \times (1 - p_{G3D})$.

Scenario 4: 40 to 45 week environmental test positive. First pre-molt egg test positive. Second pre-molt egg test positive. Farm eventually tests out of diversion.

• The 40 to 45 week environmental test is positive. One of the first four pre-molt egg tests is positive, triggering diversion. One of the second four pre-molt egg tests is also positive. Because the farm is already under diversion at the time of molt no post-molt test is needed. However, the farm eventually tests out of diversion. Eggs are tested monthly for the remaining life of the flock.

• In this case there will be eight egg tests (occurring in 2 week intervals), tests every 2 weeks for half of the remaining life of the flock, and monthly tests for the remainder of the life of the flock. The total cost of egg testing is therefore: $Cost_{GT} = (C_{GT} + C_{GL} + C_{GG}) \times N_{GT} \times [8 + 2.17 \times (LF_4 - 1) \div 2 + (LF_4 - 1) \div 2]$.

• Diversion costs will be borne by the producer for the 8 weeks of the second set of egg tests plus half of the remaining lay period. The total cost of diversion is: $Cost_D = DC \times 0.72 \times HS \times [56 + 30 \times (LF_4 - 1) \div 2]$.

• This scenario occurs with a probability $PS_4 = p_{N1} \times p_{N2} \times p_{G1E} \times p_{G2E} \times (1 - p_{G3E})$, where p_{G3e} is the probability that a farm with two positive sets of egg tests will not be able to test off of diversion.

Scenario 5: 40 to 45 week environmental test positive. First pre-molt egg test positive. Second pre-molt egg test positive. Farm diverts until depopulation.

• The 40 to 45 week environmental test is positive. One of the first four pre-molt egg tests is positive, triggering diversion. One of the second four pre-molt egg tests is also positive. Because the farm is already under diversion at the time of molt, no post-molt test is needed. The farm is never able to test out of diversion.

• The cost of egg testing is equivalent to the cost of testing every two weeks for the life of the flock following the first egg positive, or $Cost_{GT} = (C_{GT} + C_{GL} + C_{GG}) \times N_{GT} \times [8 + 2.17 \times (LF_5 - 1)]$.

• In this case, diversion costs will be borne by the producer for the 16 weeks following each second set of egg tests plus the remaining lay period. The total cost of diversion is: $Cost_D = DC \times 0.72 \times HS \times [56 + 30 \times (LF_5 - 1)]$.

• This scenario occurs with a probability $PS_5 = p_{N1} \times p_{N2} \times p_{G1E} \times p_{G2E} \times p_{G3E}$.

Appendix B to the PRIA: The Expected Cost of Testing and Diversion

The expected cost of testing and diversion is found by summing over all scenarios the product of scenario cost and scenario probability. This can represented mathematically as follows:

Cost per house for non-molted layers:

Environmental testing costs for a given house $Env_S = \sum_{i=1}^{6}(Cost_{NTi} \times PS_i)$

Egg testing costs for a given house $Egg_S = \sum_{i=1}^{6}(Cost_{GTi} \times PS_i)$

Diversion Costs for a given house $Div_S = \sum_{i=1}^{6}(Cost_{Di} \times PS_i)$

Total testing and diversion costs $= \sum_{i=1}^{6}[(Cost_{NTi} + Cost_{GTi} + Cost_{Di}) \times PS_i] = Env_S + Egg_S + Div_S$

where, $\sum_{i=1}^{6} PS_i = 1$

Cost per house for molted layers:

Environmental testing costs for a given house $Env_S = \sum_{i=1a}^{6}(Cost_{NTi} \times PS_i)$

Egg testing costs for a given house $Egg_S = \sum_{i=1a}^{6}(Cost_{GTi} \times PS_i)$

Diversion costs for a given house $Div_S = \sum_{i=1a}^{6}(Cost_{Di} \times PS_i)$

Total testing and diversion costs $= \sum_{i=1a}^{6}[(Cost_{NTi} + Cost_{GTi} + Cost_{Di}) \times PS_i] = Env_S + Egg_S + Div_S$

where, $\sum_{i=1a}^{6} PS_i = 1$

Total cost of testing and diversion. The cost of environmental testing and diversion varies by house size. Thus, in our calculations we estimate these costs for the typical house on farms with less than 3,000 layers, 3,000 to 19,999 layers, 20,000 to 49,999 layers, 50,000 to 99,999 layers, and over 100,000 layers. This is done for both molted and non-molted flocks. The total costs of testing and diversion are calculated using the following equations:

Total cost of environmental testing $= \sum_{S=0}^{4}(Env_S \times N_S)$

Total cost of egg testing $= \sum_{S=0}^{4}(Egg_S \times N_S)$

Total cost of diversion $= \sum_{S=0}^{4}(Div_S \times N_S)$

Total cost of testing and diversion $= \sum_{S=0}^{4}[(Env_S \times Egg_S + Div_S) \times N_S]$

where, N_S = the number of houses in each size category.

Appendix C to the PRIA: Distributions Used in the Analysis of Uncertainty

DISTRIBUTIONS USED IN THE ANALYSIS OF UNCERTAINTY

Variable	@Risk Formula Used	Notes
Coverage of the Proposed Rule		
Farms Selling to Retail (50 to 99 layers)	Risk Uniform (0%, 50%)	Egg Safety Action Group Approved Assumption
Farms Selling to Retail (100 to 399 layers)	Risk Uniform (10%, 90%)	Egg Safety Action Group Approved Assumption
Farms Selling to Retail (400 to 3000 layers)	Risk Uniform (50%, 100%)	Egg Safety Action Group Approved Assumption
Farms Not Selling in Retail that Sell Directly to Consumers	Risk Uniform (0%, 100%)	Egg Safety Action Group Approved Assumption
Number of Houses per Farm Site (3,000 to 19,999 layers)	Risk Normal (1.7, 0.5)	From Layers 99
Number of Houses per Farm Site (20,000 to 49,999 layers)	Risk Normal (1.8, 0.2)	From Layers 99
Number of Houses per Farm Site (50,000 to 99,999 layers)	Risk Normal (2.4, 0.3)	From Layers 99
Number of Houses per Farm Site (Over 100,000 layers)	Risk Normal (7.4, 0.8)	From Layers 99
Egg Prices		
Wholesale Price of Table Eggs- North Atlantic	Risk Uniform ($0.66, $0.70)	USDA
Wholesale Price of Table Eggs- North Central	Risk Uniform ($0.57, $0.69)	USDA
Wholesale Price of Table Eggs- South Atlantic	Risk Uniform ($0.63, $0.76)	USDA
Wholesale Price of Table Eggs- South Central	Risk Uniform ($0.69, $0.83)	USDA
Wholesale Price of Table Eggs- West	Risk Uniform ($0.75, $0.95)	USDA
Value of Checks/UnderGrades - North Atlantic	Risk Uniform ($0.14, $0.19)	USDA
Value of Checks/UnderGrades - North Central	Risk Uniform ($0.15, $0.18)	USDA
Value of Checks/UnderGrades - South Atlantic	Risk Uniform ($0.14, $0.19)	USDA
Value of Checks/UnderGrades - South Central	Risk Uniform ($0.15, $0.18)	USDA
Benefits Estimation		
Percent of SE cases from Eggs	Risk Uniform (53%, 79%)	CDC Range from Outbreaks
Percent of Illnesses Resulting in Arthritis	Risk Pert (0%, 3%, 10%)	Range Estimated in Traceback Studies
Arthritis Cases that are Short-Term	Risk Beta (10, 19)	Based on Zorn and Klontz
Percent of SE Positive Eggs Diverted in First Four Years	Risk Uniform (6.7%, 9.4%)	Estimate is a Synthesis of 'Initial' and 'Eventual' Estimates from the Testing and Diversion Model
SE Monitored Chicks/Pullets		
Percent of Pullets in NPIP SE Monitored Program	Risk Normal (94.5%, 1.8%)	Layers 99
Biosecurity		
Percent of Large Houses with Footbaths	Risk Uniform (Risk Normal (24.5%, 5.4%), Risk Normal (24.6%, 6.4%))	Layers 99
Rodent and Pest Control - Primary Method of Fly Control		
Residual Spray (less than 20,000 layers)	Risk Normal (42.1%, 22.2%)	Layers 99
Baits (less than 20,000 layers)	Risk Normal (11.4%, 6.5%)	Layers 99
Larvicide (feed) (less than 20,000 layers)	Risk Normal (17.2%, 9.8%)	Layers 99
Biological Predators less than 20,000 layers)	Risk Normal (20.1%, 15.8%)	Layers 99

DISTRIBUTIONS USED IN THE ANALYSIS OF UNCERTAINTY—Continued

Variable	@Risk Formula Used	Notes
Other (less than 20,000 layers)	Risk Normal (2.4%, 2.3%)	Layers 99
None (less than 20,000 layers)	Risk Normal (6%, 4.8%)	Layers 99
Residual Spray (20,000 to 49,999 layers)	Risk Normal (14.2%, 7.4%)	Layers 99
Baits (20,000 to 49,999 layers)	Risk Normal (32.6%, 9.4%)	Layers 99
Larvicide (spot) (20,000 to 49,999 layers)	Risk Normal (0.9%, 0.6%)	
Larvicide (feed) (20,000 to 49,999 layers)	Risk Normal (26.6%, 12.6%)	Layers 99
Sprays/Foggers (20,000 to 49,999 layers)	Risk Normal (4.2%, 2.3%)	Layers 99
Other (20,000 to 49,999 layers)	Risk Normal (4%, 2%)	Layers 99
None (20,000 to 49,999 layers)	Risk Normal (17.5%, 6.9%)	Layers 99
Residual Spray (50,000 to 99,999 layers)	Risk Normal (24%, 7.2%)	Layers 99
Baits (50,000 to 99,999 layers)	Risk Normal (38.5%, 8%)	Layers 99
Larvicide (feed) (50,000 to 99,999 layers)	Risk Normal (12.8%, 6.1%)	Layers 99
Sprays/Foggers (50,000 to 99,999 layers)	Risk Normal (12.9%, 6.8%)	Layers 99
Biological Predators (50,000 to 99,999 layers)	Risk Normal (6.8%, 3.1%)	Layers 99
None (50,000 to 99,999 layers)	Risk Normal (5%, 2.1%)	Layers 99
Residual Spray (Over 100,000 layers)	Risk Normal (14%, 3.9%)	Layers 99
Baits (Over 100,000 layers)	Risk Normal (39.1%, 8%)	Layers 99
Larvicide (spot) (Over 100,000 layers)	Risk Normal (0.8%, 0.7%)	Layers 99
Larvicide (feed) (Over 100,000 layers)	Risk Normal (9.2%, 2.9%)	Layers 99
Sprays/Foggers (Over 100,000 layers)	Risk Normal (10.4%, 4%)	Layers 99
Biological Predators (Over 100,000 layers)	Risk Normal (12.9%, 6.4%)	Layers 99
Other (Over 100,000 layers)	Risk Normal (4.8%, 2.3%)	Layers 99
None (Over 100,000 layers)	Risk Normal (8.8%, 2.4%)	Layers 99
Rodent and Pest Control - Primary Method of Rodent Control		
Chemicals or Bait (less than 20,000 layers)	Risk Normal (63.6%, 17.6%)	Layers 99
Traps or Tape (less than 20,000 layers)	Risk Normal (17.6%, 15.7%)	Layers 99
Cats (less than 20,000 layers)	Risk Normal (18.8%, 10.3%)	Layers 99
Chemicals or Bait (20,000 to 49,999 layers)	Risk Normal (71.6%, 6.4%)	Layers 99
Traps or Tape (20,000 to 49,999 layers)	Risk Normal (7.4%, 3.6%)	Layers 99
Cats (20,000 to 49,999 layers)	Risk Normal (18%, 6.6%)	Layers 99
None (20,000 to 49,999 layers)	Risk Normal (3%, 2%)	Layers 99
Chemicals or Bait(50,000 to 99,999 layers)	Risk Normal (94%, 2%)	Layers 99
Traps or Tape (50,000 to 99,999 layers)	Risk Normal (2.2%, 1%)	Layers 99
Cats (50,000 to 99,999 layers)	Risk Normal (3.8%, 1.6%)	Layers 99
Chemicals or Bait (Over 100,000 layers)	Risk Normal (90.6%, 2.7%)	Layers 99
Traps or Tape (Over 100,000 layers)	Risk Normal (6.6%, 2.4%)	Layers 99
Cats (Over 100,000 layers)	Risk Normal (1.4%, 0.7%)	Layers 99

DISTRIBUTIONS USED IN THE ANALYSIS OF UNCERTAINTY—Continued

Variable	@Risk Formula Used	Notes
Other (Over 100,000 layers)	Risk Normal (1%, 0.5%)	Layers 99
None (Over 100,000 layers)	Risk Normal (0.4%, 0.3%)	Layers 99
Rodent and Pest Control - Other		
Cost of Fly Control (3,000 to 19,999 layers)	Risk Uniform ($3,028, $5,560)	RTI costs using assumptions of low and high severity fly problems
Cost of Fly Control (20,000 to 49,999 layers)	Risk Uniform ($5,342, $9,675)	RTI costs using assumptions of low and high severity fly problems
Cost of Fly Control (50,000 to 99,999 layers)	Risk Uniform ($9,873, $17,979)	RTI costs using assumptions of low and high severity fly problems
Cost of Fly Control (Over 100,000 layers)	Risk Uniform ($48,626, $88,228)	RTI costs using assumptions of low and high severity fly problems
Cleaning and Disinfecting		
Manure Removal - Between Each Flock	Risk Normal (96.6%, 1.6%)	Layers 99
Manure Removal - After 2 or More Flocks	Risk Normal (3.4%, 1.6%)	Layers 99
Dry Clean - Between Each Flock	Risk Normal (79.4%, 3.7%)	Layers 99
Dry Clean - After 2 or More Flocks	Risk Normal (1.1%, 0.6%)	Layers 99
Wet Clean - Between Each Flock	Risk Normal (30.6%, 4.5%)	Layers 99
Wet Clean - After 2 or More Flocks	Risk Normal (23%, 5.7%)	Layers 99
Disinfect - Between Each Flock	Risk Normal (44.5%, 5.4%)	Layers 99
Disinfect - After 2 or More Flocks	Risk Normal (20.6%, 5.9%)	Layers 99
Training		
Tuition	Risk Uniform ($450, $550)	Web Sources
Travel	Risk Pert ($0,$250,$1000)	See Text
Farms Not on a QA Plan that will be Affected by the Proposed Rule	Risk Uniform (0%, 100%)	Assumption
Testing and Diversion		
Current Positive Environmental Tests	Risk Uniform (7.1%, Risk Pert (2%, 8%, 40%))	See Text
Probability Random Swabbing Regime is Chosen by FDA	Risk Uniform (0%, 100%)	Assumption
Percent of Farms Adequately Testing Environments	Risk Uniform (0%, 52%)	52% are currently conducting some level of testing (Layers 99). Most of these farms will not be conducting an adequate level of testing.
Refrigeration		
Percent of Eggs Processed Off-Farm (3,000 to 19,999 layers)	Risk Normal (98.3%, 1.3%)	Layers 99
Percent of Eggs Processed Off-Farm (20,000 to 49,999 layers)	Risk Normal (96.3%, 1.4%)	Layers 99
Percent of Eggs Processed Off-Farm (50,000 to 99,999 layers)	Risk Normal (83.1%, 7.6%)	Layers 99
Percent of Eggs Processed Off-Farm (Over 100,000 layers)	Risk Normal (65.6%, 6%)	Layers 99
Percent of Eggs Stored at Less then 45 Degrees (3,000 to 19,999 layers)	Risk Normal (21.9%, 16.1%)	Layers 99

DISTRIBUTIONS USED IN THE ANALYSIS OF UNCERTAINTY—Continued

Variable	@Risk Formula Used	Notes
Percent of Eggs Stored at Less then 45 Degrees (20,000 to 49,999 layers)	Risk Normal (24.2%, 13.4%)	Layers 99
Percent of Eggs Stored at Less then 45 Degrees (50,000 to 99,999 layers)	Risk Normal (11.1%, 3.6%)	Layers 99
Percent of Eggs Stored at Less then 45 Degrees (Over 100,000 layers)	Risk Normal (27.3%, 8.6%)	Layers 99
Refrigeration		
Farms that Store Eggs at Greater than 60 Degrees (3,000 to 19,999 layers)	Risk Normal (42.7%, 22.7%)	Layers 99
Farms that Store Eggs at Greater than 60 Degrees (20,000 to 49,999 layers)	Risk Normal (22.6%, 8.8%)	Layers 99
Farms that Store Eggs at Greater than 60 Degrees (50,000 to 99,999 layers)	Risk Normal (37.7%, 10.5%)	Layers 99
Farms that Store Eggs at Greater than 60 Degrees (Over 100,000 layers)	Risk Normal (17.1%, 5.1%)	Layers 99
Farms that Store Eggs at 50 to 60 Degrees (3,000 to 19,999 layers)	Risk Normal (35.4%, 17.2%)	Layers 99
Farms that Store Eggs at 50 to 60 Degrees (20,000 to 49,999 layers)	Risk Normal (53.2%, 12.1%)	Layers 99
Farms that Store Eggs at 50 to 60 Degrees (50,000 to 99,999 layers)	Risk Normal (51.2%, 13%)	Layers 99
Farms that Store Eggs at 50 to 60 Degrees (Over 100,000 layers)	Risk Normal (55.6%, 17.4%)	Layers 99
Egg Room Construction (3,000 to 19,999 layers)	Risk Uniform ($3,723, $5,584)	RTI estimates for costs of $50 and $75 per square foot
Egg Room Construction (20,000 to 49,999 layers)	Risk Uniform ($8,036, $12,054)	RTI estimates for costs of $50 and $75 per square foot
Egg Room Construction (50,000 to 99,999 layers)	Risk Uniform ($15,936, $23,903)	RTI estimates for costs of $50 and $75 per square foot
Egg Room Construction (Over 100,000 layers)	Risk Uniform ($69,625, $104,438)	RTI estimates for costs of $50 and $75 per square foot

Note. We list the formulas used by @Risk, the program we used to run the simulations. Risk Uniform generates a uniform distribution with parameters representing minimum and maximum values. Risk Normal is the normal distribution, with the parameters representing mean and standard deviation. Risk Pert is the Beta-Pert Distribution; the three parameters represent the minimum, most likely, and maximum values. Risk Beta is a Beta distribution with parameters based on the number of successes (adjusted for prior) and the number of failures (adjusted for prior).

[FR Doc. 04–21219 Filed 9–20–04; 11:00 am]
BILLING CODE 4160–01–S

Federal Register

Wednesday,
September 22, 2004

Part III

Department of the Interior

Office of Surface Mining Reclamation and Enforcement

30 CFR Parts 870 and 872
Coal Production Fees and Fee Allocation; Proposed Rulemaking; Republication

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Parts 870 and 872

RIN 1029–AC47

Coal Production Fees and Fee Allocation; Republication

Editorial Note: Federal Register Proposed Rule document 04–20998 was published originally in the **Federal Register** of Friday, September 17, 2004 at 69 FR 56132. In the paper edition of the September 17 issue, page 56132 appeared as a blank page, due to a technical malfunction. The online edition of the **Federal Register** was not affected. A complete version of the document appears on page 56132 in both the HTML and PDF versions posted online on GPO Access (*http://www.gpoaccess.gov/fr/index.html*). The corrected document is republished in its entirety.

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

ACTION: Proposed rule.

SUMMARY: This rule sets forth the criteria and procedures that we are proposing to use to establish fees under the abandoned mine reclamation program provisions of the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). The fixed-rate fees established under SMCRA expire September 30, 2004. However, the Act requires that, for coal produced after that date, fees be established to continue to provide for transfers from the Abandoned Mine Reclamation Fund (the AML Fund or the Fund) to the Combined Benefit Fund (the Combined Fund or CBF). This proposed rule would implement that requirement in part. We are also publishing a final rule in today's **Federal Register** that mirrors the fee establishment criteria and procedures in this proposed rule and establishes a fee for the fiscal year beginning October 1, 2004. Comments received on this proposed rule will assist us in determining whether to modify that final rule. We are also proposing to revise our regulations governing allocation and disposition of the fees collected and of other AML Fund income.

DATES: *Electronic or written comments:* We will accept written comments on the proposed rule until 4:30 p.m., Eastern time, on or by November 16, 2004.

Public hearing: If you wish to testify at a public hearing, you must submit a request on or before 4:30 p.m., eastern time, on October 18, 2004. We will hold a public hearing only if there is sufficient interest. Hearing arrangements, dates and times, if any, will be announced in a subsequent **Federal Register** notice. If you are a disabled individual who needs special accommodation to attend a public hearing, please contact the person listed under **FOR FURTHER INFORMATION CONTACT.**

ADDRESSES: If you wish to comment on this proposed rule, you may submit your comments by any of the following methods to the address indicated:

- *E-mail: osmregs@osmre.gov.* Please include docket number 1029–AC47 in the subject line of the message.
- *Mail/Hand-Delivery/Courier:* Office of Surface Mining Reclamation and Enforcement, Administrative Record, Room 210, 1951 Constitution Avenue, NW., Washington, DC 20240. Please identify the comments as pertaining to docket number 1029–AC47.
- *Federal e-Rulemaking Portal: http://www.regulations.gov.* Follow the instructions provided at *http://www.regulations.gov* under the "How to Comment" heading for this rule.

You may submit a request for a public hearing on the proposed rule to the person and address specified under **FOR FURTHER INFORMATION CONTACT.** If you are disabled and require special accommodation to attend a public hearing, please contact the person listed under **FOR FURTHER INFORMATION CONTACT.**

FOR FURTHER INFORMATION CONTACT: Dennis Rice, Office of Surface Mining Reclamation and Enforcement, 1951 Constitution Avenue, NW., Washington, DC 20240. Telephone: (202) 208–2829. E-mail address: *drice@osmre.gov.* You will find additional information concerning OSM, fees on coal production, the Abandoned Mine Reclamation Fund, and abandoned mine reclamation in general on our home page at *http://www.osmre.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background information
A. What Is the History of the SMCRA Fee on Coal Production?
B. What Is the Combined Benefit Fund?
C. Why Do We Transfer Monies From the AML Fund to the CBF and How Do We Determine the Amount To Transfer?
II. How Do We Propose To Determine the Total Amount of Fees To Collect Each Year?
III. How Are We Proposing To Revise 30 CFR Part 870?
IV. What Alternatives Did We Consider in Developing the Proposed Changes to 30 CFR Part 870?
V. What Is the Rationale for the Cap on Annual Transfers to the CBF?
VI. What Would the Fees Be Under This Proposed Rule for Coal Produced After September 30, 2004?
VII. How Would the Fees Collected for Coal Produced After September 30, 2004, Be Used?
VIII. How Else Are We Proposing To Revise the AML Fund Rules in 30 CFR 872.11?
IX. Why Are We Publishing a Final Rule at the Same Time as This Proposed Rule?
X. How Do I Submit Comments on the Proposed Rule?
XI. Procedural Matters

I. Background Information

A. What Is the History of the SMCRA Fee on Coal Production?

Title IV SMCRA created an abandoned mine land reclamation program funded by a fee, known as the reclamation fee, assessed on each ton of coal produced for sale, transfer, or use ("produced"). The fees collected are placed in the AML Fund. We, either directly or through grants to States and Indian tribes with approved AML reclamation plans under SMCRA, use appropriations from the Fund primarily to reclaim lands and waters adversely impacted by mining conducted before the enactment of SMCRA and to mitigate the adverse impacts of mining on individuals and communities. In addition, subject to appropriation, up to $10 million per year may be used for the small operator assistance program under section 507(c) of SMCRA, which pays for certain costs involved with the preparation of coal mining permit applications under Title V of SMCRA. Also, since Fiscal Year (FY) 1996, an amount equal to the interest earned by and paid to the Fund has been available for direct transfer to the United Mine Workers of America Combined Benefit Fund to defray the cost of providing health care benefits for certain retired coal miners and their dependents.

Section 402(a) of SMCRA and existing 30 CFR 870.13 fix the reclamation fee at 35 cents per ton (or 10 percent of the value of the coal, whichever is less) for surface-mined coal other than lignite; 15 cents per ton (or 10 percent of the value of the coal, whichever is less) for coal from underground mines; and 10 cents per ton (or 2 percent of the value of the coal, whichever is less) for lignite. Under section 402(b) of SMCRA, our authority to collect fees at those rates will expire with respect to coal produced after September 30, 2004, as will our authority to collect fees for AML reclamation purposes. However, unappropriated monies remaining in the Fund after that date will remain available for grants to State and tribal AML reclamation programs and the other purposes for which the AML Fund was established.

As originally enacted, section 402 of SMCRA authorized collection of reclamation fees for 15 years following the date of enactment (August 3, 1977), meaning that our fee collection authority would have expired August 3, 1992. However, Congress has twice extended that deadline. As enacted on November 5, 1990, Section 6003(a) of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101–508, 104 Stat. 1388) extended both the fees and our fee collection authority through September 30, 1995. Section 6002(c) of that law also required that the Fund be invested in interest-bearing public debt securities, with the interest becoming part of the Fund. Section 19143(b) of Title XIX of the Energy Policy Act of 1992 (Pub. L. 102–486, 106 Stat. 2776, 3056) subsequently extended the fees and our fee collection authority through September 30, 2004.

Section 2515 of Title XXV of the Energy Policy Act (106 Stat. 2776, 3113) further amended section 402(b) of SMCRA by adding the requirement that, after September 30, 2004, "the fee shall be established at a rate to continue to provide for the deposit referred to in subsection (h) [of section 402 of SMCRA]." *See* 30 U.S.C. 1232(b). The rule that we are proposing today would implement this provision of SMCRA by establishing criteria and procedures for establishment of the fee for coal produced on or after October 1, 2004.

B. What Is the Combined Benefit Fund?

The Energy Policy Act of 1992 also included provisions known as the Coal Industry Retiree Health Benefit Act of 1992 (the Coal Act), which is codified at 26 U.S.C. 9701, *et seq.* *See* Public Law 102–486, 106 Stat. 2776, 3036. The Coal Act created the United Mine Workers of America (UMWA) Combined Fund or CBF by merging two financially troubled health care plans, the UMWA 1950 Benefit Plan and Trust and the UMWA 1974 Benefit Plan and Trust, effective February 1, 1993. *See* 26 U.S.C. 9702. The CBF is a private employee benefit trust fund that provides health care and death benefits to UMWA coal industry retirees and their dependents and survivors who were both eligible to receive and were receiving benefits from the 1950 Benefit Plan or the 1974 Benefit Plan on July 20, 1992. *See* 26 U.S.C. 9703(f). Most current beneficiaries are widows and dependents of coal miners. The CBF health insurance plan provides "Medigap" coverage; *i.e.*, it pays for health care expenses remaining after Medicare and Medicaid reimbursement and covers prescription drugs.

Under the Coal Act, the Social Security Administration (SSA) has the duty of assigning retirees and their dependents to former employers or related companies. *See* 26 U.S.C. 9706. Coal operators and related companies pay monthly premiums (also determined by the SSA) to the CBF to cover the costs of benefits for the beneficiaries assigned to them. In addition, under 26 U.S.C. 9704(a)(3), those companies must pay a monthly premium for the health care costs of eligible unassigned beneficiaries; *i.e.*, those beneficiaries associated with now-defunct coal operators for which no related company exists or remains in business. However, as discussed in Part I.C. below, Congress created a mechanism to wholly or partially offset premium costs for unassigned beneficiaries by transferring an amount equal to certain interest earned by the AML Fund to the CBF.

C. Why Do We Transfer Monies From the AML Fund to the CBF and How Do We Determine the Amount To Transfer?

In paragraphs (a) and (b) of section 19143 of the Energy Policy Act of 1992, respectively, Congress amended the Internal Revenue Code of 1986 and SMCRA to require that, at the beginning of each fiscal year, starting with FY 1996, an amount equal to the AML Fund's estimated interest earnings for that year be transferred to the CBF to help defray the cost of health care benefits for unassigned beneficiaries. *See* section 402(h) of SMCRA (30 U.S.C. 1232(h)) and section 9705(b) of the Internal Revenue Code (26 U.S.C. 9705(b)). *See also* Public Law 102–486, 106 Stat. 3047 and 3056.

Section 9705(b)(2) of the Internal Revenue Code provides that any amount transferred to the CBF under section 402(h) of SMCRA "shall be used to proportionately reduce the unassigned beneficiary premium under section 9704(a)(3) of each assigned operator for the plan year in which transferred." However, to the extent that these transfers do not fully cover costs for unassigned beneficiaries, assigned operators remain obligated to pay the difference under 26 U.S.C. 9704(a)(3) and (d)(3)(A).

Section 402(h) of SMCRA (30 U.S.C. 1232(h)) states that—

(1) In the case of any fiscal year beginning on or after October 1, 1995, with respect to which fees are required to be paid under this section, the Secretary shall, as of the beginning of such fiscal year and before any allocation under subsection (g), make the transfer provided in paragraph (2).

(2) The Secretary shall transfer from the [AML] fund to the United Mine Workers of America Combined Benefit Fund established under section 9702 of the Internal Revenue Code of 1986 for any fiscal year an amount equal to the sum of—

(A) the amount of interest which the Secretary estimates will be earned and paid to the Fund during the fiscal year, plus

(B) the amount by which the amount described in subparagraph (A) is less than $70,000,000.

(3)(A) The aggregate amount which may be transferred under paragraph (2) for any fiscal year shall not exceed the amount of expenditures which the trustees of the Combined Fund estimate will be debited against the unassigned beneficiaries premium account under section 9704(e) of the Internal Revenue Code of 1986 for the fiscal year of the Combined Fund in which the transfer is made.

(B) The aggregate amount which may be transferred under paragraph (2)(B) for all fiscal years shall not exceed an amount equivalent to all interest earned and paid to the fund after September 30, 1992, and before October 1, 1995.

(4) If, for any fiscal year, the amount transferred is more or less than the amount required to be transferred, the Secretary shall appropriately adjust the amount transferred for the next fiscal year.

In sum, section 402(h)(2)(A) of SMCRA requires an annual transfer of estimated interest earnings from the AML Fund to the CBF. Paragraphs (h)(2)(B) and (3)(B) of section 402 require the transfer of an additional amount from a reserve (the interest earned on the AML Fund between FY 1993 and FY 1995) if the estimated interest earnings during the fiscal year will not cover eligible estimated CBF expenditures for that year. However, as explained further below, the amounts in the reserve fund were fully utilized in FY 2003 and no longer are available to supplement the annual transfer. In addition, the total amount transferred under paragraphs (h)(2)(A) and (B) for any one year may not exceed $70 million, as discussed more fully in Part V below.

The section 402(h)(2)(A) transfer is further limited by section 402(h)(3)(A), which precludes the transfer of monies to the CBF in excess of the CBF's yearly costs for health benefits for unassigned beneficiaries. However, under a memorandum of understanding between OSM and the CBF trustees, which was signed on January 19, 2001, the amount transferred is not limited to estimated costs based on premium amounts determined by the SSA—it includes all actual health care expenditures for all unassigned beneficiaries, up to the amount authorized in section 402(h)(3) of SMCRA (subject to the $70 million cap). This approach reflects language in the conference report accompanying the FY 2001 appropriations bill for Interior

and related agencies. Page 200 of that report (H.R. Rep. No. 106–914) states:

> As a general matter, the managers note that it has been the practice for the amount of the annual interest transfers under current law to be based on a calculation which multiplies the number of unassigned beneficiaries by that year's per beneficiary premium rate established by the Social Security Administration (SSA) with adjustments made later (normally two years after the initial transfer) to reflect the Combined Benefit Fund's actual expenditures for unassigned beneficiaries. This practice has an adverse effect on the Combined Benefit Fund's cash flow and is contributing to its financial difficulties. * * * The managers believe that the interest transfer at the beginning of each fiscal year should be based on the Combined Benefit Fund trustees' estimate of the year's actual expenditures for unassigned beneficiaries, which may be adjusted to the actual amount of those expenditures at a later time if the initial transfer proves to be either too high or too low. This approach is completely consistent with the underlying statutory provision found in section 402(h) of the Surface Mining Control and Reclamation Act of 1977 which provides that the amount of interest transferred "shall not exceed the amount of expenditures that the trustees of the Combined Fund estimate will be debited against the unassigned beneficiaries premium account."

The transfer from the AML Fund to the CBF occurs at the beginning of the fiscal year based on our estimate of interest the AML Fund will earn during the fiscal year and the CBF trustees' estimate of their health care expenditures for unassigned beneficiaries for that year. After the close of the fiscal year, we adjust the amount of the transfer to reflect actual interest earnings and CBF expenditures. There is no statute of limitations on adjustments to the number of beneficiaries. Therefore, several adjustments to the transfer for a particular year may be made in following years as figures are refined (usually as a result of bankruptcies and litigation), provided that the statutory transfer cap of $70 million for that year has not been reached. For example, our transfer in FY 2002 included adjustments to our first transfer in FY 1996.

II. How Do We Propose To Determine the Total Amount of Fees To Collect Each Year?

As explained above, section 402(b) of SMCRA requires the establishment of a fee "to continue to provide for the deposit referred to in subsection (h)" of SMCRA. We interpret that language as requiring establishment of a fee that will generate revenue up to, but not more than, the amount of net interest that the AML Fund is anticipated to earn in the coming fiscal year, subject to certain limitations described in detail below. This interpretation gives meaning to the section 402(b) requirement that some "rate" be established. Furthermore, this reading construes the phrase "deposit referred to subsection (h)" in section 402(b) to mean only what is currently provided for in section 402(h) (*i.e.*, the transfer of an amount of money equal to estimated AML Fund interest earnings subject to the "caps" described below) and nothing more.

The legislative history of paragraphs (b) and (h) of section 402 sheds little light on congressional intent with respect to the amount of fees to be collected for coal produced after September 30, 2004. The provision in section 402(b) concerning post-September 30, 2004, fees appears to have originated in two bills introduced in 1992 in the 102nd Congress. Those bills, H.R. 4344 and H.R. 776, both included a version of section 402(h) that would have required an annual transfer of $50 million from the AML Fund to the CBF. However, H.R. 4344 was never adopted, and the House removed the CBF transfer provisions from H.R. 776 prior to passage. In acting on H.R. 776, the Senate added a variation of the provisions that the House had removed. However, instead of authorizing the transfer of $50 million from the AML Fund to the CBF each year as in the prior House version of section 402(h), the Senate version authorized transfer only of an amount equal to interest earned or estimated to be earned by the Fund. *See* 138 Cong. Rec. 10558, July 29, 1992. The Senate did not make any conforming changes to section 402(b). The House subsequently accepted the Senate version without change and the provisions became law as part of the Energy Policy Act of 1992.

Thus, the rationale for the fee collection target in section 870.13(b)(2) of the proposed rule that we are publishing today is the plain language of the statute and the absence of any legislative history to support a contrary reading. Section 402(b) of SMCRA provides that, after September 30, 2004, "the fee shall be established at a rate to continue to provide for the deposit referred to in subsection (h)." Section 402(h) of the Act lists two components of the deposit:

(1) An estimate of the interest that will be earned by and paid to the AML Fund during the fiscal year (paragraph (h)(2)(A)); and

(2) A "supplement" to increase that amount to $70 million if necessary (paragraph (h)(2)(B)), but with a cap on the total amount of the supplement for "all fiscal years" equal to the interest earned and paid to the AML Fund from October 1, 1992 to September 30, 1995 (paragraph (h)(3)(B)), and further capped by the needs of the CBF (paragraph (h)(3)(A)).

The supplement referenced in paragraph (h)(2)(B) is no longer available because the cap in paragraph (h)(3)(B) has been reached. By its terms, the cap applies to "all fiscal years" without any limitation. There is nothing in the legislative history to suggest that in section 402(b) Congress meant to refer only to certain portions of section 402(h). That is, we have no indication that Congress intended to continue the supplement in paragraph (h)(2)(B) without regard to the cap on that supplement in paragraph (h)(3)(B)). Moreover, the cap resulted in a transfer from the AML Fund to the CBF of only $49.8 million in FY 2004, which was based only on the estimate of interest that the Fund would earn in FY 2004. There was no supplement provided to raise that amount because the supplement already was exhausted. It would be anomalous to suggest that Congress intended for the cap in paragraph (h)(3)(B) to apply to the transfer in FY 2004 (as it did), but not in FY 2005, when the plain language of that paragraph applies the cap to "all fiscal years."

In sum, at this time nothing in SMCRA authorizes transfer of any monies to the CBF in excess of an amount equal to estimated interest earnings for that year (adjusted in future years to reflect actual interest earnings). Furthermore, there is no indication in the legislative history of sections 402(b) and (h) that Congress intended otherwise.

Therefore, the reference in section 402(b) to "the deposit referred to in subsection (h)" is best read as meaning that the fees established for coal produced after September 30, 2004, must be designed to generate an amount of revenue equal to the estimated interest earnings transferred to the CBF at the beginning of each fiscal year, with any modifications needed to reflect the true-up adjustments required by section 402(h)(4).

For the reasons discussed above, we believe that the proposed rule is a reasonable reconciliation of the statutory language with congressional intent as evidenced by the legislative history.

III. How Are We Proposing To Revise 30 CFR Part 870?

As discussed in Part IX of this preamble, we are publishing a final rule in today's **Federal Register** that adopts the same changes to Part 870 that we are

proposing in this rule and puts them into effect immediately. However, we will fully consider all comments that we receive on this proposed rule. If we determine that changes are needed in response to those comments, we will issue a new final rule containing the appropriate modifications. As mentioned in Part IX, we seek comment on whether those changes should be effective as of October 1, 2004.

We are proposing to revise 30 CFR 870.13 by—

- Changing the section heading from "Fee computations" to "Fee rates";
- Redesignating existing paragraphs (a) through (d) as paragraphs (a)(1) through (4);
- Adding a new title and introductory language for paragraph (a) to clarify that the rates in that paragraph apply only to fees for coal produced on or before September 30, 2004; and
- Adding a new paragraph (b), which would establish criteria and procedures for use in establishing fees for coal produced after September 30, 2004.

In addition, in a conforming technical change, we are proposing to revise 30 CFR 870.12(d) to remove the September 30, 2004, expiration date for fee payment obligations.

Proposed paragraph 870.13(b) would implement in part the provision in section 402(b) of SMCRA that requires that, after September 30, 2004, "the fee shall be established at a rate to continue to provide for the deposit referred to in subsection (h)." As discussed in Part I.C. above, section 402(h) of SMCRA essentially requires the transfer from the AML Fund to the CBF, at the beginning of each fiscal year, of an amount equal to estimated AML Fund interest earnings during that year to defray the cost of health care benefits for the plan's unassigned beneficiaries. Those transfers effectively are capped at the estimated AML Fund interest earnings for that year, $70 million, or the CBF's estimated expenditures for health care benefits for unassigned beneficiaries for that year, whichever is the smallest amount. Therefore, effective October 1, 2004, we must determine the fee based on the amount of the transfer from the AML Fund to the CBF.

We recognize that section 402(h) of SMCRA does not expressly require adjustments to reflect differences between estimated and actual AML Fund interest earnings and estimated and actual CBF expenditures for unassigned beneficiaries. Paragraphs (h)(1), (2), and (3) of section 402 refer only to the use of estimates when determining the amount required to be transferred. However, section 402(h)(4) of the Act provides that, "[i]f, for any fiscal year, the amount transferred is more or less than the amount required to be transferred, the Secretary shall appropriately adjust the amount transferred for the next fiscal year." In our view, that provision essentially requires that the Secretary adjust the amount transferred to reflect any difference between the estimates used to determine the transfer amount at the beginning of the year and actual data for that year, as determined at a later date. Otherwise, section 402(h)(4) would have no real meaning, which would conflict with established principles of statutory construction. We invite comment on whether there is any other interpretation that would give effective meaning to section 402(h)(4). If so, we may reconsider adoption of proposed 30 CFR 870.13(b)(2)(ii).

Proposed paragraph 870.13(b)(1) would require us to establish fees on an annual basis. We selected this frequency because the amount transferred to the CBF each year will vary. We would publish the fees for each fiscal year after FY 2005 in the **Federal Register** at least 30 days before the start of the fiscal year to which the fees would apply. Although not specified in the rule, we also would provide notice of the new fees by modifying the Abandoned Mine Land Payer Handbook (*http://ismdfmnt5.osmre.gov*), revising the OSM–1 form, and issuing Payer Letters to permittees.

Under the proposed rule, once we publish the fees for a given fiscal year, they would not change during that year. Later in this preamble we explain how we would make adjustments for differences between the estimates (for factors as interest earnings and coal production) used to establish the fees and actual data once the actual data becomes available.

Proposed paragraph 870.13(b)(2) of the rule essentially would require that each year's fee be established to generate an amount of revenue equal to the amount of estimated AML Fund interest earnings that will transfer from the AML Fund to the trustees of the CBF at the beginning of that year under section 402(h) of SMCRA. Consistent with paragraphs (h)(2)(B) and (h)(3)(A) of section 402 of SMCRA (*see* Part V of this preamble), paragraph (b)(2)(i) of the rule would cap the amount of estimated interest earnings transferred—and hence the total amount of fee collections needed—at the lesser of either $70 million or the amount that the trustees of the CBF estimate will be debited against the unassigned beneficiaries premium account under section 9704(e) of the Internal Revenue Code of 1986 (26 U.S.C. 9704(e)) for that fiscal year.

Under proposed section 870.13(b)(2), calculation of the total amount of fee collections needed would be a three-step process. First, under proposed paragraph (b)(2)(i), we would estimate the amount that must be transferred to the CBF at the beginning of that fiscal year. We would compare the net amount of interest the AML Fund is estimated to earn during that fiscal year, the most recent estimate from the CBF trustees of their needs for unassigned beneficiaries for that year, and the statutory cap of $70 million. The estimated transfer amount would be the smallest of the three numbers.

The second step, under proposed paragraph (b)(2)(ii), would be to adjust the estimated transfer amount to account for overcollections or undercollections in prior years. SMCRA requires us to establish a fee that will provide for the transfer under section 402(h). As explained above, the initial transfer to the CBF under that section of the Act is based on estimates of AML Fund interest earnings and the CBF's needs for unassigned beneficiaries during that year. After the close of the fiscal year, the amount of the transfer is adjusted to reflect actual interest earnings (and, if necessary, actual CBF expenditures) when that data becomes available. As explained more fully below, any difference between estimated and actual data would not result in a revision of the previously established fee for that year. We would account for any excess fees collected, or any deficiencies, by adjusting the next fee scheduled to be determined.

For example, if we underestimate interest earnings, we would transfer the difference to the CBF, provided the CBF needs that amount for expenditures from the unassigned beneficiary premium account during that year and the transfer would not exceed the $70 million statutory cap. We would then need to increase fee collections in the following year to recover the additional amount transferred. On the other hand, if we overestimate interest earnings or if the CBF's expenditures were lower than the original amount transferred, the CBF would refund the difference and we would need to address the excess amount of fees collected. However, this requirement would apply only to adjustments for fiscal years after FY 2004. Therefore, if we determine in FY 2005 that we underestimated FY 2003 interest earnings by $10 million, we would not include that adjustment in the fee calculation for FY 2006 (*i.e.*, we would not increase the fee collection needs for FY 2006 by $10 million), although we would send the $10 million to the CBF.

The third step under proposed paragraph (b)(2)(iii) would be to adjust the estimated transfer amount to reflect differences between estimated and actual coal production in prior years. As explained above, the fee calculation for a fiscal year would essentially be a fraction. The numerator would be the amount of total fees to be collected for that fiscal year (with all adjustments), and the denominator would be based on our estimate of coal production for that year. If we overestimate production, the calculated per-ton fee would be too low and we would undercollect for that year. Conversely, if we underestimate production, the calculated per-ton fee would be too high and we would overcollect for that year. Therefore, just like when we adjust the estimated interest and CBF needs to actual in step two, when we obtain actual production figures for fiscal years after October 1, 2004, we would calculate the fees we overcollected or undercollected and that number would become an adjustment in the next fee calculation.

We identified two options to remedy fee undercollections and overcollections. Under the first option, we would recalculate the fee and have all operators submit amended reports with additional payments or requests for credit or refund. We find this option impractical for several reasons. First, it would impose a huge paperwork burden on both operators and OSM. Second, we often make several adjustments over a number of years as actual data become available for comparison with the estimates used to establish the fees. Therefore, multiple supplemental reports would be required. Third, the adjustments likely would be very small (fractions of a cent), so the cost to operators and OSM of accounting for adjustments may exceed the dollar value of the adjustment. For all these reasons, we propose to reject this option. Under this proposed rule, we would not change the fee for a given fiscal year after we publish that fee in the **Federal Register**.

Instead, we are proposing to adopt the second possible approach to account for adjustments. Under that approach, we would adjust fee calculations for future years to account for adjustments to transfers in prior years. However, we would not adjust the fee calculations for future years when the transfer adjustments relate to FY 2004 or earlier fiscal years. Adjustments for transfers in those years would be inappropriate because the fee was statutorily set for those years.

The following example illustrates how this process would work: Assume estimated AML Fund interest earnings for FY 2008 are $60 million and the CBF's estimated unassigned beneficiary needs are $85 million. Under that scenario, the amount transferred to the CBF would be $60 million. Under paragraph (b)(2)(i) of the proposed rule, that amount also would be the starting point for our fee calculations for FY 2008. Assume further that in FY 2006 we overestimate AML Fund interest earnings by $3 million, which means that fee collections for FY 2006 are $3 million higher than they should have been. To correct this situation, we would subtract the $3 million overcollection for FY 2006 from the $60 million estimated transfer in FY 2008, thereby reducing fees collected for that year. Hence, in FY 2008 operators as a group would recover the $3 million fee overcollection in FY 2006.

If there are multiple adjustments for more than one prior fiscal year, they all would be incorporated in the next fee calculation. In addition, if we later find that further adjustments are needed for a previously adjusted fiscal year, we would account for that adjustment in the next fee calculation. Thus, returning to the example in the previous paragraph, if we determine in FY 2008 that FY 2006 interest was overestimated by $4 million, not $3 million, we would adjust the next scheduled fiscal year's fee calculation (*i.e.*, FY 2009) by the additional $1 million.

Finally, if Congress were to specifically appropriate additional funds for transfer from the AML Fund to the CBF, that appropriation would not become part of the fee calculation process. Thus, for example, if, in the FY 2007 appropriations act for the Department of the Interior, Congress designated a one-time $25 million supplemental payment to the CBF, we would not include that $25 million in the fee calculations for FY 2007.

Proposed paragraph 870.13(b)(3) provides that we would determine per-ton fees after comparing the amount of the estimated transfer to the CBF (and hence the total amount of fee collections needed) with projected coal production for that fiscal year. Proposed paragraph (b)(3)(ii) specifies that the new fees would maintain the same proportionality among surface-mined coal, coal produced by underground mining, and lignite as did the fees previously in effect under section 402(a) of SMCRA. In section 402(a) of SMCRA, Congress originally established lower fees for lignite and for coal produced by underground methods than it did for non-lignite coal produced by surface mining methods. According to the legislative history, the lower fees for underground mining reflect the "disproportionately high social costs incurred by underground coal mine operators in meeting responsibilities under the Coal Mine Safety and Health Act of 1969, as amended." H.R. Rep. No. 94–1445 (1976), at 85. Section 402(b) of SMCRA is silent on the question of whether this fee differential should continue to apply to coal produced after September 30, 2004.

After evaluating those factors, we propose to retain the per-ton fee ratios that have been in place since the enactment of SMCRA. Therefore, under proposed paragraph (b)(3)(ii), the fee per ton of non-lignite coal produced by underground methods would be 43 percent of the fee per ton of non-lignite coal produced by surface methods and the fee per ton of lignite coal produced would be 29 percent of the fee per ton of non-lignite coal produced by surface methods. The provision concerning fees for coal produced by in situ mining methods also would remain substantively unchanged from the rule governing fees for coal produced by in situ mining methods before October 1, 2004, in that it would continue to apply the underground fee to all non-lignite coal produced by in situ methods and the lignite fee to lignite coal produced by in situ methods.

IV. What Alternatives Did We Consider in Developing the Proposed Changes to 30 CFR Part 870?

In developing this proposed rule, we considered and rejected the following options to implement the provision of section 402(b) of SMCRA requiring the establishment of a fee for coal produced after September 30, 2004:

- Set the fee at zero and transfer only estimated interest earnings.

This option is inconsistent with the principles of statutory construction because it would render the section 402(b) provision concerning establishment of post-September 30, 2004, fee rates superfluous and essentially inoperative. *See In re Surface Mining Regulation Litigation*, 627 F.2d 1346, 1362 (D.C. Cir. 1980) ("It is, however, a fundamental principal of statutory construction that 'effect must be given, if possible, to every word, clause and sentence of a statute * * * so that no part will be inoperative or superfluous, void or insignificant.' "), quoting from and citing to 2A Sutherland, *Statutory Construction*, at § 46.06 (4th ed. 1973). See also *Boise Cascade Corp.* v. *EPA*, 942 F.2d 1427, 1432 (9th Cir. 1991) (statutes should not be construed so as to render any of their provisions superfluous). In addition, a fee of zero likely would not satisfy the section 402(h)(1) requirement that

transfers from the AML Fund to the CBF may be made only when "fees are required to be paid under this section." Under this approach, the AML Fund and, consequently, the interest earned thereon, would decline the fastest.

- Assess fees at a rate that would generate revenues adequate to maintain the AML Fund at a level that would earn an amount of interest sufficient to meet CBF needs for unassigned beneficiaries, up to a maximum of $70 million.
- This option could be construed to comply with the requirement to establish a fee that provides for the transfer to the Combined Fund under section 402(h). However, to maintain the principal in the AML Fund at a level that would earn sufficient interest to continue to provide for transfers to the CBF at recent levels, the fees under this option could be almost equal to, or even higher than, the current fees. There is no evidence that, in enacting section 402(b), Congress intended that the principal balance of the AML Fund would or should be maintained at a level adequate to generate interest sufficient to meet CBF needs. This option also could have the effect of indefinitely extending the AML reclamation program by requiring collection of fees to replace appropriations for grants to States and tribes for those programs. There is no evidence that Congress intended for fees collected from coal produced after September 30, 2004, to be used for this purpose. Instead, the fact that Congress terminated the statutorily established reclamation fee in section 402(a) as of September 30, 2004, suggests the opposite, as does the language in section 402(b) that requires that, after September 30, 2004, the fee be established at a rate sufficient to continue to provide for transfers to the CBF.
- Assess a fee at a rate sufficient to meet any deficit between anticipated CBF health care benefit needs for unassigned beneficiaries (or $70 million, whichever is less) and the amount of estimated interest earnings transferred.

There is insufficient statutory authority to implement this option because nothing in either the statutory language or the legislative history of SMCRA suggests that, in section 402(b), Congress intended for any transfers to be made to the CBF in excess of an amount equal to yearly estimated AML Fund interest earnings (plus the reserve supplement of prior interest earnings, which is now depleted). Moreover, it would be anomalous to suggest that Congress intended for the CBF to receive a transfer of funds in an amount equal to estimated interest earnings in FY 2004 (as it did) and then to receive transfers in excess of that amount in FY 2005 and thereafter.

V. What Is the Rationale for the Cap on Annual Transfers to the CBF?

Proposed 30 CFR 870.13(b) and 872.11(e) would cap the amount transferred to the CBF at the beginning of each fiscal year at the estimated amount of interest earned by the AML Fund, estimated CBF expenditures for health care benefits for unassigned beneficiaries, or $70 million, whichever is the smallest amount. The first two items would later be adjusted to reflect actual interest earnings and actual CBF expenditures for that fiscal year, provided the adjustments would not cause aggregate transfers for that year to exceed $70 million. This cap is consistent with both historical practice and section 402(h) of SMCRA. Paragraphs (3)(A) and (4) of section 402(h) impose the cap relating to CBF expenditures. The $70 million cap receives implied support from section 402(h)(2)(B) of SMCRA, which allows transfers of estimated interest earnings to be supplemented by prior interest earnings, but only up to a total transfer amount of $70 million. It also reflects the intent of Congress as described in the conference report on the Energy Policy Act. *See* 138 Cong. Rec. 17578, 17605 (1992) ("provision is made for monies to be transferred from the Abandoned Mine Land Fund in an amount up to, but not more than, $70 million per year * * *"). In addition, a report from the House Resources Committee on a bill approved by the Committee but never adopted by the full House characterizes section 402(h) in its entirety as allowing "the transfer to the CBF of not more than $70 million annually." *See* H.R. Rep. No. 106–1014, pt. 1 (2000).

VI. What Would the Fees Be Under This Proposed Rule for Coal Produced After September 30, 2004?

Under proposed 30 CFR 870.13(b)(1), we would determine fees on an annual basis, with notice of the fees for each year published in the **Federal Register** 30 days before the beginning of the fiscal year to which they would apply.

Part VII of the preamble to the final rule that we are publishing in today's **Federal Register** establishes fees for FY 2005.

Table 1 shows the fees for FY 2005 and our projection of fees for the following ten years based on this rule; on currently available estimates on interest rates, CBF needs, and coal production; and on maintaining current congressional appropriations, grant formulas, and AML Fund assets available for investment.

TABLE 1.—FEES FOR FY 2005 AND FEE PROJECTIONS FOR FY 2006–2015

Fiscal year	Estimated AML fund interest earnings (millions of dollars)	Estimated CBF needs for unassigned beneficiaries (millions of dollars)	Fees for non-lignite coal produced by surface methods (cents per short ton)	Fees for non-lignite coal produced by underground methods (cents per short ton)	Fees for lignite coal (cents per short ton)
2005	69.0	85.0	8.8	3.8	2.5
2006	72.0	99.6	8.7	3.7	2.5
2007	71.9	97.9	8.5	3.7	2.4
2008	69.4	96.3	8.5	3.6	2.4
2009	65.8	94.1	7.8	3.4	2.2
2010	61.6	92.2	7.3	3.1	2.1
2011	22.1	90.1	2.6	1.1	0.7
2012	17.6	87.7	2.0	0.9	0.6
2013	14.2	85.4	1.6	0.7	0.5
2014	10.9	83.2	1.2	0.5	0.4
2015	46.4	81.0	5.2	2.2	1.5

In accordance with proposed 30 CFR 870.13(b) and 872.11(e), the fees in Table 1 are based upon a maximum annual transfer to the CBF of $70 million or the amount of estimated AML Fund interest earnings for that year, whichever is less. (The other limiting factor, estimated CBF needs for unassigned beneficiaries, does not come into play because those estimates are in excess of $70 million for all years shown in the table.)

Because section 402(h)(2)(A) of SMCRA refers to the transfer of an amount equal to the estimated interest "earned and paid to the Fund during the fiscal year," we originally invested the Fund's assets only in short-term securities so as to maximize the amount of interest actually paid to the Fund during each year. By so doing, we also maximized the amount available for transfer to the CBF. However, we reevaluated that policy when short-term interest rates declined to the point that the Fund was earning less than $70 million in interest each year. We determined that interest on long-term securities could be deemed to be constructively earned and paid to the Fund on a prorated basis over the life of those securities even though it is not physically collected until the securities reach maturity. The estimated annual interest earnings reported in Table 1 reflect this interpretation. After changing our policy, in FY 2004, we invested $1.3 billion of the Fund in long-term public debt securities with an average interest rate of 4.18 percent. That rate is significantly more than the minuscule returns (currently hovering around one percent) recently available on short-term securities. However, we anticipate that we will need to redeem those long-term securities before their maturity dates to meet future Fund obligations because Congress has not reauthorized collection of a fee for AML reclamation. Consequently, the net interest earnings shown in Table 1 for FY 2011–2014 reflect the early redemption penalties that we expect to incur in those years. In other words, we will need to subtract early redemption penalties from the total estimated interest earnings in each of those years. The increase in net interest earnings shown for FY 2015 reflects the fact that, based on current estimates and assumptions, as of the end of FY 2014, all long-term securities will have been redeemed and that we will therefore incur no further early redemption penalties. By that time, the AML Fund would be invested exclusively in short-term securities and all estimated interest earnings on those securities would be available for transfer without first deducting any early redemption penalties for long-term securities.

Table 2 contains the coal production estimates that we used to establish fees for FY 2005 and to estimate fees for the other years in Table 1.

TABLE 2.—ESTIMATED COAL PRODUCTION FOR COAL SUBJECT TO FEE PAYMENT REQUIREMENTS

[In millions of short tons]

Fiscal year	Non-lignite surface mines	Underground mines	Lignite	Total
2005	628	317	82	1,027
2006	640	327	85	1,052
2007	651	335	87	1,073
2008	643	346	91	1,080
2009	672	340	86	1,098
2010	672	350	86	1,108
2011	680	346	86	1,112
2012	695	345	82	1,122
2013	707	352	82	1,141
2014	709	351	82	1,142
2015	723	359	82	1,164

The total production estimates in Table 2 are based upon projections in the Annual Energy Outlook (December 2003) prepared by the Energy Information Administration within the Department of Energy (DOE). We reduced those projections by ten percent to reflect our historical experience concerning the difference between DOE data and the tonnage subject to SMCRA's fee payment requirements. Allocation among the three production categories (surface, underground, and lignite) is based upon an extrapolation of our fee collection data for FY 2003.

VII. How Would the Fees Collected for Coal Produced After September 30, 2004, Be Used?

Section 401(b) of the Act provides that the AML Fund consists of "amounts deposited in the fund," including, among other things, "reclamation fees levied under section 402," and "interest credited to the fund under subsection (e)." Thus, under section 401(b) of SMCRA, fees collected under section 402 of the Act must be deposited into the AML Fund. Consistent with this requirement, the proposed rule considers all fees collected to be Fund revenues. *See* proposed 30 CFR 872.11(a).

The proposed rule would not affect the process by which transfers are made between the AML Fund and the CBF. That process will remain the same as in previous fiscal years under applicable law and our agreements with the Treasury Department and the CBF trustees.

Section 402(g) of the Act establishes an allocation formula that has been applied to date to the fees collected and to other AML Fund income. Fifty percent of the fees collected (but no other type of Fund income) was allocated to the appropriate State or tribal share account ("State share" or "Tribal share"). The remaining fifty percent of the fees collected, together with all other Fund income (including interest), were allocated among three other accounts, which are sometimes referred to collectively as the "Federal share," as follows:

- Twenty percent to the Secretary of Agriculture for use under section 406 of the Act, which authorizes use of those funds for the rural abandoned mine program (RAMP). This account is known as the RAMP allocation.
- Forty percent for supplemental AML reclamation grants to non-certified States and tribes, based on historical coal production before August 3, 1977. This account is known as the historical production allocation.
- Forty percent for the other purposes of Title IV, including items such as the small operator assistance program, the Clean Streams program, the emergency

reclamation program, reclamation of high priority AML sites in States and tribes without approved AML reclamation plans, minimum program makeup grants, and the cost of administering the AML program and collecting fees. This account is known as the Secretary's discretionary share.

The existing regulations at 30 CFR 872.11(a) and (b) implement the statutory requirements discussed above. Under our proposed rule, fees collected for coal produced for sale, transfer, or use before October 1, 2004, would be allocated according to the statutory scheme. Similarly, any other Fund income listed in section 401(b) of SMCRA, including, but not limited to, interest, user charges, recovered monies, and donations, would continue to be allocated according to that scheme.

However, we are proposing to add new paragraphs (d) and (e) to section 872.11 to address the disposition of fees collected for coal produced for sale, transfer, or use after September 30, 2004, and modify paragraphs (a) and (b) accordingly. Paragraph (d) would allocate fees collected for coal produced in any fiscal year beginning after September 30, 2004, only to the accounts from which the amount of the transfer to the CBF (as provided in new paragraph (e)) was taken at the beginning of that year. Fee collections would be distributed among the contributing accounts in amounts proportionate to which those accounts contributed to the transfer.

We are proposing to adopt this approach because we believe that the direction in SMCRA section 402(b) to establish the fee at a rate to provide for the CBF transfer conflicts with the allocation scheme in section 402(g) and that the two provisions cannot both be given effect. Section 402(b) states that, after September 30, 2004, "the fee shall be established at a rate to continue to provide for [transfers to the CBF]." SMCRA section 402(b), 30 U.S.C. 1232(b). The only purpose of the fee after September 30, 2004, is to support the continued funding of the CBF. In this regard, any fees collected would effectively replace the amount transferred to the CBF. Thus, we believe that the section 402(b) requirement to establish a fee to provide for the CBF transfer provides us with a directive to put whatever fees are collected back into the account from which the transfer was taken.

Transfers to the CBF after September 2004 will take place in the manner illustrated by the following example for FY 2005. On or about October 1, 2004, we will direct the Treasury Department to transfer from the AML Fund to the CBF an amount equal to the amount of interest that is estimated to be earned by the Fund during FY 2005. We will note from which accounts the transferred funds were withdrawn. We will levy a fee on mine operators pursuant to section 402(b) of the Act, with the goal of achieving aggregate fee collections in an amount equal to the amount transferred to the CBF. The section 402(b) directive can be construed as a requirement to use those fees, once collected, to replenish the accounts that contributed monies for the transfer to the CBF at the beginning of the year.

We recognize that the section 402(g) allocation formula arguably conflicts with that requirement. However, we believe that it is anomalous to suggest that Congress intended, in requiring establishment of the fee based on the CBF transfer, to also require that the fees collected continue to be allocated in accordance with the formula established in section 402(g) of the Act. Thus, for fees from coal produced after September 30, 2004, there is an inherent conflict between the direction in section 402(b) and the allocation scheme in section 402(g).

When there is an ambiguity that cannot be reconciled, the agency has discretion to reasonably interpret the statute. It is well-settled that when a court reviews an agency's construction of a statute that the agency administers, the first question for the court is—

> whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress * * * [I]f the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute.

Chevron, U.S.A., Inc. v. *Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842–43 (1984) (footnotes omitted).

Here, the question is whether Congress has directly spoken to the precise question at issue; *i.e.*, whether the statute mandates the allocation of fees collected for coal produced after September 30, 2004, and, if not, whether an interpretation that such allocation is not required is reasonable. In this case, the statute does not unambiguously require allocation of these fees. Therefore, the agency may make the reasonable interpretation that fees collected pursuant to section 402(b) for transfer to the CBF are not required to be allocated pursuant to section 402(g). Our proposed addition of paragraph (d) to section 872.11 of our rules reflects this interpretation.

VIII. How Else Are We Proposing To Revise the AML Fund Rules in 30 CFR 872.11?

We are proposing to reorganize 30 CFR 872.11 to incorporate plain language principles and make the rules more user-friendly. Those changes are not substantive revisions. In addition, we are proposing to eliminate redundant or unnecessary language, improve clarity and consistency of terminology, consolidate provisions concerning interest, and add a paragraph reflecting the statutory requirements concerning transfers to the CBF. The most significant proposed changes (other than those discussed in Part VII of this preamble) are listed below:

- Removal of the sentence from 30 CFR 872.11(a)(6) providing that interest and other non-fee income to the Fund will be credited only to "the Federal share." "Federal share" is an anachronistic term that refers to the structure of section 402(g) of SMCRA as originally enacted. At that time, there were only two types of accounts: State/tribal share and the Secretary's discretionary share. However, as part of the Abandoned Mine Reclamation Act of 1990 (Pub. L. 101–508, 104 Stat. 1388–289 through 1388–299), Congress carved several other mandatory allocations (the RAMP allocation and the historical production allocation) from the original Secretary's discretionary share. The preamble to 30 CFR 872.11(a)(6), as revised on May 31, 1994 (*see* 59 FR 28148–49), clarifies that the term Federal share refers to three separate allocations (RAMP, historical production, and the Secretary's discretionary share), consistent with the changes that Congress made to section 402(g) of the Act.

Paragraph (b) of 30 CFR 872.11 also specifies that interest must be allocated among those three accounts. Therefore, we are proposing to remove this sentence from paragraph (a), both to eliminate any confusion that it may cause and because it is redundant to provisions in paragraph (b). Furthermore, the purpose of paragraph (a) is to identify all types of Fund revenues, not to allocate those revenues. Paragraph (b) addresses allocations.

- Removal of language from 30 CFR 872.11(a)(6), (b)(3), and (b)(4) that references transfers from the AML Fund to the CBF. Proposed new paragraph (e) would address those transfers in a comprehensive fashion. Specifically, consistent with paragraphs (g)(1) and (h)(1) of section 402 of SMCRA, proposed new paragraph (e)(4), like the language proposed for deletion,

specifies that the amount transferred the CBF is not subject to the allocation provisions of section 402(g) of the Act and 30 CFR 872.11(b).

• Modification of the introductory language of paragraph (b) of section 872.11 to clarify that that paragraph governs allocation of all Fund revenues (except fees collected for coal produced after September 30, 2004, and an amount of other revenues equal to monies transferred to the CBF), not just those appropriated by Congress.

• Modification of the provision in paragraphs (b)(1) and (2) of section 872.11 concerning withdrawal of unexpended grant funds from States and Indian tribes to clarify that we will withdraw those funds only if the State or tribe no longer has any eligible and available abandoned mine sites to reclaim. This change is consistent with the explanation of the meaning of this provision in the preamble to the existing rule (*see* 59 FR 28150–51, May 31, 1994). In relevant part, the preamble states at 59 FR 28151 that:

> OSM's practice since the beginning of the AML program is not to withdraw funds from the States/Indian tribes. Rather, funds which are not expended by a State/Indian tribe during the grant period are returned to the State/Indian tribe account for future grants.

Therefore, we are proposing in paragraphs (b)(1)(iii) and (2)(ii) to specify that unexpended grant funds will be reallocated only if the Director finds in writing that the amounts involved are not necessary to carry out reclamation activities on lands within the State or on Indian lands subject to the tribe's jurisdiction.

• Modification of paragraph (b)(3) of section 872.11 to specify that, consistent with the provisions of section 402(g)(2) of SMCRA, the RAMP allocation consists of 20 percent of all Fund revenues (including available interest) remaining *after* making State and tribal share allocations. The existing rule assigns RAMP ten percent of *all* Fund revenues plus 20 percent of available interest earnings and other miscellaneous Fund receipts.

• Removal of paragraph (b)(8) of section 872.11 as that paragraph merely duplicates the requirements of paragraph (b)(5)(iii).

• Revision of paragraph (b)(5)(iv) of section 872.11 to adopt language more consistent with that of section 402(g)(3)(D), which provides that money from the Secretary's discretionary share may be used "[f]or the administration of this title by the Secretary." Existing paragraph (b)(5)(iv) provides that the Secretary may use those monies for "[a]dministration of the Abandoned Mine Land Reclamation Program." To avoid any confusion about the scope of that provision, we are proposing to revise this paragraph to authorize expenditures for "[a]dministration of title IV of the Act and this subchapter [subchapter R of our regulations]."

• Modification of paragraph (b)(7) of section 872.11 to replace references to statutory provisions with references to the corresponding provisions of our regulations. This change would make our regulations more specific and user-friendly as the reader would not have to flip through the statute and then compare those provisions to our regulations to determine their applicability.

• Addition of a new paragraph (e) to section 872.11 to provide a partial counterpart in our regulations to the CBF transfer requirements of section 402(h) of SMCRA and to clarify certain of those requirements, especially the applicability of the $70 million cap on annual transfers (*see* part V of this preamble).

IX. Why Are We Publishing a Final Rule at the Same Time as This Proposed Rule?

In this proposed rule, we are publishing and seeking comment on the same changes that we are making to 30 CFR part 870 in a final rule published separately in today's **Federal Register**. As explained in the preamble to the final rule, we are making those changes effective immediately because of the need to have a fee in place on October 1, 2004, and ensure the continued transfer of monies to the Combined Benefit Fund. As discussed in parts VII and VIII of this preamble, the proposed rule also includes changes to 30 CFR part 872, the most significant of which would provide that the new fees need not be allocated under section 402(g) of SMCRA. After considering comments on the proposed rule, we may make changes to any or all of the provisions of this proposed rule. Because the proposed rule mirrors the final rule that we are adopting today with respect to 30 CFR part 870, the public will have the opportunity to comment on all issues that we are addressing in both the proposed and final rules. However, the final rule that we are adopting today will remain in place until the effective date of any changes that we make. We invite comment on whether any changes that we make to 30 CFR part 870 as a result of comments received should be made effective as of October 1, 2004, to ensure that they apply during the entirety of FY 2005.

X. How Do I Submit Comments on the Proposed Rule?

Electronic or Written Comments

Your comments should reference a specific portion of the proposed rule or preamble, explain the reason for any recommended change or objection, and include supporting data when appropriate. The most helpful comments are those that include citations to and analyses of SMCRA, its legislative history, its implementing regulations, case law, other pertinent Federal laws or regulations, technical literature, or other relevant publications or that involve personal experience.

We will not consider anonymous comments, but you may request that identifying information be withheld as discussed below under "Availability of comments." Please include the docket number for this rulemaking (1029–AC47) at the beginning of all written comments and in the subject line of all electronic comments. Except for comments provided in electronic format, please submit three copies of your comments if practicable. Comments received after the close of the comment period (*see* **DATES**) or at locations other than those listed above under **ADDRESSES** will not be considered or included in the administrative record of this rulemaking.

Availability of Comments

Except as noted below, all comments, including the names and addresses of commenters, will be available for review during regular business hours in our Administrative Record room at the location listed under **ADDRESSES.**

You may request that we withhold your home address from the administrative record. We will honor all such requests from individual commenters to the extent allowable by law. We also will withhold your identity upon request, to the extent allowable by law. If you wish us to withhold your name and/or address, you must state this request prominently at the beginning of your comment. In addition, if you wish this information withheld, please do not submit your comments by electronic means.

We will not withhold names or addresses in comments submitted by organizations, business entities, or individuals identifying themselves as representatives or officials of organizations or business entities. All such comments will be available for public inspection in their entirety.

Public Hearings

We will hold a public hearing on the proposed rule upon request only. We

will announce the time, date, and address for any hearing in the **Federal Register** at least 7 days before the hearing.

If you wish to testify at a hearing please contact the person listed in FOR **FURTHER INFORMATION CONTACT**, either orally or in writing, by 4:30 p.m., eastern time, on November 16, 2004. If no one expresses an interest in testifying at a hearing by that date, we will not hold a hearing. If only one person expresses an interest, we will hold a public meeting rather than a hearing. We will place a summary of the public meeting in the administrative record of this rulemaking.

The public hearing will continue on the specified date until all persons scheduled to speak have been heard. If you are in the audience and have not been scheduled to speak but wish to do so, you will be allowed to testify after the scheduled speakers. We will end the hearing after all persons scheduled to speak and persons present in the audience who wish to speak have been heard. To assist the transcriber and ensure an accurate record, we request, if possible, that each person who testifies at a public hearing provide us with a written copy of his or her testimony.

Public meeting: If there is only limited interest in a hearing, we may hold a public meeting in place of a public hearing. If you wish to meet with us to discuss the proposed rule, you may request a meeting by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**. All meetings will be open to the public and, if appropriate, we will post notice of the meetings. A written summary of each public meeting will be included in the administrative record of this rulemaking.

XI. Procedural Matters

A. Executive Order 12866

This proposed rule is considered a significant rule and is subject to review by the Office of Management and Budget under Executive Order 12866.

a. This proposed rule would not have an effect of $100 million or more on the economy. It would not adversely affect in a material way the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities. The rule would not add to the existing cost of operating a mine under an approved regulatory program in any significant fashion. We anticipate that the average fee under this rule over the next ten years would be 5.7 cents per ton of surface-mined coal, which is less than 0.2 percent of the value of the coal, assuming an average price of $30 per ton. Furthermore, the fees established under this rule would be lower than the existing AML reclamation fees, which expire on September 30, 2004. The fees imposed under this rule would result in the collection of an estimated $469 million from the coal industry during FY 2005–2014, an average of $46.9 million per year. That amount is approximately $3 billion less than what would be collected if the existing AML reclamation fee were extended another 10 years.

b. This proposed rule would not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency.

c. This proposed rule would not alter the budgetary effects of entitlements, grants, user fees, or loan programs or the rights or obligations of their recipients.

d. This proposed rule raises novel legal and policy issues, which is why the rule is considered significant under Executive Order 12866.

B. Regulatory Flexibility Act

The Department of the Interior certifies that this proposed rule would 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.*). *See* the discussion in part XI.A. above.

C. Executive Order 13211—Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This proposed rule is not considered a significant energy action under Executive Order 13211. The replacement of the AML reclamation fee by a much smaller fee for continuation of the transfers to the CBF would not have a significant effect on the supply, distribution, or use of energy.

D. Small Business Regulatory Enforcement Fairness Act

This proposed rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. For the reasons stated in part XI.A. above, this proposed rule would not:

a. Have an annual effect on the economy of $100 million or more.

b. Cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions.

c. Have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises for the reasons stated above.

E. Executive Order 12630—Takings

This proposed rule does not have any significant takings implications under Executive Order 12630. Therefore, a takings implication assessment is not required.

F. Executive Order 13132—Federalism

This proposed rule does not have significant federalism implications because it does not concern relationships between the Federal government and State or local governmental units. Therefore, there is no need to prepare a Federalism Assessment.

G. Executive Order 13175—Consultation and Coordination With Indian Tribal Governments

To the extent that this proposed rule may have a substantial direct effect 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, potentially affected tribal governments will be notified through this publication in the **Federal Register**, and by direct notification from OSM, of the ramifications of this rulemaking. This will enable tribal officials and other tribal constituencies throughout Indian Country to have meaningful and timely input in the development of the final rule. Upon receipt and evaluation of all comments, we will publish a document addressing the comments and making any appropriate changes to the final rule.

H. Executive Order 12988 on Civil Justice Reform

The Department of the Interior has determined that this proposed rule meets the requirements of sections 3(a) and 3(b)(2) of Executive Order 12988, "Civil Justice Reform" (56 FR 55195).

I. Unfunded Mandates Reform Act

This proposed rule would not impose a cost of $100 million or more in any given year on any governmental entity or the private sector.

J. Federal Paperwork Reduction Act

The Department of the Interior has determined that this rule does not contain collections of information which require approval by the Office of Management and Budget under 44 U.S.C. 3501 *et seq.* OMB has previously approved the collection activities and assigned clearance numbers 1029–0063 and 1029–0090 for the OSM–1 form and

coal weight determination, respectively. Under this rule, the only change to the OSM–1 form would be a reduction in the fee rates printed on the form.

K. National Environmental Policy Act

OSM has determined that this rulemaking action is categorically excluded from the requirement to prepare an environmental document under the National Environmental Policy Act of 1969, as amended, 42 U.S.C. 4332 *et seq.* In addition, we have determined that none of the "extraordinary circumstances" exceptions to the categorical exclusion apply. This determination was made in accordance with the Departmental Manual (516 DM 2, Appendixes 1.9 and 2).

L. Clarity of This Regulation

Executive Order 12866 requires each agency to write regulations that are easy to understand. We invite your comments on how to make this rule easier to understand, including answers to questions such as the following:

(1) Are the requirements in the rule clearly stated?

(2) Does the rule contain technical language or jargon that interferes with its clarity?

(3) Does the format of the rule (grouping and order of sections, use of headings, paragraphing, etc.) aid or reduce its clarity?

(4) Would the rule be easier to understand if it were divided into more numerous but shorter sections? (A "section" appears in bold type and is preceded by the symbol "§" and a numbered heading; for example, "§ 870.13.")

(5) Is the description of the rule in the **SUPPLEMENTARY INFORMATION** section of this preamble helpful in understanding the rule?

(6) What else could we do to make the rule easier to understand?

Send a copy of any comments that concern how we could make this rule easier to understand to: Office of Regulatory Affairs, Department of the Interior, Room 7229, 1849 C Street, NW., Washington, DC 20240. You may also e-mail the comments to this address: *Exsec@ios.doi.gov.*

List of Subjects

30 CFR Part 870

Abandoned Mine Reclamation Fund, Reclamation fees, Reporting and recordkeeping requirements, Surface mining, Underground mining.

30 CFR Part 872

Abandoned Mine Reclamation Fund, Indian lands, Reclamation fees, Reporting and recordkeeping requirements, Surface mining, Underground mining.

Dated: September 7, 2004.

Chad Calvert,

Acting Assistant Secretary, Land and Minerals Management.

For the reasons set forth in the preamble, the Department is proposing to amend 30 CFR parts 870 and 872 as follows:

PART 870—ABANDONED MINE RECLAMATION FUND—FEE COLLECTION AND COAL PRODUCTION REPORTING

1. The authority citation for part 870 continues to read as follows:

Authority: 28 U.S.C. 1746, 30 U.S.C. 1201 *et seq.*, and Pub. L. 105–277.

2. In § 870.12, paragraph (d) is revised to read as follows:

§ 870.12 Reclamation fee.

* * * * *

(d) The reclamation fee shall be paid after the end of each calendar quarter beginning with the calendar quarter starting October 1, 1977.

3. Amend § 870.13 as follows:

A. Revise the section heading.

B. Redesignate paragraphs (a) through (d) as paragraphs (a)(1) through (4).

C. Add a heading for paragraph (a).

D. Add a new paragraph (b).

The revision and additions read as follows.

§ 870.13 Fee rates.

(a) *Fees for coal produced for sale, transfer, or use through September 30, 2004.* (1) * * *

* * * * *

(b) *Fees for coal produced for sale, transfer, or use after September 30, 2004.* In this paragraph (b), "we" refers to OSM, "Combined Fund" refers to the United Mine Workers of America Combined Benefit Fund established under section 9702 of the Internal Revenue Code of 1986 (26 U.S.C. 9702), and "unassigned beneficiaries premium account" refers to the account established under section 9704(e) of the Internal Revenue Code of 1986 (26 U.S.C. 9704(e)).

(1) *Fees to be set annually.* We will establish the fee for each ton of coal produced for sale, transfer, or use after September 30, 2004, on an annual basis. The fee per ton is based on the total fees required to be paid each fiscal year, as determined under paragraph (b)(2) of this section, allocated among the estimated coal production categories, as provided in paragraph (b)(3) of this section. We will publish the fees for each fiscal year after Fiscal Year 2005 in the **Federal Register** at least 30 days before the start of that fiscal year. Once we publish the fees, they will not change for that fiscal year and they will apply to all coal produced during that fiscal year.

(2) *Calculation of the total fee collections needed.* The total amount of fee collections needed for any fiscal year is the amount that must be transferred from the Fund to the Combined Fund under section 402(h) of the Act (30 U.S.C. 1232(h)) for that fiscal year, with any necessary adjustments for the amount of any fee overcollections or undercollections in prior fiscal years. We will calculate the amount of total fee collections needed as follows:

(i) *Step one.* We will determine the smallest of the following numbers:

(A) The estimated net interest earnings of the Fund during the fiscal year;

(B) $70 million; or

(C) The most recent estimate provided by the trustees of the Combined Fund of the amount that will be debited against the unassigned beneficiary premium account for that fiscal year ("the Combined Fund's needs").

(ii) *Step two.* We will increase or decrease, as appropriate, the amount determined under step one by the amount of any adjustments to previous transfers to the Combined Fund resulting from a difference between estimated and actual interest earnings or the estimated and actual Combined Fund's needs. This paragraph (b)(2)(ii) applies only to adjustments to transfers for prior fiscal years beginning on or after October 1, 2004, and only to those adjustments that have not previously been taken into account in establishing fees for prior years.

(iii) *Step three.* We will adjust the amount determined under steps one and two of this section by an amount equal to the difference between the fees actually collected (based on estimated production) and the amount that should have been collected (based on actual production) for any prior fiscal year beginning on or after October 1, 2004, if the difference has not previously been taken into account in establishing fees for prior years.

(3) *Establishment of fees.* We will use the following procedure to establish the per-ton fees for each fiscal year:

(i) *Step one.* We will estimate the total tonnage of coal that will be produced during that fiscal year and for which a fee payment obligation exists, categorized by the types of coal and mining methods described in paragraph (b)(3)(ii) of this section.

(ii) *Step two.* We will allocate the total fee collection needs determined under paragraph (b)(2) of this section among the various categories of estimated coal production under paragraph (b)(3)(i) of this section to establish a per-ton fee based upon the following parameters:

(A) The per-ton fee for anthracite, bituminous or subbituminous coal produced by underground methods will be 43 percent of the rate for the same type of coal produced by surface methods.

(B) Regardless of the method of mining, the per-ton fee for lignite coal will be 29 percent of the rate for other types of coal mined by surface methods.

(C) The per-ton fee for in situ mined coal will be the same as the fees set under paragraphs (b)(3)(ii)(A) and (B) of this section, depending on the type of coal mined. The fee will be based upon the quantity and quality of gas produced at the site, converted to Btu's per ton of coal upon which in situ mining was conducted, as determined by an analysis performed and certified by an independent laboratory.

PART 872—ABANDONED MINE RECLAMATION FUNDS

4. The authority citation for part 872 is revised to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*

5. Amend § 872.11 as follows:

A. In paragraph (a):

i. Revise the introductory text.

ii. Revise paragraph (a)(1).

iii. Remove the word "and" in paragraph (a)(4).

iv. Remove the period and add in its place "; and" in paragraph (a)(5).

v. Revise paragraph (a)(6).

B. In paragraph (b):

i. Revise the introductory text.

ii. Revise paragraphs (b)(1) through (b)(5).

iii. Add a new heading in paragraph (b)(6).

iv. Revise paragraph (b)(7).

v. Remove paragraph (b)(8).

C. Add paragraphs (d) and (e).

The revisions and additions read as follows:

§ 872.11 Abandoned Mine Reclamation Fund.

(a) *Fund revenues.* Revenues to the Fund include—

(1) Fees collected under section 402 of the Act and part 870 of this chapter;

* * * * *

(6) Interest and any other income earned from investment of the Fund.

(b) *Allocation of Fund revenues.* Except as provided in paragraphs (d) and (e) of this section, monies deposited in the Fund will be allocated and used as follows, subject to appropriation by Congress—

(1) *State share.* An amount equal to 50 percent of the reclamation fees collected under § 870.13(a) of this chapter during each fiscal year will be allocated at the end of that year to the State in which they were collected.

(i) Reclamation fees collected from Indian lands will not be included in the calculation of amounts to be allocated to a State.

(ii) No monies will be allocated to any State that advises OSM in writing that it does not intend to submit a State abandoned mine reclamation plan under section 405 of the Act.

(iii) Amounts granted to a State that have not been expended within three years from the date of grant award will be available for use under paragraph (b)(5) of this section if the Director finds in writing that the amounts involved are not necessary to carry out reclamation activities on lands within the State.

(2) *Tribal share.* An amount equal to 50 percent of the reclamation fees collected from Indian lands under § 870.13(a) of this chapter during each fiscal year will be allocated at the end of that year to the Indian tribe or tribes having an interest in the lands from which the fees were collected.

(i) No monies will be allocated to any Indian tribe that advises OSM in writing that it does not intend to submit a tribal abandoned mine reclamation plan under section 405 of the Act.

(ii) Amounts granted to an Indian tribe that have not been expended within three years from the date of grant award will be available for use under paragraph (b)(5) of this section if the Director finds in writing that the amounts involved are not necessary to carry out reclamation activities on Indian lands subject to the tribe's jurisdiction.

(3) *Rural Abandoned Mine Program.* An amount equal to 20 percent of the monies collected and deposited in the Fund each fiscal year (including interest but excluding monies allocated under paragraphs (b)(1) and (2) of this section) will be allocated for transfer to the Secretary of Agriculture for the Rural Abandoned Mine Program authorized by section 406 of the Act.

(4) *Grants based on historical coal production.* An amount equal to 40 percent of the monies collected and deposited in the Fund each fiscal year (including interest but excluding monies allocated under paragraphs (b)(1) and (2) of this section) will be allocated for use by the Secretary to supplement annual grants to States and Indian tribes under section 405 of the Act.

(i) States and Indian tribes eligible for supplemental grants are those that have not—

(A) Certified the completion of all eligible coal-related reclamation needs under section 411(a) of the Act; and

(B) Completed the reclamation of all sites meeting the priorities in paragraphs (a)(1) and (2) of section 403 of the Act.

(ii) In allocating these funds to eligible States and Indian tribes, the Secretary will use a formula based upon the amount of coal historically produced before August 3, 1977, in the State or from the Indian lands concerned.

(iii) The Secretary will not provide funds under this paragraph to a State or Indian tribe in any year in which funds to be granted during that year from the State's allocation under paragraph (b)(1) of this section or the tribe's allocation under paragraph (b)(2) of this section will be sufficient to address all remaining eligible coal-related sites in the State or on the tribe's Indian lands that meet the priorities in paragraphs (a)(1) and (2) of section 403 of the Act.

(iv) Funds awarded to a State or Indian tribe under this paragraph may not exceed the amount needed to fully address all remaining eligible coal-related sites in the State or on the tribe's Indian lands that meet the priorities in paragraphs (a)(1) and (2) of section 403 of the Act after utilizing all available funds under paragraph (b)(1) or (2) of this section.

(5) *Secretary's discretionary share.* Monies collected and deposited in the Fund that are not allocated under paragraphs (b)(1) through (4) of this section may be used for any of the following purposes—

(i) Up to $10 million per year for the small operator assistance program under section 507(c) of the Act;

(ii) Emergency projects under section 410 of the Act, including grants to States and Indian tribes for this purpose;

(iii) Non-emergency abandoned mine land reclamation projects on eligible lands in States without an approved abandoned mine reclamation plan under section 405 of the Act or on eligible Indian lands where the Indian tribe does not have an approved abandoned mine reclamation plan under section 405 of the Act;

(iv) Administration of title IV of the Act and this subchapter; and

(v) Projects authorized under section 402(g)(4) of the Act in States without an approved abandoned mine reclamation plan under section 405 of the Act or on Indian lands where the Indian tribe does not have an approved abandoned mine

reclamation plan under section 405 of the Act.

(6) *Minimum program grants.* * * *

(7) *Special allocation provisions.* Funds allocated or expended by the Secretary under paragraphs (b)(3) and (5) of this section will not be deducted from funds allocated or granted to a State or Indian tribe under paragraphs (b)(1), (2), (4), and (6) of this section.

* * * * *

(d) *Disposition of fees collected for coal produced after September 30, 2004.* Fees collected under § 870.13(b) of this chapter for a fiscal year will be allocated to the accounts from which the amount transferred under paragraph (e) of this section was taken at the beginning of that fiscal year. The amount allocated to each account will be proportionate to the amount transferred from that account.

(e) *Transfers to Combined Benefit Fund.* (1) At the beginning of each fiscal year for which fees must be paid under section 402 of the Act and § 870.13 of this chapter, the Secretary will transfer monies from the Fund to the United Mine Workers of America Combined Benefit Fund established under section 9702 of the Internal Revenue Code of 1986 (26 U.S.C. 9702) for the purpose described in section 402(h)(3)(A) of the Act and in the amount prescribed in paragraphs (h)(2) through (4) of section 402 of the Act.

(2) The amount of estimated Fund interest earnings transferred to the Combined Benefit Fund under paragraph (e)(1) of this section in any one fiscal year may not exceed the lesser of $70 million or the amount of the expenditures described in section 402(h)(3)(A) of the Act.

(3) If actual Combined Benefit Fund expenditures differ from the estimates provided under section 402(h)(3)(A) of the Act, or if interest earnings differ from the projections used to determine the amount of the transfer under section 402(h)(2)(A) of the Act, the amount transferred from the Fund to the Combined Benefit Fund in future years will be adjusted accordingly. However, the total amount ultimately transferred for any one fiscal year may not exceed $70 million, although adjustments for transfers in prior fiscal years may result in the transfer of more than $70 million during any given year.

(4) The amount transferred under paragraph (e)(1) of this section will be deducted from the amount of Fund revenues subject to allocation under paragraphs (b)(3) through (5) of this section at the end of the fiscal year.

[FR Doc. 04–20998 Filed 9–16–04; 8:45 am]

Editorial Note: Federal Register Proposed Rule document 04–20998 was published originally in the **Federal Register** of Friday, September 17, 2004 at 69 FR 56132. In the paper edition of the September 17 issue, page 56132 appeared as a blank page, due to a technical malfunction. The online edition of the **Federal Register** was not affected. A complete version of the document appears on page 56132 in both the HTML and PDF versions posted online on GPO Access (*http://www.gpoaccess.gov/fr/index.html*). The corrected document is republished in its entirety.

[FR Doc. R4–20998 Filed 9–21–04; 8:45 am]

BILLING CODE 1505–01–D

Federal Register

Wednesday,
September 22, 2004

Part IV

The President

Notice of September 21, 2004—Continuation of the National Emergency With Respect to Persons Who Commit, Threaten To Commit, or Support Terrorism

Federal Register
Vol. 69, No. 183
Wednesday, September 22, 2004

Presidential Documents

Title 3—

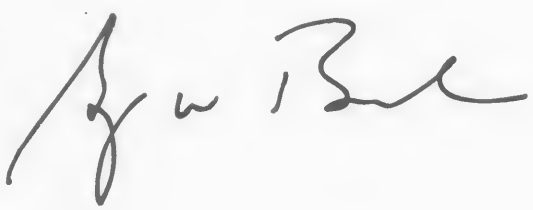
The President

Notice of September 21, 2004

Continuation of the National Emergency With Respect to Persons Who Commit, Threaten To Commit, or Support Terrorism

On September 23, 2001, by Executive Order 13224, I declared a national emergency with respect to persons who commit, threaten to commit, or support terrorism, pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701–1706). I took this action to deal with the unusual and extraordinary threat to the national security, foreign policy, and economy of the United States constituted by the grave acts of terrorism and threats of terrorism committed by foreign terrorists, including the terrorist attacks in New York, in Pennsylvania, and against the Pentagon committed on September 11, 2001, and the continuing and immediate threat of further attacks against United States nationals or the United States. Because the actions of these persons who commit, threaten to commit, or support terrorism continue to pose an unusual and extraordinary threat to the national security, foreign policy, and economy of the United States, the national emergency declared on September 23, 2001, and the measures adopted on that date to deal with that emergency, must continue in effect beyond September 23, 2004. Therefore, in accordance with section 202(d) of the National Emergencies Act (50 U.S.C. 1622(d)), I am continuing for 1 year the national emergency with respect to persons who commit, threaten to commit, or support terrorism.

This notice shall be published in the **Federal Register** and transmitted to the Congress.



THE WHITE HOUSE,
September 21, 2004.

[FR Doc. 04–21484
Filed 9–21–04; 12:47 pm]
Billing code 3195–01–P

Reader Aids

Federal Register

Vol. 69, No. 183

Wednesday, September 22, 2004

CUSTOMER SERVICE AND INFORMATION

Federal Register/Code of Federal Regulations	
General Information, indexes and other finding aids	202–741–6000
Laws	741–6000
Presidential Documents	
Executive orders and proclamations	741–6000
The United States Government Manual	741–6000
Other Services	
Electronic and on-line services (voice)	741–6020
Privacy Act Compilation	741–6064
Public Laws Update Service (numbers, dates, etc.)	741–6043
TTY for the deaf-and-hard-of-hearing	741–6086

ELECTRONIC RESEARCH

World Wide Web

Full text of the daily Federal Register, CFR and other publications is located at: **http://www.gpoaccess.gov/nara/index.html**

Federal Register information and research tools, including Public Inspection List, indexes, and links to GPO Access are located at: **http://www.archives.gov/federal_register/**

E-mail

FEDREGTOC-L (Federal Register Table of Contents LISTSERV) is an open e-mail service that provides subscribers with a digital form of the Federal Register Table of Contents. The digital form of the Federal Register Table of Contents includes HTML and PDF links to the full text of each document.

To join or leave, go to **http://listserv.access.gpo.gov** and select *Online mailing list archives, FEDREGTOC-L, Join or leave the list (orchange settings);* then follow the instructions.

PENS (Public Law Electronic Notification Service) is an e-mail service that notifies subscribers of recently enacted laws.

To subscribe, go to **http://listserv.gsa.gov/archives/publaws-l.html** and select *Join or leave the list* (or change settings); then follow the instructions.

FEDREGTOC-L and **PENS** are mailing lists only. We cannot respond to specific inquiries.

Reference questions. Send questions and comments about the Federal Register system to: **fedreg.info@nara.gov**

The Federal Register staff cannot interpret specific documents or regulations.

FEDERAL REGISTER PAGES AND DATE, SEPTEMBER

53335–53602 1
53603–53790 2
53791–53998 3
53999–54192 7
54193–54556 8
54557–54748 9
54749–55060 10
55061–55314 13
55315–55498 14
55499–55718 15
55719–55940 16
55941–56152 17
56153–56344 20
56345–56664 21
56665–56924 22

CFR PARTS AFFECTED DURING SEPTEMBER

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.

3 CFR

Proclamations:
7463 (See Notice of September 10, 2004) 55313
7807 54737
7808 54739
7809 55711
7810 55713
7811 55715
7812 55717
7813 56147
7814 56149
7815 56151
7816 56661
7817 56663

Executive Orders:
12333 (See EO 13354) 53589
12333 (Amended by EO 13355) 53593
12333 (See EO 13356) 53599
12958 (See EO 13354) 53589
12958 (See EO 13356) 53599
13223 (See Notice of September 10, 2004) 55313
13224 (See Notice of September 21, 2004) 56665
13235 (See Notice of September 10, 2004) 55313
13253 (See Notice of September 10, 2004) 55313
13286 (See Notice of September 10, 2004) 55313
13311 (See EO 13356) 53599
13353 53585
13354 53589
13355 53593
13356 53599
13357 56665

Administrative Orders:
Notices:
Notice of September 10, 2004 55313
Notice of September 21, 2004 56923
Presidential Determinations:
No. 2004–44 of September 10, 2004 56153
No. 2004–45 of September 10, 2004 55497
No. 2004–46 of September 10, 2004 56155

5 CFR

550 55941

Proposed Rules:
531 56721

7 CFR

59 53784
226 53502
301 ..... 53335, 55315, 56157
319 55719
457 ..... 53500, 54179
635 56345
916 53791
917 53791
920 ..... 54193, 55733
924 54199
958 56667
980 56667
1435 55061
1469 56159

Proposed Rules:
784 54049
1032 56725

8 CFR

215 53603
235 53603
252 53603

10 CFR

35 55736

Proposed Rules:
110 55785

12 CFR

Proposed Rules:
205 55996
345 56175
615 55362

14 CFR

21 53335
23 56348
25 ..... 56672, 56674
39 ..... 53336, 53603, 53605, 53607, 53609, 53794, 53999, 54201, 54204, 54206, 54211, 54213, 54557, 55320, 55321, 55323, 55326, 55329, 55943, 56160, 56480, 56676, 56680, 56682, 56683, 56687, 56688
71 ..... 53614, 53976, 54000, 54749, 54750, 55499, 55947, 56690
73 ..... 53795, 53796
91 53337
97 ..... 53798, 56161

254.....56692
Proposed Rules:
23.....55367
25.....53841
39.....53366, 53655, 53658, 53846, 53848, 53853, 53855, 53858, 54053, 54055, 54058, 54060, 54065, 54250, 54596, 55120, 55369, 56175, 56375, 56730, 56733, 56735
71.....53661, 53860, 53861, 54758

15 CFR

744.....56693
801.....54751

16 CFR

305.....54558, 55063
309.....55332
Proposed Rules:
436.....53661

17 CFR

1.....55949
200.....54182
240.....54182
270.....54728
Proposed Rules:
37.....53367
38.....53367
210.....53550
240.....53550
248.....56304
249.....53550

18 CFR

342.....53800

19 CFR

122.....54179
Proposed Rules:
351.....56738

20 CFR

422.....55065
Proposed Rules:
404.....55874
1002.....56266

21 CFR

20.....53615
201.....53801
522.....53617, 53618
1301.....55343
Proposed Rules:
16.....56824
20.....53662
118.....56824

22 CFR

22.....53618

23 CFR

630.....54562

24 CFR

24.....53978
236.....53558
Proposed Rules:
291.....56118

26 CFR

1.....53804, 55499, 55740, 55743
20.....55743
25.....55743
31.....55743
40.....55743
41.....55743
44.....55743
53.....55743
55.....55743
156.....55743
301.....55743
Proposed Rules:
1.....53373, 53664, 54067, 55790
26.....53862
301.....54067, 56377

28 CFR

549.....53804

29 CFR

1915.....55668
4022.....55500
4044.....55500
Proposed Rules:
1210.....53373

30 CFR

204.....55076
870.....56122
914.....55347
920.....55353
943.....55356
Proposed Rules:
870.....56132, 56908
872.....56132, 56908
917.....55373
946.....55375

31 CFR

1.....54002
356.....53619
Proposed Rules:
356.....54251

32 CFR

199.....55358

33 CFR

100.....54572, 55949, 55951
110.....55952
117.....53337, 53805, 54572, 55747
165.....54215, 54573, 55502, 55952, 55954, 56695
277.....54215
Proposed Rules:
100.....53373, 54598
117.....53376, 56379
165.....55122, 55125, 56011

36 CFR

7.....53626, 53630
292.....55092
1254.....55505
Proposed Rules:
7.....54072
294.....54600
1228.....54091, 56015

37 CFR

1.....55505, 56482
5.....56482
10.....56482
41.....55505, 56482
104.....56482

38 CFR

19.....53807
20.....53807

39 CFR

111.....53641, 53808, 54005
310.....54006
320.....54006
501.....55506
Proposed Rules:
111.....53664, 53665, 53666

40 CFR

52.....53778, 53835, 52006, 54019, 54216, 54574, 54575, 55749, 55752, 56163, 56170, 56171, 56351, 56355
62.....54753
63.....53338, 53980, 55218, 55759
70.....54244
81.....55956, 56163, 56697
170.....53341
180.....55506, 55963, 55975, 56711
239.....54756
258.....54756
261.....56357
281.....56363
432.....54476
761.....54025
1620.....55512
Proposed Rules:
16.....55377
51.....53378
52.....54097, 54600, 54601, 55386, 55790, 56182, 56381
62.....54759
63.....53380, 53987, 55791
70.....54254
82.....56182
85.....54846
86.....54846
89.....54846
90.....54846
91.....54846
92.....54846
94.....54846
112.....56182, 56184
136.....55547, 56480
166.....53866
239.....54760
258.....54760
261.....56382
312.....54097, 56016, 56382
1039.....54846
1048.....54846
1051.....54846
1065.....54846
1068.....54846

42 CFR

414.....55763

43 CFR

Proposed Rules:
25.....54602

44 CFR

64.....53835
201.....55094
206.....55094
Proposed Rules:
67.....56383

45 CFR

61.....56364
160.....55515
2552.....56718
2553.....56718

46 CFR

67.....53838
221.....54247
296.....54347

47 CFR

0.....55097
1.....55097, 55516
2.....54027, 55982
5.....54581
15.....54027
22.....55516
24.....55516
25.....53838, 54037, 54581, 55516
32.....53645
51.....53645, 54589, 55111
54.....55097, 55983
64.....53346, 55765, 55985
65.....53645
73.....53352, 55112, 55517, 55780, 55781
97.....54581
Proposed Rules:
51.....55128
64.....53382
73.....54612, 54613, 54614, 54760, 54761, 54762, 55547

48 CFR

207.....55986
209.....55987
217.....55987
219.....55986
225.....55989
226.....55989
237.....55991
246.....55987
252.....55989, 55992
511.....55934
552.....55934, 55938
1871.....53652
Proposed Rules:
2.....56316
10.....56316
12.....56316
16.....56316
19.....53780
52.....53780, 56316

49 CFR

106.....54042
107.....54042
171.....53352, 54042, 55113
172.....54042, 55113
173.....54042, 55113
178.....54042
179.....54042
180.....54042
192.....54248, 54591
195.....54591
541.....53354
571.....54249, 55517, 55531, 55993
1552.....56324
Proposed Rules:
10.....53385
229.....54255
395.....53386

571 .....54255, 55548, 55896
572.....55550
585.....55896
595.....56018
1507.....54256

50 CFR

17.....56367
20 .....53564, 53990, 55994
31.....54350
32.....54350, 55994
216.....55288
600.....53359
635.....53359, 56719
648 .....53359, 53839, 54593, 56373
660 .....53359, 53362, 54047, 55360
679 .....53359, 53364, 53653, 54594, 55361, 55782, 55783, 55784, 55995

Proposed Rules:

221.....54615
223.....54620
224.....54620, 55135
635.....56024, 56741
648.....55388
660.....56550
679.....53397, 56384
680.....53397

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 SEPTEMBER 22, 2004

COMMERCE DEPARTMENT
Industry and Security Bureau
Export administration regulations:
Entity list—
India; entity removed and license review policy revised; clarification; published 9-22-04

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE
Foster Grandparent Program and Retired and Senior Volunteer Program; correction; published 9-22-04

ENVIRONMENTAL PROTECTION AGENCY
Pesticides; tolerances in food, animal feeds, and raw agricultural commodities:
Tribenuron methyl; published 9-22-04
Water pollution; effluent guidelines for point source categories:
Concentrated aquatic animal production facilities; published 8-23-04

HEALTH AND HUMAN SERVICES DEPARTMENT
Food and Drug Administration
Medical devices:
Dental devices—
Gold-based alloys, precious metal alloys, and base metal alloys; special controls designation; published 8-23-04

TRANSPORTATION DEPARTMENT
Maritime Administration
Coastwise trade laws; administrative waivers for eligible vessels; published 8-23-04

COMMENTS DUE NEXT WEEK

ACTUARIES, JOINT BOARD FOR ENROLLMENT
Joint Board for Enrollment of Actuaries
Employee Retirement Income Security Act of 1974; implementation:
Actuarial services; revisions; comment request; comments due by 9-28-04; published 6-30-04 [FR 04-14719]

AGRICULTURE DEPARTMENT
Agricultural Marketing Service
Apricots and cherries (sweet) grown in—
Washington; comments due by 9-27-04; published 7-29-04 [FR 04-17272]
Cotton classing, testing and standards:
Classification services to growers; 2004 user fees; Open for comments until further notice; published 5-28-04 [FR 04-12138]
Oranges and grapefruit grown in—
Texas; comments due by 9-27-04; published 7-29-04 [FR 04-17273]

COMMERCE DEPARTMENT
National Oceanic and Atmospheric Administration
Fishery conservation and management:
Northeastern United States fisheries—
Northeast multispecies; comments due by 9-29-04; published 9-14-04 [FR 04-20693]

COMMODITY FUTURES TRADING COMMISSION
Commodity Exchange Act:
Derivatives transaction execution facility registration or contract market designation; application procedures; comments due by 10-1-04; published 9-1-04 [FR 04-19946]

COURT SERVICES AND OFFENDER SUPERVISION AGENCY FOR THE DISTRICT OF COLUMBIA
Semi-annual agenda; Open for comments until further notice; published 12-22-03 [FR 03-25121]

DEFENSE DEPARTMENT
Army Department
Personnel:
Decorations, medals, ribbons, and similar devices; comments due by 9-27-04; published 7-28-04 [FR 04-16226]

DEFENSE DEPARTMENT
Acquisition regulations:
Overseas contracts; tax procedures; comments due by 10-1-04; published 8-2-04 [FR 04-17471]
Grant and agreement regulations; OMB policy directives; comments due by 9-27-04; published 7-28-04 [FR 04-16933]

ENERGY DEPARTMENT
Energy Efficiency and Renewable Energy Office
Consumer products; energy conservation program:
Energy conservation standards—
Commercial packaged boilers; test procedures and efficiency standards; Open for comments until further notice; published 12-30-99 [FR 04-17730]

ENERGY DEPARTMENT
Federal Energy Regulatory Commission
Electric rate and corporate regulation filings:
Virginia Electric & Power Co. et al.; Open for comments until further notice; published 10-1-03 [FR 03-24818]
Electric utilities (Federal Power Act):
Generator interconnection agreements and procedures; standardization; comments due by 10-1-04; published 8-17-04 [FR 04-18892]

ENVIRONMENTAL PROTECTION AGENCY
Air pollutants, hazardous; national emission standards:
Vegetable oil production; solvent extraction; comments due by 10-1-04; published 9-1-04 [FR 04-19919]
Air programs:
Ambient air quality standards, national—
Idaho; ozone monitoring season; comments due by 9-29-04; published 8-30-04 [FR 04-19728]
Idaho; ozone monitoring season; comments due by 9-29-04; published 8-30-04 [FR 04-19729]
Air programs; approval and promulgation; State plans for designated facilities and pollutants:
Maryland; comments due by 9-30-04; published 8-31-04 [FR 04-19821]
Air quality implementation plans:
Preparation, adoption, and submittal—
8-hour ozone national ambient air quality standard; implemenation; comments due by 10-1-04; published 9-1-04 [FR 04-19921]
Air quality implementation plans; approval and promulgation; various States:
California; comments due by 9-30-04; published 8-31-04 [FR 04-19816]
Indiana; comments due by 9-27-04; published 8-26-04 [FR 04-19434]
Maryland; comments due by 9-30-04; published 8-31-04 [FR 04-19820]
Environmental statements; availability, etc.:
Coastal nonpoint pollution control program—
Minnesota and Texas; Open for comments until further notice; published 10-16-03 [FR 03-26087]
Water pollution; effluent guidelines for point source categories:
Meat and poultry products processing facilities; Open for comments until further notice; published 9-8-04 [FR 04-12017]

FEDERAL COMMUNICATIONS COMMISSION
Digital television stations; table of assignments:
North Carolina; comments due by 9-27-04; published 8-13-04 [FR 04-18463]
Radio stations; table of assignments:
Various States; comments due by 9-30-04; published 8-17-04 [FR 04-18830]
Television broadcasting:
Joint sales agreements; attribution; comments due by 9-27-04; published 8-26-04 [FR 04-19468]

FEDERAL ELECTION COMMISSION
Rulemaking petitions:
Bauer, Robert F.; comments due by 9-27-04; published 8-26-04 [FR 04-19526]

FEDERAL MARITIME COMMISSION
Filing and service fees; revision; comments due by 9-29-04; published 8-31-04 [FR 04-19772]

HEALTH AND HUMAN SERVICES DEPARTMENT
Centers for Medicare & Medicaid Services
State Children's Health Insurance Program:

Allotments and grants to States—
Payment error measurement rate; comments due by 9-27-04; published 8-27-04 [FR 04-19603]

HEALTH AND HUMAN SERVICES DEPARTMENT
Food and Drug Administration
Medical devices:
Dental devises—
Tricalcium phosphate granules and other bone grafting material for dental bone repair; comments due by 9-28-04; published 6-30-04 [FR 04-14767]
Reports and guidance documents; availability, etc.:
Evaluating safety of antimicrobial new animal drugs with regard to their microbiological effects on bacteria of human health concern; Open for comments until further notice; published 10-27-03 [FR 03-27113]
Medical devices—
Dental noble metal alloys and base metal alloys; Class II special controls; Open for comments until further notice; published 8-23-04 [FR 04-19179]

HOMELAND SECURITY DEPARTMENT
Coast Guard
Anchorage regulations:
Maryland; Open for comments until further notice; published 1-14-04 [FR 04-00749]
Drawbridge operations:
Massachusetts; comments due by 10-1-04; published 9-1-04 [FR 04-19958]
Marine equipment; review and standards update; comments due by 9-28-04; published 6-30-04 [FR 04-14368]
Regattas and marine parades:
Columbus Day Regatta; comments due by 10-1-04; published 9-1-04 [FR 04-19913]
International Search and Rescue Competition; Elizabeth River, Portsmouth, VA; comments due by 9-29-04; published 8-30-04 [FR 04-19732]

HOMELAND SECURITY DEPARTMENT
Citizenship and Immigration Services Bureau
Immigration:
Employment authorization documents; issuance; comments due by 9-28-04; published 7-30-04 [FR 04-16938]

HOMELAND SECURITY DEPARTMENT
Federal Emergency Management Agency
National Flood Insurance Program:
Private sector property insurers; assistance; comments due by 9-28-04; published 7-30-04 [FR 04-17358]

HOUSING AND URBAN DEVELOPMENT DEPARTMENT
Mortgage and loan insurance programs:
Multifamily rental projects and health care facilities; revisions; comments due by 10-1-04; published 8-2-04 [FR 04-16782]

INTERIOR DEPARTMENT
Fish and Wildlife Service
Endangered and threatened species permit applications
Recovery plans—
Paiute cutthroat trout; Open for comments until further notice; published 9-10-04 [FR 04-20517]

NATIONAL CREDIT UNION ADMINISTRATION
Credit unions:
Conversion of insured credit unions to mutual savings banks; information disclosure; comments due by 10-1-04; published 8-2-04 [FR 04-17463]
Mergers of federally-insured credit unions; voluntary termination or conversion of insured status; communication and disclosure requirements; comments due by 9-27-04; published 7-29-04 [FR 04-17256]

NUCLEAR REGULATORY COMMISSION
Environmental statements; availability, etc.:
Fort Wayne State Developmental Center; Open for comments until further notice; published 5-10-04 [FR 04-10516]

POSTAL SERVICE
Domestic Mail Manual:
High-editorial, heavy-weight, small-circulation publications; experimental outside-country periodicals co-palletization discounts; comments due by 10-2-04; published 9-2-04 [FR 04-19976]

SECURITIES AND EXCHANGE COMMISSION
Investment companies:
Portfolio managers of registered management investment companies; disclosure requirements; comments due by 10-1-04; published 8-27-04 [FR 04-19575]
Securities:
Annual and quarterly reports; acceleration of periodic filing dates and disclosure concerning web site access to reports; final phase-in postponed; comments due by 10-1-04; published 9-1-04 [FR 04-19785]

SMALL BUSINESS ADMINISTRATION
Disaster loan areas:
Maine; Open for comments until further notice; published 2-17-04 [FR 04-03374]

OFFICE OF UNITED STATES TRADE REPRESENTATIVE
Trade Representative, Office of United States
Generalized System of Preferences:
2003 Annual Product Review, 2002 Annual Country Practices Review, and previously deferred product decisions; petitions disposition; Open for comments until further notice; published 7-6-04 [FR 04-15361]

TRANSPORTATION DEPARTMENT
Federal Aviation Administration
Air carrier certification and operations:
Transport airplane fuel tank systems; special maintenance program requirements; compliance extension; aging airplane program update; comments due by 9-29-04; published 8-23-04 [FR 04-19252]
Airworthiness directives:
Agusta S.p.A.; comments due by 10-1-04; published 8-2-04 [FR 04-17369]
Airbus; comments due by 9-27-04; published 7-29-04 [FR 04-16914]
Boeing; comments due by 10-1-04; published 8-17-04 [FR 04-18744]
General Electric Co.; comments due by 9-27-04; published 7-29-04 [FR 04-17284]
MD Helicopters, Inc.; comments due by 9-27-04; published 7-29-04 [FR 04-17223]
Class E airspace; comments due by 10-1-04; published 8-17-04 [FR 04-18821]

TRANSPORTATION DEPARTMENT
National Highway Traffic Safety Administration
Motor vehicle safety standards:
Child restraint systems—
Child restraint anchorage systems; comments due by 9-27-04; published 8-11-04 [FR 04-18199]
Defect and noncompliance—
Recalled tires disposition; comments due by 9-27-04; published 8-13-04 [FR 04-18354]
Lamps, reflective devices, and associated equipment—
Signal lamps and reflectors; geometric visibility requirements; worldwide harmonization; comments due by 9-27-04; published 8-11-04 [FR 04-18297]
Occupant crash protection—
Seat belt assemblies; comments due by 10-1-04; published 8-4-04 [FR 04-17702]

TRANSPORTATION DEPARTMENT
Research and Special Programs Administration
Hazardous materials:
Transportation—
Materials transported by aircraft; information availability; comments due by 10-1-04; published 9-1-04 [FR 04-19963]

TREASURY DEPARTMENT
Foreign Assets Control Office
Zimbabwe sanctions regulations; comments due by 9-27-04; published 7-29-04 [FR 04-17206]

TREASURY DEPARTMENT
Internal Revenue Service
Excise taxes:
Communication services; information request; comments due by 9-30-04; published 7-2-04 [FR 04-15125]

VETERANS AFFAIRS DEPARTMENT
Adjudication; pensions, compensation, dependency, etc.:

Presumptions of service connection for certain disabilities and related matters; comments due by 9-27-04; published 7-27-04 [FR 04-16758]

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/public_laws/public_laws.html.*

The text of laws is not published in the **Federal Register** but may be ordered in "slip law" (individual pamphlet) form from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 (phone, 202–512–1808). The text will also be made available on the Internet from GPO Access at *http://www.gpoaccess.gov/plaws/index.html.* Some laws may not yet be available.

H.R. 5005/P.L. 108–303
Emergency Supplemental Appropriations for Disaster Relief Act, 2004 (Sept. 8, 2004; 118 Stat. 1124)
Last List August 18, 2004

Public Laws Electronic Notification Service (PENS)

PENS is a free electronic mail notification service of newly enacted public laws. To subscribe, go to *http://listserv.gsa.gov/archives/publaws-l.html*

Note: This service is strictly for E-mail notification of new laws. The text of laws is not available through this service. **PENS** cannot respond to specific inquiries sent to this address.

Public Laws

108th Congress

Pamphlet prints of public laws, often referred to as slip laws, are the initial publication of Federal laws upon enactment and are printed as soon as possible after approval by the President. Legislative history references appear on each law. Subscription service includes all public laws, issued irregularly upon enactment, for the 108th Congress.

Individual laws also may be purchased from the Superintendent of Documents, U.S. Government Printing Office. Prices vary. See Reader Aids Section of the Federal Register for announcements of newly enacted laws or access the online database at http://www.access.gpo.gov/nara1/nara005.html

---

Superintendent of Documents **Subscriptions** Order Form

Order Processing Code:
*** 6216**

☐ **YES**, enter my subscription(s) as follows:

Charge your order. It's Easy! MasterCard VISA

To fax your orders (202) 512–2250
Phone your orders (202) 512–1800

_____ subscriptions to **PUBLIC LAWS** for the 108th Congress for $285 per subscription.

The total cost of my order is $ _____. **Price includes regular domestic postage and handling** and is subject to change. International customers please add 25%.

Company or personal name (Please type or print)

Additional address/attention line

Street address

City, State, ZIP code

Daytime phone including area code

Purchase order number (optional)

May we make your name/address available to other mailers? YES ☐ NO ☐

Please Choose Method of Payment:

☐ Check Payable to the Superintendent of Documents
☐ GPO Deposit Account ☐☐☐☐☐☐-☐
☐ VISA ☐ MasterCard Account

☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

☐☐☐☐ (Credit card expiration date)

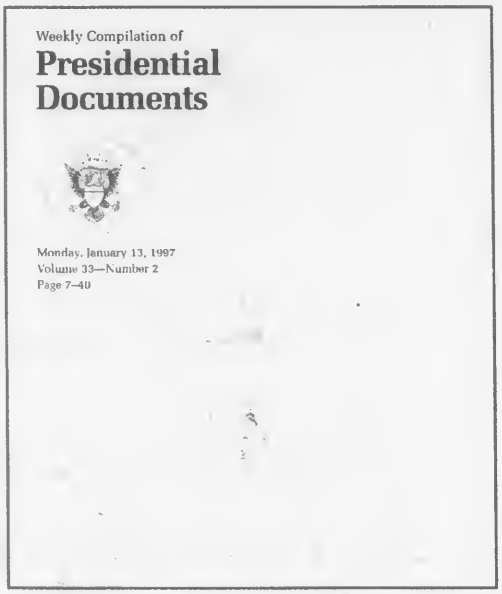
Thank you for your order!

Authorizing signature 2/03

Mail To: Superintendent of Documents
P.O. Box 371954, Pittsburgh, PA 15250–7954

The authentic text behind the news . . .

The Weekly Compilation of **Presidential Documents**



This unique service provides up-to-date information on Presidential policies and announcements. It contains the full text of the President's public speeches, statements, messages to Congress, news conferences, and other Presidential materials released by the White House.

The Weekly Compilation carries a Monday dateline and covers materials released during the preceding week. Each issue includes a Table of Contents, lists of acts approved by the President, nominations submitted to the Senate, a checklist of White House press releases, and a digest of other Presidential activities and White House announcements. Indexes are published quarterly.

Published by the Office of the Federal Register, National Archives and Records Administration.

Superintendent of Documents **Subscription** Order Form

Order Processing Code
*** 5420**

Charge your order. It's Easy!

To fax your orders (202) 512–2250
Phone your orders (202) 512–1800

☐ **YES**, please enter _____ one year subscriptions for the **Weekly Compilation of Presidential Documents** (PD) so I can keep up to date on Presidential activities.

☐ $133.00 Per Year

The total cost of my order is $ _____. **Price includes regular domestic postage and handling** and is subject to change. International customers please add 25%.

Company or personal name (Please type or print)

Additional address/attention line

Street address

City, State, ZIP code

Daytime phone including area code

Purchase order number (optional)

May we make your name/address available to other mailers? YES ☐ NO ☐

Please Choose Method of Payment:

☐ Check Payable to the Superintendent of Documents
☐ GPO Deposit Account ☐☐☐☐☐☐☐ – ☐
☐ VISA ☐ MasterCard Account
☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐
☐☐☐☐ (Credit card expiration date)

Thank you for your order!

Authorizing signature 7/04

Mail To: Superintendent of Documents
P.O. Box 371954, Pittsburgh, PA 15250–7954

Public Papers of the Presidents of the United States

William J. Clinton

1997
(Book I) $69.00

1997
(Book II) $78.00

1998
(Book I) $74.00

1998
(Book II) $75.00

1999
(Book I) $71.00

1999
(Book II) $75.00

2000–2001
(Book I) $68.50

2000–2001
(Book II) $63.00

2000–2001
(Book III) $75.00

George W. Bush

2001
(Book I) $70.00

(Book II) $47.00

Published by the Office of the Federal Register,
National Archives and Records Administration

Mail order to:
Superintendent of Documents
P.O. Box 371954, Pittsburgh, PA 15250–7954
(Rev 5/04)

Public Laws

108th Congress

Pamphlet prints of public laws, often referred to as slip laws, are the initial publication of Federal laws upon enactment and are printed as soon as possible after approval by the President. Legislative history references appear on each law. Subscription service includes all public laws, issued irregularly upon enactment, for the 108th Congress.

Individual laws also may be purchased from the Superintendent of Documents, U.S. Government Printing Office. Prices vary. See Reader Aids Section of the Federal Register for announcements of newly enacted laws or access the online database at http://www.access.gpo.gov/nara1/nara005.html

---

Superintendent of Documents **Subscriptions** Order Form

Order Processing Code
*** 6216**

☐ **YES**, enter my subscription(s) as follows:

Charge your order. It's Easy! MasterCard VISA

To fax your orders (202) 512–2250
Phone your orders (202) 512–1800

_____ subscriptions to **PUBLIC LAWS** for the 108th Congress for $285 per subscription.

The total cost of my order is $ _____. **Price includes regular domestic postage and handling** and is subject to change. International customers please add 25%.

Company or personal name (Please type or print)

Additional address/attention line

Street address

City, State, ZIP code

Daytime phone including area code

Purchase order number (optional)

May we make your name/address available to other mailers? YES ☐ NO ☐

Please Choose Method of Payment:

☐ Check Payable to the Superintendent of Documents
☐ GPO Deposit Account ☐☐☐☐☐☐☐ – ☐
☐ VISA ☐ MasterCard Account
☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐
☐☐☐☐ (Credit card expiration date)

Thank you for your order!

Authorizing signature 2/03

Mail To: Superintendent of Documents
P.O. Box 371954, Pittsburgh, PA 15250–7954

Printed on recycled paper